3 July 2012

Executive Summary

Uniform Formulary Beneficiary Advisory Panel Comments
21 June 2012

The Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) commented on the recommendations from the DoD Pharmacy and Therapeutics (P&T) Committee May 2012 Meeting

UF CLASS REVIEWS: SMOKING CESSATION PROGRAM

1. Smoking Cessation Program: Panel Vote on Coverage Recommendations

The P&T Committee recommended varenicline (Chantix), bupropion SR 150 mg, and nicotine (as a patch, gum, lozenge, nasal spray, and inhaler) be covered agents in the TRICARE Smoking Cessation Program, contingent on signing of the Final Rule. No smoking cessation drugs were recommended to be excluded from the program.

Summary of Panel Vote/Comments:

Ms. Fryar asked whether there was a vote on a prior authorization for coverage of a 3rd quit attempt. Dr. Meade answered, the Final Rule states there should be two quit attempts per year. However, a 3rd quit attempt may be authorized by the provider with prior authorization.

Dr. Sampsel asked whether counseling would be required for beneficiaries to get the smoking cessation drugs after the Final Rule is signed. The presenters mention that patients have the most success when counseling is paired with the use of the drugs. Dr. Meade answered that the Rule recommends counseling or some type of interaction but it does not mandate counseling. Dr. Lounsbery noted that the MTFs have the freedom to design their own programs and most of the MTF do require counseling as part of the getting the drugs. In closing, Dr. Sampsel noted that smokers often stop smoking only to become addicted to whatever they used to quit smoking.

Dr. Cohoon agreed that counseling is important in addition to conversations with the provider to discuss the best options to ensure success. The fact the counseling is not mandated causes concerns.

Dr. Cohoon asked whether it was a Proposed or Final Rule. Dr. Meade stated that it was in the final stages and would be the Final Rule once it is signed.

Dr. Cohoon noted that the drugs are available at the MTF and mail order but not in retail. She asked how reservists and the Guard, who do not have access to the MTF, would receive their 1st

time fill if the drugs are not available in the retail network pharmacies. Dr. Meade said the prescriptions would be filled in the mail order program. She asked how long it would take for mail order to fill the prescriptions. Dr. Meade said it would take approximately two weeks or the time needed for ESI to receive, process, and send the drugs. Dr. Cohoon expressed concerns about patients waiting two weeks or more for the prescription to be filled after the initial appointment/consultation with their physician. Dr. Meade said that the P&T committee is limited to what the final rule states.

Dr. Cohoon noted that many active duty service members start smoking while in theater and have difficulties quitting when they return. She asked if the drugs would be available in theater. Dr. Meade stated that the drugs are already being dispensed in theater.

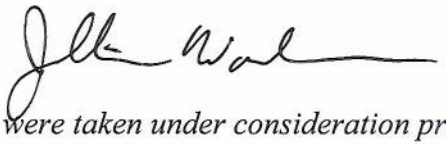
Dr. Cohoon requested clarification regarding co-pay and where the drugs would be placed on the formulary. Dr. Meade said that it did not make a difference because there is no co-pay. It will be on the UF as a covered drug. The rule states that there is no co-pay and it will be part of implementation after the rule is signed.

Dr. Cohoon noted that a PA is required for a 3rd quit attempt. She asked what constitutes an attempt. Dr. Meade answered; the Rule states 120 days of therapy constitute one attempt. In defining a quit attempt, Dr. Meade reiterated that an attempt is 120 days of therapy and it was his understanding that if the patient tries another drug that is another attempt.

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

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

  There were no further comments from the Panel.

  Director, TMA: 

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

2. SMOKING CESSATION PROGRAM: Varnicline (Chantix) PA Recommendations

The P&T Committee rejected the proposal that PA criteria should apply to varenicline (Chantix). PA criteria for varenicline were proposed for safety concerns, primarily neuropsychiatric AEs. While the Committee recognized the potential for safety concerns with varenicline, they also concluded that PA was not required to ensure safe prescribing with the medication because the risks with varenicline are understood by prescribing providers and can be successfully managed without PA criteria.

NOTE: Ms. Fryar clarified that NO PRIOR AUTHORIZATION for Chantix is required.

Summary of Panel Vote/Comments:

Dr. Salom, Dr. Sampsel, Ms. Fryar and Ms. O'Neill-Tracy non concurred with the PA recommendation. The each expressed concerns about the seriousness of the side effects, safety concerns and the need for a PA for this particular drug.

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

  Concur: 6 Non-Concur: 4 Abstain: 0 Absent: 0

  There were no further comments from the Panel

  Director, TMA:

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

3. Smoking Cessation Program: Covered Beneficiary Criteria and PA 3rd Quit Attempt

Prior to reading the recommendation, Ms. Fryar noted that an attempt is 120 days of therapy for all the smoking cessation drugs.

The P&T Committee recommended the following coverage criteria should apply to all seven smoking cessation products [varenicline (Chantix), buproprion SR 150 mg, nicotine gum, patch, lozenge, nasal spray, and inhaler], consistent with the requirements in the Proposed Rule, and contingent on signing of the Final Rule. Coverage not approved for patients under the age of 18 or for Medicare-eligible beneficiaries. Coverage for a 3rd quit attempt within one year may be pre-approved if the provider has verified that the patient would benefit from a 3rd quit attempt.

Summary of Panel Vote/Comments:

Dr. Crum stated that he thinks the 3rd attempt PA criteria would be difficult to administer, unnecessary and obstruct treatment.

- **Without further discussion, the Panel Voted on the Covered Beneficiary Criteria and PA 3rd Quit Attempt as follows:**

  Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

  There were no further comments from the Panel.

  Director, TMA:

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

4. SMOKING CESSATION PROGRAM: UF and PA Implementation Period

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period in the MTF and mail order POS, contingent on signing of the Final Rule.

Summary of Panel Vote/Comments:

Mr. Duane Tackitt stressed the importance of patients participating in a smoking cessation program if they are receiving these drugs. He ask the PEC to support the programs, advertise, and do whatever possible to ensure that patients are a part of a program.

Dr. Cohoon asked the committee to ensure that providers and patients are aware of the coverage limitations for those patients approaching 65 or over 65. Their eligibility changes after the age of 65.

Dr. Khurana noted that provider education will be very important in treating patients with psychiatric issues. She also believes that Medical Readiness is an important aspect. The program could greatly help patients suffering from COPD and could reduce ER/urgent care visits and also improve quality of life for the patient.

- **Without further discussion, the Panel voted on the UF and PA implementation period as follows:**

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

  There were no further comments from the Panel.

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

UF CLASS REVIEWS – NEWER SEDATIVE HYPONTICS DRUG CLASS RELATIVE CLINICAL EFFECTIVENESS

1. SED-1s: UF Recommendations

The P&T Committee recommended the following:

1. Zolpidem IR and zalephon be designated formulary on the UF and step-preferred. This recommendation incorporates step therapy, which requires a trial of zolpidem IR and zaleplon (step-preferred drugs) in new users befor use of another SED-1s drug;

2. Zolidem CR, Doxepin (Silenor), and eszopiclone (Lunesta) be designated formulary on the UF and non-step-perferred;

3. Ramelteon (Rozerem) and zolpidem SL (Edluar) remain NF and non-step-preferred (behind the step);

4. **Corrected statement**: Zolpidem oral spray: Zolpimist is not covered at the retail POS without a manual PA., due to the manufacturer's lack of participation in the Federal Supply Schedule/Veterans Health Care Act pricing program.

   Dr. Meade noted a correction for Zolpidem Oral Spray: Coverage in the retail network will be approved by manual PA criteria, contraindicated and cannot be obtained for home delivery. This only applies to the retail POS. Ms. Fryar asked if it would be on the UF recommendation vote only.

Summary of Panel Vote/Comments:

Ms. Fryar requested clarification regarding a comment on Table 2. The handout states the following:

- Zolpidem IR (Ambien) and Zaleplon (Sonata) are formulary with documented trial or contraindication, and;
- Zolpidem IR (Ambien) and Zaleplon (Sonata) are non-formulary with a documented trial or contraindication.

Dr. Meade answered that step therapy remains in place. Anything after Zalepon and Zolpidem IR require the trial of those two drugs for new users. The others can either have formulary status after the step or non-formulary after the step.

Dr. Salom requested clarification about the vote count in the handout and the information briefed. Dr. Meade stated that there were 15 members total.

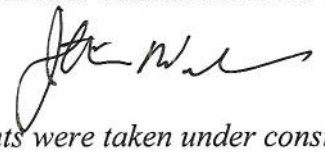
- **Without further discussion, the Panel voted on the UF Recommendations as follows:**

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

  Additional Panel Comments:

  Dr. Cohoon asked whether mail order was formulary or non-formulary for the Zolpidem oral spray. Dr. Meade answered that it would be available at the higher co-pay. Dr. Cohoon clarified that it would be non-formulary mail order with the higher co-pay.

There were no further comments from the Panel.

Director, TMA: 

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

2. SED-1s: PA Criteria

The P&T Committee recommended the following PA criteria should apply to the SED1s class. Coverage would be approved if the patient met any of the following criteria.

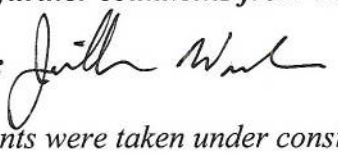
1. Automated PA criteria: The patient has received a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

2. Manual (paper) PA criteria, if automated criteria are not met: The patient has had an inadequate response to zolpidem IR or zaleplon (e.g., hypersensititvity, aberrant behaviors, or intolerable rebound insominia).

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

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

There were no further comments from the Panel:

Director, TMA: 

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

3. SED-1s: UF and PA Implementation Plan

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

Summary of Panel Vote/Comments:

Dr. Crum noted that there are publications reporting the wide-spread use of atypical anti-psychotics and sleepers with active duty service members. This is a concern! He asks whether this implementation plan is an opportunity to do some education about appropriate use of sleepers and sedative medications at MTFs.

- **Without further discussion, the Panel votes on the UF and PA implementation plan was:**

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

  There were 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. GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): UF Recommendations

The P&T Committee recommended gabapentin enacarbil (Horizant) and gabapentin (Gralise) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

Summary of Panel Vote/Comments:

Ms. Fryar asked for clarification regarding committee vote on the UF recommendations and whether the implementation plan began on the first Wednesday or Thursday after the signing of the P&T committee minutes. Dr. Meade answered that it was (14 for, 0 opposed, 1 abstained, 0 absent) and that the implementation plan began on the first Wednesday.

Dr. Cohoon requested clarification about the dosage (multiple times a day) and approximately how many pills are taken for each dose. Dr. Meade answered three times a day and the pill burden could be as many as 6. He does not have the exact dosage. She also asked if there was anything on the formulary does not require multiple doses or where patient would not be required take 6 pills three times per day. Dr. Meade answered not within the GABA subclass for non-opioid pain.

- **Without further discussion, the Panel votes on the UF recommendations were:**

  Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

  There were no further comments from the Panel:

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

2. GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): PA CRITERIA

The P&T Committee recommended that both gabapentin enaqcarbil (Horizant) and gabapentin (Gralise) 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:

1. Automated PA criteria:
   a. The patient has filled a prescription for gabapentin at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

   OR

2. Manual (paper) PA criteria, if automated criteria are not met:
   a. The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.
   b. The patient has experienced AEs with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.

Summary of Panel Vote/Comments:

Dr. Sampsel noted that any patient filling a prescription for gabapentin within the last 180 days would be able to get this drug through the PA. The population of patients receiving gabapentin is large. If there is some sort of utilization management in place, the approval criteria should be taken a step further than just an automatic claims review in 180 days.

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

  Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

  There were no further comments from the Panel:

  Director, TMA:

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

3. GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision.

Summary of Panel Vote/Comments:

Dr. Khurana and Ms. Fryar had concerns about the 30 day implementation period. They noted it should be longer to allow time to disseminate information.

Lisa LeGette stated that 30 days is long enough for ESI. The challenge is have the time to get the letter out.

- **Without further discussion, the Panel voted on the PA Implementation Plan as follows:**

  Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

  There were no further comments from the Panel:

  Director, TMA:

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

BENEFICIARY NOTIFICATION LETTERS

(Read into the Record)

BENEFICIARY INQUIRY RE: STELARA – Letter #1

I would like to urge the BAP to include Stelara in the TRICARE formulary. It is currently specifically excluded from coverage under pharmacy benefits. TRICARE covers the medication under medical benefits, but this causes myriad problems with getting the medication.

I have been under three different primary insurance companies since I retired, and all of them cover Stelara under pharmacy benefits. This causes a problematic catch-22 for the patient. My dermatologist (and all others I asked) doesn't buy and dispense Stelara as a medical treatment. It is ordered from the specialty pharmacy under pharmacy coverage and then sent to and administered in the office. The secondary claim with Tricare is disapproved by express-scripts because of the specific exclusion, and therefore specialty pharmacies can't coordinate benefits.

If I didn't have other health insurance, I couldn't even get the medication under the medical benefits, as doctors don't stock it. The coordination of benefits problem is so bad that I had to get a sample from the manufacturer, because I couldn't get the medicine dispensed in time for my November 2011 injection.

I have tried myriad other treatments for Psoriasis, and Stelara is the only medication that has been able to get it under control. It would be incredibly helpful if TRICARE conformed to how the medication is normally dispensed (pharmacy benefits) so the patient can follow the normal claims and dispensing process for specialty prescription medications.

Very Respectfully,

BENEFICIARY INQUIRY: THE SMOKING CESSATION PROGRAM – Letter #2

American Lung Association

Statement of Charles D. Connor, Capt, U.S. Navy (ret)
President and CEO

June 21, 2012
American Lung Association
Meeting of the Uniform Formulary Beneficiary Advisory Panel

The American Lund Association appreciates the opportunity to comment on the Department of Defense (DoD) Pharmacy & Therapeutics Committee recommendations for the Uniform Formulary regarding Smoking Cessation Agents.

The Committee made these recommendations in anticipation of the implementation of DoD's proposed rule regarding *Smoking Cessation Program Under TRICARE* (DOD-2011-HA-0038). The American Lung Association, along with twenty public health partners, submitted comments on this proposed rule, recognizing the comprehensive approach DoD took in proposing the program. [1] **The American Lung Association commends the DoD Pharmacy & Therapeutics Committee for adopting a similar comprehensive approach in recommending smoking cessation medications, and urges the Beneficiary Advisory Panel to concur with this recommendation.**

Tobacco Use in the Military

Tobacco use remains the leading cause of preventable death in the United States and not surprisingly, is a significant problem within the military as well. The 2008 Department of Defense Survey of Health Behaviors among Active Duty Personnel found that while smoking rates among active duty personnel have essentially remained steady since 2002, smoking rates among deployed personnel are significantly higher. Alarmingly, *more than one in seven (15 percent) of active duty personnel begin smoking after joining the service.*[2]

Currently, the smoking rate for active duty military is 30.5 percent, with smoking rates highest among personnel ages 18-25. Smoking rates are especially high among soldiers and Marines. The Department of Veterans Affairs estimates that at one time, more than 50 percent of all active

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[1] American Lung Association and partners' comments regarding DOD-2011-HA-0038 can be found at: http://www.lung.org/get-involved/advocate-documents/partners-tricare.pdf

[2] Department of Defense, Military Health System. 2008 Department of Defense Survey of Health Behaviors among Active Duty Personnel December 2009, Available at: http://www.tricare.mil/tma/studiesEval.aspx

duty personnel stationed in Iraq smoked[3] - an indication of the need for tobacco cessation services under TRICARE now that they have returned to Iraq. The use of tobacco compromises military readiness and the performance of our men and women in the armed forces. Studies have found the smoking is one of the best predictors of training failure, and it has also been shown to increase soldiers' chances of physical injury and hospitalization.[4] Tobacco use not only costs the DoD in troop readiness and health – it also costs the DoD money. The Pentagon spends over $1.6 billion non tobacco-related medical care, increased hospitalization and lost days of work.[5] These reasons make it crucial that DoD ensure that all members of the military and their families have access to a comprehensive tobacco cessation benefit through TRICARE.

A Comprehensive Tobacco Cessation Benefit

The U.S. Public Health Service details the most current science on tobacco cessation treatment in the *Treating Tobacco Use and Dependence* Guideline. The most recent edition of the Guidance recommends seven medications (Nicotine gum, patch, lozenge, nasal spray and inhaler; and bupropion and varenicline) and three types of counseling (individual, group and phone counseling) as evidence-based treatments to help tobacco users quit.

Treatment for smoking cessation is not one-size-fits-all. Just like other medical conditions, patients respond to treatment differently. It is normal for patients to try more than one treatment before finding the right one. For all these reasons, it is important that cessation benefits offered to smokers be *comprehensive* – meaning they include all treatments proven effective.

By including all seven medications recommended by the Guidance in its recommendation for the Uniform Formulary, the Committee has taken a crucial step in providing soldiers and their families with the best possible chance to quit tobacco.

In the legislation directing DoD to create this Smoking Cessation Program, it is required that smoking cessation medications be provided through TRICARE at no cost to the beneficiary. This is another important step in making it as easy as possible for TRICARE members to quit smoking. The American Lung Association encourages DoD to continue to take steps to make these medications and counseling easily accessible to all TRICARE members, and urges the Beneficiary Advisory Panel to recommend this. Any provision – including cost sharing – that makes it harder for a tobacco user to get treatment will potentially discourage them from quitting or cause failure to quit.[6]

Three years have passed since Congress enacted the TRICARE Smoking Cessation Program, and the American Lung Association is excited to see the implementation of the program. The Lung Association asks the Beneficiary Advisory Panel to encourage DoD to give military members and their families the best chance to quit smoking and be healthier, more productive

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[3] Hamlett-Berry, KW, as cited in Beckham, JC et al. Preliminary findings form a clinical demonstration project for veterans returning from Iraq and Afghanistan, Military Medicine, May 2008; 173(5):448-51

[4] Institute of Medicine. Combating Tobacco Use in Military and Veteran Population – 2009; 3-4.

[5] Institute of Medicine. Combating Tobacco Use in Military and Veteran Population – 2009; 56.

[6] See pages 139=141. Fiore MC, BaileyWC, Cohen SJ, et al. Treating Tobacco Use and Dependence. A Clinical Practice Guideline. http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf.

and combat-ready – ultimately saving lives and money.

Thank you.

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
June 21, 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
- 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
- Dr. Elizabeth Sampsel, Medical Professional, Academy of Manage Care Pharmacy
- Amit Khurana, Medical Professional, TriWest
- Duane Tackitt, The Association of Military Surgeons of the U.S., representing the Military Coalition

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 May 16, 2012 Department of Defense (DoD) Pharmacy and Therapeutic (P&T) Committee meeting held 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/Program Reviews:*
    - Smoking Cessation Agents
    - Newer Sedative Hypnotics

  - *Designated Newly-Approved Drugs*
    - Non-opioid pain syndromes – Gabapentin enacarbil (Horizant) and Gabapentin (Gralise)

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 are:

- To review and comment on the recommendations of the P&T Committee concerning the establishment of the UF and subsequent recommended changes. Comments to the Director, TMA, regarding recommended formulary status, pre-authorizations, and the effective dates for changing drugs from "formulary" to "non-formulary" status must be reviewed by the Director, 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 9 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. The following letters were submitted to the Panel for review and were read into the record at the request of the Chairman.

BENEFICIARY INQUIRY RE: STELARA – Letter #1

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[1] American Lung Association and partners' comments regarding DOD-2011-HA-0038 can be found at: http://www.lung.org/get-involved/advocate-documents/partners-tricare.pdf
[2] Department of Defense, Military Health System. 2008 Department of Defense Survey of Health Behaviors among Active Duty Personnel December 2009, Available at: http://www.tricare.mil/tma/studiesEval.aspx
[3] Hamlett-Berry, KW, as cited in Beckham, JC et al. Preliminary findings form a clinical demonstration project for veterans returning from Iraq and Afghanistan, Military Medicine, May 2008; 173(5):448-51

increase soldiers' chances of physical injury and hospitalization.[4] Tobacco use not only costs the DoD in troop readiness and health – it also costs the DoD money. The Pentagon spends over $1.6 billion non tobacco-related medical care, increased hospitalization and lost days of work.[5] These reasons make it crucial that DoD ensure that all members of the military and their families have access to a comprehensive tobacco cessation benefit through TRICARE.

A Comprehensive Tobacco Cessation Benefit

The U.S. Public Health Service details the most current science on tobacco cessation treatment in the *Treating Tobacco Use and Dependence* Guideline. The most recent edition of the Guidance recommends seven medications (Nicotine gum, patch, lozenge, nasal spray and inhaler; and bupropion and varenicline) and three types of counseling (individual, group and phone counseling) as evidence-based treatments to help tobacco users quit.

Treatment for smoking cessation is not one-size-fits-all. Just like other medical conditions, patients respond to treatment differently. It is normal for patients to try more than one treatment before finding the right one. For all these reasons, it is important that cessation benefits offered to smokers be *comprehensive* – meaning they include all treatments proven effective.

By including all seven medications recommended by the Guidance in its recommendation for the Uniform Formulary, the Committee has taken a crucial step in providing soldiers and their families with the best possible chance to quit tobacco.

In the legislation directing DoD to create this Smoking Cessation Program, it is required that smoking cessation medications be provided through TRICARE at no cost to the beneficiary. This is another important step in making it as easy as possible for TRICARE members to quit smoking. The American Lung Association encourages DoD to continue to take steps to make these medications and counseling easily accessible to all TRICARE members, and urges the Beneficiary Advisory Panel to recommend this. Any provision – including cost sharing – that makes it harder for a tobacco user to get treatment will potentially discourage them from quitting or cause failure to quit.[6]

Three years have passed since Congress enacted the TRICARE Smoking Cessation Program, and the American Lung Association is excited to see the implementation of the program. The Lung Association asks the Beneficiary Advisory Panel to encourage DoD to give military members and their families the best chance to quit smoking and be healthier, more productive and combat-ready – ultimately saving lives and money.

Thank you.

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[4] Institute of Medicine. Combating Tobacco Use in Military and Veteran Population – 2009; 3-4.
[5] Institute of Medicine. Combating Tobacco Use in Military and Veteran Population – 2009; 56.
[6] See pages 139=141. Fiore MC, BaileyWC, Cohen SJ, et al. Treating Tobacco Use and Dependence. A Clinical Practice Guideline. http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf.

CDR Lawrence then introduced the individual Panel members (see list above) and introduced 3 new panel members: Dr. Amit Khurana, TriWest; Dr. Elizabeth Sampsel, AMCP; Mr. Duane Tackitt, AMSUS. He noted housekeeping considerations, then turned the meeting over to the Panel Chairperson, Ms. Deborah Fryar.

Chairperson's Opening Remarks

The Chair welcomed the audience, new panel members 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 are Commander Joe Lawrence the PEC Director and Major Misty Cowen, the PEC Army medical consultant. Also joining us today is COL Doreen Lounsbery, 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 Kugler, the chairmen of the P&T Committee and a retired Army Colonel and physician, is also here. Joining us from the TMA is Mr. William Blanche, TPharm Program Manager and the Alternate DFO for the Uniform Formulary Beneficiary Advisory Panel.

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.

   a. 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 one Uniform Formulary drug class – Newer Sedative Hypnotic Agents. Additionally, we'll present the Uniform Formulary recommendations for the Smoking Cessation Program that is in the final stages of approval. Two newly approved drugs that were reviewed were gabapentin enacarbil (Horizant) and gabapentin (Gralise**)**.

4) The DoD P&T Committee's recommendation as to the effective date of the agents being changed from formulary tier to the non-formulary tier of the Uniform Formulary. Based on 32 C.F.R. 199.21, such change will not be longer than 180 days from the final decision date but may be less.

We've given you a handout which includes the Uniform Formulary recommendations for all the drugs discussed today; these are found on pages 2 through 5. There are tables and utilization figures for all the drug classes. We'll be using trade names as much as possible, so you can refer to your handout throughout the presentation.

The Chairperson then called for the first drug class presentation:

SMOKING CESSATION PROGRAM

PEC Script:

Major Cowan: *Background Relative Clinical Effectiveness*—Drugs for smoking cessation (Table 1on page 2) are currently excluded from the TRICARE® benefit by regulation (32 C.F.R 199.4(g)(65)). The Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 requires the availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation to select beneficiary groups with a limitation on the availability of such pharmaceuticals to the national mail order pharmacy program under the TRICARE program if appropriate. The Proposed Rule, which provides that smoking cessation pharmaceutical agents, including FDA-approved over-the-counter pharmaceutical agents, are available through the TRICARE Mail Order Pharmacy or the MTF, has been published in the Federal Register (76 FR 58199), comments have been received, and the Final Rule is pending publication.

SMOKING CESSATION PROGRAM: Relative Clinical Effectiveness

Major Cowan: *Relative Clinical Effectiveness*— agreed (15 for, 0 opposed, 0 abstained, 0 absent) to accept the following clinical effectiveness conclusions:

- Varenicline (Chantix), bupropion SR, and nicotine replacement therapy (NRT) are efficacious versus placebo for improving long-term smoking abstinence. There is additive efficacy when the smoking cessation drugs are combined with behavioral therapy.
- For combination therapy, nicotine patch plus gum or nasal spray is the most efficacious smoking cessation therapy. Use of the nasal spray is limited by poor tolerability.
- Varenicline (Chantix) is the most efficacious monotherapy for smoking cessation.
- Safety concerns exist for varenicline (Chantix). Although the available data has limitations in study design and shows conflicting results, overall there appears to be an association between varenicline and adverse neuropsychiatric events to include behavioral changes, agitation, suicide/suicidal ideation, and depression.
- Caution should be exercised if varenicline is prescribed to patients with active psychiatric conditions.
- Varenicline has shown efficacy in patients with cardiovascular (CV) disease and chronic obstructive pulmonary disease. There is conflicting data as to whether varenicline is associated with a higher risk of adverse CV events, including non-fatal heart attack, need for coronary by-pass, hospitalization for heart pain, and peripheral vascular disease. However, the benefits of smoking cessation with varenicline are felt to outweigh the risks in patients with pre-existing, stable CV disease.
- Varenicline is more efficacious in terms of abstinence at 52 weeks than bupropion SR. Bupropion SR is more efficacious than the NRT patch. There is additive efficacy if bupropion SR is added on to NRT (either gum or patch). However, the combination is no better than bupropion monotherapy if the bupropion is initiated first.
- When varenicline is compared to bupropion SR in randomized, controlled trials, the most commonly reported AEs are nausea (29%), insomnia (14%), abnormal dreams (13%), and headache (13%). The most common AEs with bupropion include insomnia (21%), nausea (7%), and dry mouth (10%).
- Bupropion carries a black box warning for changes in behavior, depressed mood, hostility, and suicidal ideation.
- All smoking cessation drugs show poor rates of compliance in both effectiveness and efficacy trials. Patient preference for a particular medication modality will determine compliance. Long-term abstinence may occur in cases of incomplete compliance. The typical long-term abstainer will make four or more serious quit attempts before finding success.
- Local MTFs remain at liberty to design their own smoking cessation program, defining which elements will be included in that program.

SMOKING CESSATION PROGRAM: Relative Cost Effectiveness

Dr. Meade:

Relative Cost-Effectiveness Conclusion— CMAs, and cost-effectiveness analyses (CEAs) and budget impact analyses (BIA) were used to evaluate the relative cost-effectiveness of the Smoking Cessation Program. Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee (15 for, 0 against, 0 abstained, 0 absent) the following:

- CMA results showed that nicotine patch and gum were the least costly products among available NRTs, and bupropion SR was the least costly non-NRT option.

- CEA results demonstrated that, in adult patients who smoke more than 10 cigarettes a day, combination therapy (nicotine patch plus gum) was the most cost-effective treatment for tobacco dependence offering the greatest improvement in rates of long-term smoking abstinence. Although less cost-effective than combination therapy, varenicline was recognized as a cost-effective option when evaluating abstinence rates with monotherapy.

- BIA results showed that inclusion of bupropion SR, varenicline, and nicotine (as patch, gum, lozenge, nasal spray, and inhaler) in the TRICARE Smoking Cessation Program was the most favorable scenario for the MHS.

SMOKING CESSATION PROGAM: Coverage 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 (13 for, 1 opposed, 1 abstained, 0 absent): varenicline (Chantix), bupropion SR 150 mg, and nicotine (as patch, gum, lozenge, nasal spray, and inhaler) be covered agents in the TRICARE Smoking Cessation Program, contingent on publication of the Final Rule. No smoking cessation drugs were recommended to be excluded from the program.

SMOKING CESSATION PROGRAM: PA Recommendation

The P&T Committee recommended (6 in favor of prior authorization for varenicline, 8 opposed, 1 abstained, 0 absent) the proposal that PA criteria should apply to varenicline (Chantix). PA criteria for varenicline were proposed for safety concerns, primarily neuropsychiatric AEs.

SMOKING CESSATION PROGRAM: Program Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in the MTF and mail order POS, following publication of the Final Rule.

SMOKING CESSATION PROGRAM: Committee Physician's Perspective

COL Lounsbery stated that this was a slightly different category of drugs because the P&T Committee was defining the benefit rather than recommending what drugs would be include in the UF. She noted that most of the MTFs already offer smoking cessation programs and the smoking cessation products are available to active duty military that live near MTFs. The clinical and cost effectiveness analysis shows that the nicotine patch plus gum is the best treatment option for most people. However, the biggest concerns and discussions were about the issues with varenicline (Chantix). As an Army physician, she is aware of the amount of behavioral health issue in the Army. There has been a lot of concern through-out the Army about Chantix, the side effects, the rates of suicide, and other issues.

Col Lounsbery noted that she served as the DoD Co-Chair for the group that drafts VA DoD Clinical Practice guidelines. This group adopted the Public Health Service guidelines, when they were published, with the exception of the medication recommendations. She said that there have been may other studies that show the effectiveness of Chantix but there are still concerns regarding the safety risks with Chantix. Although she voted for the PA, she is not upset that majority vote that a PA was not required. To ensure that providers understand the side effects of these types of drugs, the P&T committee work to provide materials to educate providers and patients about the safety risks.

SMOKING CESSATION PROGRAM: Panel Questions and Comments

Ms. Fryar asked whether there was a vote on a prior authorization for coverage of a 3rd quit attempt. Dr, Meade answered, the Final Rule states there should be two quit attempts per year. However, a 3rd quit attempt may be authorized by the provider with prior authorization.

Dr. Sampsel asked whether counseling would be required for beneficiaries to get the smoking cessation drugs after the Final Rule is signed. The presenters mention that patients have the most success when counseling is paired with the use of the drugs. Dr. Meade answered that the Rule recommends counseling or some type of interaction but it does not mandate counseling. Dr. Lounsbery noted that the MTFs have the freedom to design their own programs and most of the MTF do require counseling as part of the getting the drugs. In closing, Dr. Sampsel noted that smokers often stop smoking only to become addicted to whatever they used to quit smoking.

Dr. Cohoon agreed that counseling is important in addition to conversations with the provider to discuss the best options to ensure success. The fact the counseling is not mandated causes concerns.

Dr. Cohoon asked whether it was a Proposed or Final Rule. Dr. Meade stated that it was in the final stages and would be the Final Rule once it is signed.

Dr. Cohoon noted that the drugs are available at the MTF and mail order but not in retail. She asked how reservists and the Guard, who do not have access to the MTF, would receive their 1st time fill if the drugs are not available in the retail network pharmacies. Dr. Meade said the prescriptions would be filled in the mail order program. She asked how long it would take for mail order to fill the

prescriptions. Dr. Meade said it would take approximately two weeks or the time needed for ESI to receive, process, and send the drugs. Dr. Cohoon expressed concerns about patients waiting two weeks or more for the prescription to be filled after the initial appointment/consultation with their physician. Dr. Meade said that the P&T committee is limited to what the final rule states.

Dr. Cohoon noted that many active duty service members start smoking while in theater and have difficulties quitting when they return. She asked if the drugs would be available in theater. Dr. Meade stated that the drugs are already being dispensed in theater.

Dr. Cohoon requested clarification regarding co-pay and where the drugs would be placed on the formulary. Dr. Meade said that it did not make a difference because there is no co-pay. It will be on the UF as a covered drug. The rule states that there is no co-pay and it will be part of implementation after the rule is signed.

Dr. Cohoon noted that a PA is required for a 3rd quit attempt. She asked what constitutes an attempt. Dr. Meade answered; the Rule states 120 days of therapy constitute one attempt. In defining a quit attempt, Dr. Meade reiterated that an attempt is 120 days of therapy and it was his understanding that if the patient tries another drug that is another attempt.

SMOKING CESSATION PROGRAM: Panel Vote on Coverage Recommendations

The P&T Committee recommended varenicline (Chantix), bupropion SR 150 mg, and nicotine (as a patch, gum, lozenge, nasal spray, and inhaler) be covered agents in the TRICARE Smoking Cessation Program, contingent on signing of the Final Rule. No smoking cessation drugs were recommended to be excluded from the program.

The Panel votes on the coverage recommendations for the Smoking Cessation Program were:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

There were no Panel comments regarding this recommendation.

SMOKING CESSATION PROGRAM: Varnicline (Chantix) PA Recommendations

The P&T Committee rejected the proposal that PA criteria should apply to varenicline (Chantix). PA criteria for varenicline were proposed for safety concerns, primarily neuropsychiatric AEs. While the Committee recognized the potential for safety concerns with varenicline, they also concluded that PA was not required to ensure safe prescribing with the medication because the risks with varenicline are understood by prescribing providers and can be successfully managed without PA criteria.

NOTE: Ms. Fryar clarified that NO PRIOR AUTHORIZATION for Chantix is required.

The Panel votes for the PA recommendations were:

Concur: 6 Non-Concur: 4 Abstain: 0 Absent: 0

Additional Panel Comments:

Dr. Salom, Dr. Sampsel, Ms. Fryar and Ms. O'Neill-Tracy non concurred with the PA recommendation. The each expressed concerns about the seriousness of the side effects, safety concerns and the need for a PA for this particular drug.

SMOKING CESSATION PROGRAM: Covered Beneficiary Criteria and PA 3rd Quit Attempt

Prior to reading the recommendation, Ms. Fryar noted that an attempt is 120 days of therapy for all the smoking cessation drugs.

The P&T Committee recommended the following coverage criteria should apply to all seven smoking cessation products [varenicline (Chantix), buproprion SR 150 mg, nicotine gum, patch, lozenge, nasal spray, and inhaler], consistent with the requirements in the Proposed Rule, and contingent on signing of the Final Rule. Coverage not approved for patients under the age of 18 or for Medicare-eligible beneficiaries. Coverage for a 3rd quit attempt within one year may be pre-approved if the provider has verified that the patient would benefit from a 3rd quit attempt.

The Panel votes for the covered beneficiary criteria and PA for 3rd Quit Attempt were:

Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

Additional Panel Comments:

Dr. Crum stated that he thinks the 3rd attempt PA criteria would be difficult to administer, unnecessary and obstruct treatment.

SMOKING CESSATION PROGRAM: UF and PA Implementation Period

The P&T Committee recommended an effective date of the first Wednesday after a 60-day implementation period in the MTF and mail order POS, contingent on signing of the Final Rule.

The Panel votes for the UF and PA implementation period were:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Additional Panel Comments:

Mr. Duane Tackitt stressed the importance of patients participating in a smoking cessation program if they are receiving these drugs. He ask the PEC to support the programs, advertise, and do whatever possible to ensure that patients are a part of a program.

Dr. Cohoon asked the committee to ensure that providers and patients are aware of the coverage limitations for those patients approaching 65 or over 65. Their eligibility changes after the age of 65.

Dr. Khurana noted that provider education will be very important in treating patients with psychiatric issues. She also believes that Medical Readiness is an important aspect. The program could greatly help patients suffering from COPD and could reduce ER/urgent care visits and also improve quality of life for the patient.

The Chairperson then called for the next drug class presentations:

UF CLASS REVIEWS – NEWER SEDATIVE HYPONTICS DRUG CLASS RELATIVE CLINICAL EFFECTIVENESS

PEC Script:

Maj Cowan - *Background Relative Clinical Effectiveness*— The P&T Committee evaluated the relative clinical effectiveness of the newer sedative hypnotic drugs used to treat insomnia. The individual drug members of the class are listed in Table 2 of the Handout on page 2

The class as a whole was first reviewed in Aug 2007 and was one of the first classes to have step therapy

Several products have gone generic in this class, prompting the review

Figure 1 of the handout on p3 shows the utilization of the agents. Zolpidem products have the highest usage.

The review included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(1).

Moving on to the P&T conclusions:

The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 0 absent) to accept the following conclusions regarding the newer sedative hypnotics: (Table 1 of the Handout):

- The SED-1s all improve sleep latency (onset) compared to placebo. Sleep maintenance is improved with zolpidem IR, zolpidem CR, eszopiclone, and doxepin.

- Based on an indirect comparison, there do not appear to be clinically relevant differences between zolpidem CR and eszopiclone in terms of objective sleep measures.
- Doxepin improves insomnia by improving sleep maintenance; no comparative data exists with other drugs in the class.
- Zolpidem oral spray does not have comparative clinical trials with other SED-1s. FDA approval was granted based on the data originally submitted with Ambien. Zolpimist may pose additional risk for abuse given its dosage form.
- A recently published trial (Kripke, 2012) documented an increased risk of death with insomnia drugs. The interpretation of the results is hampered by several limitations in study design. No further recommendations regarding sedative hypnotic drug prescribing can be made at this time.
- The potential for abuse/misuse exists with the newer sedative hypnotics, with the exception of ramelteon and doxepin.
- The Pharmacy Outcomes Research Team (PORT) presented the results of several analyses assessing the outcomes of step therapy over the last four years. There was a decline in the number of step therapy rejections over time and an increase in utilization of the preferred product, zolpidem IR, suggesting that prescribers were aware of the step therapy requirement. The step therapy requirement did not move market share away from the MTFs, as 26% of the zolpidem IR prescriptions originated from civilian providers.

Dr. Meade:

NEWER SEDATIVE HYPNOTICS AGENTS: Relative Cost effectiveness

Relative Cost-Effectiveness Pharmacoeconomic analyses were performed for the SED-1s class, including cost minimization analysis (CMA) and budget impact analyses (BIA). A sensitivity analysis was performed to evaluate the impact of movement between generic drugs.

Refer to Table 1 on page 2 for the drugs in this class.

Relative Cost-Effectiveness Conclusion—Based on the results of the cost analysis and other clinical and cost considerations, The P&T Committee concluded (15 for, 0 against, 0 abstained, 0 absent) zolpidem IR was the least costly agent, followed by zaleplon, zolpidem CR, eszopiclone (Lunesta), doxepin (Silenor), zolpidem SL (Edluar), and ramelteon (Rozerem). BIA results showed minimal differences between scenarios, but the projected budgetary impact in the MHS did vary depending on market movement of zolpidem CR when designated step-preferred versus non-step-preferred, rate of price decline of generic zolpidem CR, and market migration of generic drugs versus branded products.

NEWER SEDATIVE HYPNOTICS: UF Recommendation

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

professional judgment, recommended (12 for, 1 opposed, 2 abstained, 0 absent): zolpidem IR and zaleplon be designated formulary on the UF and step-preferred.and formulary on the UF; zolpidem CR, doxepin (Silenor), and eszopiclone (Lunesta) be designated non-preferred and formulary on the UF; ramelteon (Rozerem) and zolpidem SL (Edluar) be designated non- zolpidem IR or zaleplon (the preferred drugs) prior to using other newer sedative hypnotics. Zolpidem oral spray (Zolpimist) is not covered by a written agreement by the manufacturer to honor the pricing required standards. Zolpimist is designated NF.

NEWER SEDATIVE HYPNOTIC: PA Criteria

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following PA criteria should apply to the Newer Sedative Hypnotic inhibitors subclass. Coverage would be approved if the patient met any of the following criteria:

1. Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

2. Manual PA criteria: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.

Zolpimist: PA Criteria -- The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following pre-authorization criteria should apply to availability of Zolpimist through retail network pharmacies. Coverage at retail network pharmacies would be approved if the patient met any of the following criteria:

1. Manual Pre-Authorization Criteria:
    a. Use of the formulary agent is contraindicated.
    b. Obtaining the product for home delivery would be detrimental to the patient.

The PA criteria listed above do not apply to any point of service other than retail network pharmacies.

NEWER SEDATIVE HYPNOTIC: UF and PA Implementation Plan

The P&T Committee recommended 13 for; 0 opposed, 1 abstained; 1 absent an effective date of the first Wednesday after a 60-day implementation period in all points of service and that TMA send a letter to beneficiaries affected by this UF decision.

NEWER SEDATIVE HYPNOTIC: Committee Physician's Perspective

COL Lounsbery informed the Panel that she presented this drug class to the BAP in 2007. This drug class is being reviewed again because there are new products available and a new generic.

The objective of the Committee was to move one more drug in front of the step so that there are two drugs that are step preferred. The other objective was to move Ambien CR from non-formulary to formulary. This opens up the opportunity to a couple of more possibilities and options for the patient. One member wanted to have an additional drug on the UF. There was no dissention regarding this decision.

NEWER SEDATIVE HYPNOTIC AGENTS: Panel Questions and Comments

Ms. Fryar requested clarification regarding a comment on Table 2. The handout states the following:

- Zolpidem IR (Ambien) and Zaleplon (Sonata) are formulary with documented trial or contraindication, and;
- Zolpidem IR (Ambien) and Zaleplon (Sonata) are non-formulary with a documented trial or contraindication.

Dr. Meade answered that step therapy remains in place. Anything after Zalepon and Zolpidem IR require the trial of those two drugs for new users. The others can either have formulary status after the step or non-formulary after the step.

Dr. Salom requested clarification about the vote count in the handout and the information briefed. Dr. Meade stated that there were 15 members total.

SED-1s: UF Recommendations

The P&T Committee recommended the following:

1. Zolpidem IR and zalephon be designated formulary on the UF and step-preferred. This recommendation incorporates step therapy, which requires a trial of zolpidem IR and zaleplon (step-preferred drugs) in new users befor use of another SED-1s drug;

2. Zolidem CR, Doxepin (Silenor), and eszopiclone (Lunesta) be designated formulary on the UF and non-step-perferred;

3. Ramelteon (Rozerem) and zolpidem SL (Edluar) remain NF and non-step-preferred (behind the step);

4. Corrected statement: Zolpidem oral spray: Zolpimist is not covered at the retail POS without a manual PA., due to the manufacturer's lack of participation in the Federal Supply Schedule/Veterans Health Care Act pricing program.

Dr. Meade noted a correction for Zolpidem Oral Spray:

Coverage in the retail network will be approved by manual PA criteria, contraindicated and cannot be obtained for home delivery. This only applies to the retail POS. Ms. Fryar asked if it would be on the UF recommendation vote only.

The Panel votes for the UF Recommendations were:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Additional Panel Comments:

Dr. Cohoon asked whether mail order was formulary or non-formulary for the Zolpidem oral spray. Dr. Meade answered that it would be available at the higher co-pay. Dr. Cohoon clarified that it would be non-formulary mail order with the higher co-pay,

SED-1s: PA Criteria

The P&T Committee recommended the following PA criteria should apply to the SED1s class. Coverage would be approved if the patient met any of the following criteria.

1. Automated PA criteria: The patient has received a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

2. Manual (paper) PA criteria, if automated criteria are not met: The patient has had an inadequate response to zolpidem IR or zaleplon (e.g., hypersensititvity, aberrant behaviors, or intolerable rebound insominia).

The Panel votes for the PA Criteria were:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

There were no further comments from the Panel:

SED-1s: UF and PA Implementation Plan

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

The Panel votes on the UF and PA implementation plan was:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

Additional Panel Comments:

Dr. Crum noted that there are publications reporting the wide-spread use of atypical anti-psychotics and sleepers with active duty service members. This is a concern! He asks whether this implementation plan is an opportunity to do some education about appropriate use of sleepers and sedative medications at MTFs.

The Chairperson then called for the next drug class presentations:

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

PEC SCRIPT

A. Depression/Non-opioid Pain Syndrome Drug Class — Gabapentin enacarbil (Horizant) and gabapentin (Gralise)- Relative Clinical Effectiveness

Major Cowan:

Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of a newly approved Gabapentin enacarbil (Horizant) and gabapentin (Gralise) which are once-daily formulations of gabapentin (Neurontin, generics). At the time of the May 2012 meeting, Horizant was FDA-approved for treating restless leg syndrome (RLS), but was undergoing FDA review for post-herpetic neuralgia. Drugs in the Depression/Non-opioid Pain Syndrome Drug Class – GABA Analog Subclass are listed in Table 3 on page 4 of your handout. This subclass was reviewed for UF status at the November 2011 DoD P&T Committee meeting. Gabapentin (Neurontin, generics) is the preferred agent in this class as step therapy/PA requires a trial of generic gabapentin prior to pregabalin (Lyrica) in new users.

Figure 2 on page 4 of your handout shows generic gabapentin immediate release is the most used product in this class.

Dosing conversion guidelines between Horizant, Gralise, and generic gabapentin are not available and these agents are not interchangeable due to differing pharmacokinetic properties. Gralise requires a large tablet burden to reach recommended dosing. Both drugs may cause significant somnolence and sedation, and Horizant carries a warning for adversely impairing driving ability.

Gabapentin enacarbil (Horizant) and gabapentin (Gralise) - Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) there is no evidence to suggest either drug has a compelling clinical advantage over the other drugs for non-opioid pain syndromes included on the UF

Dr. Meade:

Relative Cost-Effectiveness Analysis and Relative Cost-Effectiveness Conclusion

Cost minimization analysis (CMA) was performed. The weighted average cost per day at all three points of service (POS) was evaluated for gabapentin enacarbil (Horizant) and gabapentin (Gralise) in relation to the other drugs for non-opioid pain syndromes. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that Horizant and Gralise were not cost-effective when compared to other non-opioid pain syndrome agents included on the UF.

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): 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 (14 for, 0 opposed, 1 abstained, 0 absent) gabapentin enacarbil (Horizant) and gabapentin (Gralise) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): PA Criteria

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) that both gabapentin enacarbil (Horizant) and gabapentin (Gralise) be designated non-step-preferred, requiring a trial of generic gabapentin in new users. Coverage would be approved if the patient met any of the following step therapy/PA criteria:

1. Automated PA criteria:
    a. The patient has filled a prescription for gabapentin at any Military Health System (MHS) pharmacy POS [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

2. Manual (paper) PA criteria, if automated criteria are not met:
    a. The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.

    OR

    b. The patient has experienced adverse events (AEs) with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.

NEWER SEDATIVE HYPNOTIC: GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE UF and PA Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Thursday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision and that TMA send a letter to beneficiaries affected by this UF decision.

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): Committee Physician's Perspective

COL Lounsbery began by stating that generic gabapentin is dosed several times a day. These are once a day dosing's. There are no conversion guidelines from generic to these new doses. The Committee agreed that there might be some advantage but they were offset by other issues or cost. So, the committee was unanimous that there was not clinical or cost effectiveness reason to add these to the Uniform Formulary.

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): Panel Questions and Comments

Ms. Fryar asked for clarification regarding committee vote on the UF recommendations and whether the implementation plan began on the first Wednesday or Thursday after the signing of the P&T committee minutes. Dr. Meade answered that it was (14 for, 0 opposed, 1 abstained, 0 absent) and that the implementation plan began on the first Wednesday.

Dr. Cohoon requested clarification about the dosage (multiple times a day) and approximately how many pills are taken for each dose. Dr. Meade answered three times a day and the pill burden could be as many as 6. He does not have the exact dosage. She also asked if there was anything on the formulary does not require multiple doses or where patient would not be required take 6 pills three times per day. Dr. Meade answered not within the GABA subclass for non-opioid pain.

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): UF Recommendations

The P&T Committee recommended gabapentin enacarbil (Horizant) and gabapentin (Gralise) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

The Panel votes on the UF recommendations were:

Concur: 10 Non-concur: 0 Abstain: 0 Absent: 0

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): PA CRITERIA

The P&T Committee recommended that both gabapentin enaqcarbil (Horizant) and gabapentin (Gralise) 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:

1. Automated PA criteria:

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

   OR

2. Manual (paper) PA criteria, if automated criteria are not met:

   a. The patient has a contraindication to gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.

   b. The patient has experienced AEs with gabapentin or the formulary non-opioid pain syndrome agents, which is not expected to occur with Horizant or Gralise.

The Panel vote for the PA criteria was:

Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

Additional Panel Comments:

Dr. Sampsel noted that any patient filling a prescription for gabapentin within the last 180 days would be able to get this drug through the PA. The population of patients receiving gabapentin is large. If there is some sort of utilization management in place, the approval criteria should be taken a step further than just an automatic claims review in 180 days.

GABAPENTIN ENACARBIL (HORIZANT) AND GABAPENTIN (GRALISE): PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this UF decision.

The Panel vote on the PA Implementation Plan was:

Concur: 9 Non-concur: 1 Abstain: 0 Absent: 0

Additional Panel Comments:

Dr. Khurana and Ms. Fryar had concerns about the 30 day implementation period. They noted it should be longer to allow time to disseminate information.

Lisa LeGette stated that 30 days is long enough for ESI. The challenge is have the time to get the letter out.

CLOSING COMMENTS:

With the agenda completed, Ms. Fryar thanked the all panel members for their comments and input; the presenters for their briefing and thanked the audience for attending. She also mentioned made note that her household had received the TRICARE Pharmacy Program Handbook recently and expresses appreciation for this type of beneficiary education which is a great resource. She extended her thanks for the TRICARE Beneficiary handbook and website updates.

Ms. Fryar closed by thanking each of the Panel members for the time they devoted to the process and for all their dedicated work. She indicated that the next scheduled meeting of the Panel is on September 27, 2012.

CDR Lawrence, the DFO, closed the meeting at 10:30 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.

- AE — Adverse event
- AHRQ — Agency for Healthcare Research and Quality
- APR — Automated Profile Review
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- CEA — Cost-effectiveness analysis
- CFR — Code of Federal Regulations
- CMA — Cost-Minimization Analysis
- CPG — Clinical Practice Guideline
- COPD – Chronic Obstructive Pulmonary Disease
- CR — Controlled Release (a drug formulation)
- CV—Cardiovascular
- DFO — Designated Federal Officer
- DoD — Department of Defense
- ECF — Extended Core Formulary
- ER — Extended Release (a drug formulation)
- ESI — Express-Scripts, Inc.
- FACA — Federal Advisory Committee Act
- FDA — U.S. Food and Drug Administration
- IR — Immediate Release (a drug formulation)
- MHS — Military Health System
- MN — Medical Necessity
- MTF — Military Treatment Facility
- NF — Non-formulary
- NRT – Nicotine Replacement Theapy
- OTC — Over the counter
- PA — Prior Authorization
- P&T Committee — DoD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DoD Pharmacoeconomic Center
- PORT — Pharmacy Outcomes Research Team
- POS — Point of Service

- RCTs — Randomized Control Trials
- SR — Sustained release (a drug formulation)
- 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