15 July 2010

Executive Summary

UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL COMMENTS
24 June 2010

The Uniform Formulary (UF) Beneficiary Advisory Panel (BAP) commented on the recommendations from the DoD Pharmacy & Therapeutics (P&T) Committee May 2010 meeting.

1. **ANTILIPIDEMIC-1S:** The P&T Committee recommended the following:

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

(1) Ezetimibe/simvastatin (Vytorin), atorvastatin (Lipitor), simvastatin (Zocor, generics), fluvastatin (Lescol), fluvastatin ER (Lescol XL), lovastatin (Mevacor, generics), lovastatin ER (Altoprev), and pravastatin (Pravachol, generics) remain classified as formulary on the UF; and that atorvastatin/amlodipine (Caduet) and rosuvastatin (Crestor) be designated formulary agents on the UF. Prior authorization (PA) for the LIP-1s drug class would require a trial of atorvastatin (Lipitor) and the generic formulations of simvastatin or pravastatin for new patients (12 for, 0 opposed, 2 abstained, 1 absent);

(2) Ezetimibe (Zetia), niacin ER (Niaspan), lovastatin/niacin ER (Advicor), and simvastatin/niacin ER (SIMCOR) remain designated as UF (13 for, 0 opposed, 1 abstained, 1 absent);

(3) As a result of the above recommendations, there are no LIP-1s designated as non-formulary on the UF.

Summary of Panel Vote/Comments:

- Without further discussion the Panel voted 9 Concur, 0 Non-concur, 0 Abstain regarding the recommendation for formulary agents.
- Without further discussion the Panel voted 9 Concur, 0 Non-concur, 0 Abstain regarding the Prior Authorization criteria recommendation.
    - Panel comment: The Panel agreed that MHS should reconsider the wording of PA criterion (1)(a) to avoid confusion with criterion (2)(a). The suggested wording would be:
    - (a) The patient has received a prescription for a preferred *or requested* agent targeting similar LDL reduction at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.
- The Panel voted 3 Concur, 6 Non-concur, 0 Abstain regarding the implementation period of 60 days.

- Following a brief discussion, the Panel agreed on the following comments should be added for the record:
- 1. The preferred implementation time for this drug class is 30 days instead of 60 days; and
- 2. Patients don't need to receive a letter.

Director, TMA:

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

2. **ALPHA BLOCKERS FOR BPH:** The P&T Committee recommended the following:

Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend (11 for, 3 opposed, 1 abstained, 0 absent) that:

(1) tamsulosin (generic Flomax) and alfuzosin (Uroxatral) be designated as the uroselective UF alpha blockers with Uroxatral or generic tamsulosin as the step-preferred products in front of a step therapy requirement; terazosin (generic Hytrin,) and doxazosin IR (generic Cardura) be maintained as the non-uroselective UF alpha blockers;

(2) silodosin (Rapaflo) remain classified as NF with a PA requiring a trial of alfuzosin or generic tamsulosin for new patients; and

(3) doxazosin ER (Cardura XL) be classified as the NF non-uroselective alpha blocker for BPH

Summary of Panel Vote/Comments:

- Without further discussion, the Panel voted 9 Concur, 0 Non-concur, 0 Abstain regarding the recommendation for formulary and non-formulary agents.
- The Panel voted 9 Concur, 0 Non-concur, 0 Abstain regarding the Prior Authorization criteria recommendation.
- Without further discussion, the Panel voted 9 Concur, 0 Non-concur, 0 Abstain regarding the implementation period of 60 days.
    - Mr. Hutchings commented for the record that in his opinion letters should not be sent to Flomax patients, only to Cardura patients.

Director, TMA:

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

3. **NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS):** The P&T Committee recommended the following:

Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (12 for, 2 opposed, 1 abstained, 0 absent) fentanyl citrate transmucosal soluble film (Onsolis) be designated as formulary on the UF.

Summary of Panel Vote/Comments:

- Without further discussion the BAP voted 8 Concur, 1 Non-concur, 0 Abstain regarding the recommendation that fentanyl citrate transmucosal soluble film (Onsolis) be designated formulary on the UF.
    - The non-concurring Panel member commented that his vote was based on Onsolis having no proven benefits compared to Actiq.
- The Chair noted that the implementation plan doesn't apply to this drug.

***Director, TMA*:**

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

5. **TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO):** The P&T Committee recommended the following:

Taking into consideration the conclusions from the relative clinical effectiveness, 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) sumatriptan needle-free injection (Sumavel DosePro) be designated non-formulary (NF) on the UF.

Summary of Panel Vote/Comments:

- Without further discussion the BAP voted 6 Concur, 3 Non-concur, 0 Abstain regarding the recommendation that sumatriptan needle-free injection (Sumavel Dosepro) be designated non-formulary on the UF.
    - Panel comments regarding the non-concur votes were: (1) the product should be made available to everyone; (2) the product has only been available for two months and would have a Prior Authorization requirement anyway; (3) the input received sounds like the product is quite beneficial to some patients; (4) practitioner experience indicates that having another option available for patients with needle phobia would be very useful, especially for caregivers who are providing the medication; (5) this delivery mechanism, unlike needles, doesn't present a biohazard; (6) the letters seemed to emphasize that this medication has been beneficial to the beneficiaries and were helpful for Panel members. However, one panel member did note that one of the letters had indicated that it had been solicited.
- Without further discussion the BAP voted as follow 8 Concur, 1 Non-concur, 0 Abstain regarding the implementation plan of 60 days.
    - The non-concurring Panel member stated that her vote was based on earlier non-concurrence with the UF recommendation.

- ***Director, TMA*:**

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

6. **UTILIZATION MANAGEMENT—QUINE SULFATE (QUALAQUIN):** The P&T Committee recommended the following:

Due to continued safety concerns and FDA advisories recommending against use of quinine sulfate for leg cramps, the P&T Committee recommended (13 for, 1 opposed, 1 abstained, 0 absent) a PA be required for quinine sulfate (Qualaquin) that limits use to the FDA-approved indication of malaria. The PA would apply to both existing and new users of quinine sulfate. Updated estimates on the numbers of patients who would be affected by the PA are 6,600 patients, based on the numbers of users in the past 120 days.

Summary of Panel Vote/Comments:

- Without further discussion the BAP voted 9 Concur, 0 Non-concur, 0 Abstain regarding the recommendation for requiring a Quinine Sulfate Prior Authorization to limit its use to the FDA-approved indication of malaria.

  The BAP implementation plan vote was 9 Concur, 0 Non-concur, 0 Abstain regarding the 60-day implementation recommendation.

  - The Panel made a formal comment to the effect that MHS should ensure that letters are sent to affected beneficiaries before implementing this PA.

***Director, TMA*:**

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

7. **NATIONAL DEFENSE AUTHORIZATION ACT, SECTION 703-IMPLEMENTATION OF FEDERAL CEILING PRICE REGULATION:**

A. ***Committee Action – Drugs retaining UF status:***

The P&T Committee recommended by consensus the drugs listed below, retain formulary status on the UF.

Table 1.

Product Name	Subclass	Manufacturer
DEPAKENE	Anticonvulsants	ABBOTT LABS
OMNICEF	3rd gen cephalosporins	ABBOTT LABS
PCE	Macrolide	ABBOTT LABS
DIPENTUM	Medications for inflammatory bowel disease	ALAVEN PHARMA
KADIAN	Higher potency single analgesic agents	ALPHARMA BPD

ALLEGRA	2nd gen antihistamines & combos	AVENTIS PHARM
CYTOXAN	Alkylating agents	BMS ONCO/IMMUN
CATAPRES	Sympatholytics	BOEHRINGER ING.
EVOXAC	Parasympathetic agents	DAIICHI SANKYO
FLOXIN	Otic medications, anti-infective	DAIICHI SANKYO
BANZEL	Anticonvulsants/antimania medications	EISAI INC.
FRAGMIN	Anticoagulants	EISAI INC.
SALAGEN	Parasympathetic agents	EISAI INC.
ZONEGRAN	Anticonvulsants	EISAI INC.
CETROTIDE	LHRH (GNRH) antagonist, pituitary suppressant agent	EMD SERONO, INC
LUVERIS	Luteinizing hormones	EMD SERONO, INC
SEROSTIM	Growth hormone	EMD SERONO, INC
ZORBTIVE	Growth hormone	EMD SERONO, INC
BRAVELLE	FSH/LH fertility agents	FERRING PH INC
ENDOMETRIN	Pregnancy facilitating/maintaining agent	FERRING PH INC
REPRONEX	FSH/LH fertility agents	FERRING PH INC
LAMICTAL ODT	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL ODT (BLUE)	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL ODT (GREEN)	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL ODT (ORANGE)	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL XR	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
DERMA-SMOOTHE-FS	Topical corticosteroids	HILL DERM
PERANEX HC	Topical corticosteroids/immune modulators	KENWOOD LAB
FLEXERIL	Skeletal muscle relaxants	McNEIL CONS
UROCIT-K	Urinary agent	MISSION
LITHOSTAT	Ammonia inhibitors	MISSION PHARM
TINDAMAX	Antiprotozoal	MISSION PHARM
LINDANE	Misc topical anti-infectives	MORTON GROVE PH
ERGOLOID MESYLATES	Misc cardiovascular medications	MUTUAL PHARM CO
KERAFOAM	Keratolytics	ONSET THERAPEUT
OPTASE	Misc topical agents	ONSET THERAPEUT
SALKERA	Keratolytics	ONSET THERAPEUT
PROCRIT	RBC stimulants	ORTHO BIOTECH
METANX	Vitamin B preparations	PAN AMERICAN
DILANTIN	Anticonvulsants/antimania medications	PFIZER US PHARM
OGEN	Estrogens & estrogen/androgen combos	PHARMACIA/UPJOHN
TENEX	Sympatholytics	PROMIUS PHARMA
MS CONTIN	Higher potency single analgesic agents	PURDUE PHARMA L
DORAL	Sedative/hypnotics II	QUESTCOR
RIOMET	Biguanides	RANBAXY BRAND D
ANAPROX	NSAIDs	ROCHE LABS
ANAPROX DS	NSAIDs	ROCHE LABS

Table 1 continued

Product Name	Subclass	Manufacturer
KLONOPIN	Anticonvulsants	ROCHE LABS
KYTRIL	5HT3 antiemetics	ROCHE LABS
VALIUM	Anxiolytics	ROCHE LABS
VESANOID	Misc antineoplastics	ROCHE LABS
VIMPAT	Anticonvulsants/antimania medications	SCHWARZ PHARMA
AGRYLIN	Platelet reducing agents	SHIRE US INC.
CARBATROL	Anticonvulsants	SHIRE US INC.
FOSRENOL	Phosphate binders	SHIRE US INC.

LIALDA	Medications for inflammatory bowel disease	SHIRE US INC.
PENTASA	Medications for inflammatory bowel disease	SHIRE US INC.
PROAMATINE	Adrenergic vasopressors	SHIRE US INC.
NEOBENZ MICRO	Keratolytics	SKINMEDICA
ELDEPRYL	Parkinson's medications	SOMERSET PHARM
LOCOID	Topical corticosteroids	TRIAX PHARMACEU
MINOCIN	tetracyclines	TRIAX PHARMACEU
SULFAMYLON	Topical sulfonamides	UDL
ANDROID	Androgens/anabolic steroids	VALEANT
OXSORALEN	Hyperpigmentation agents	VALEANT
TESTRED	Androgens/anabolic steroids	VALEANT
QUIXIN	Ophthalmic antibiotics, quinolones	VISTAKON PHARMA
MUSE	Prostaglandins for ED	VIVUS
FIORICET	Analgesic combos	WATSON PHARMA
MYAMBUTOL	Antitubercular medications	X-GEN PHARMACEU

B. ***Committee Action – Drugs retain NF status without 703 preauthorization:***

The P&T Committee recommended by consensus the drugs listed, below, maintain NF status but not be subject to preauthorization:

Daytrana, Kapidex, Saizen, Azor, Welchol, Cardene SR, and Vyvanse

C. ***Committee Action – Drugs returned to UF status:***

The P&T Committee recommended by consensus the following Factor VIII and Factor IX drugs be returned to formulary status on the UF upon execution of the DoD Retail Refund Pricing Agreement

Human Factor VIII: Humate-P, Monoclate-P

Recombinant Factor VIII: Helixate FS

Human Factor IX: MonoNine

Summary of Panel Vote/Comments:

- Without further discussion the BAP voted 9 Concur, 0 Non-concur, 0 Abstain that drugs listed on Table return to formulary status on the UF.
- Without further discussion the BAP voted 9 Concur, 0 Non-concur, 0 Abstain that drugs listed under section B above maintain their NF status but not be subject to preauthorization under Section 703.
- Without further discussion the BAP voted 9 Concur, 0 Non-concur, 0 Abstain that drugs under section C above be returned to formulary status on the UF.

Director, TMA:

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

23 July 2010

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
June 24, 2010
Washington, D.C.

Panel Members Present:

- Deborah Fryar, National Military Family Association, representing The Military Coalition, Chairperson
- Santiago Chavez, Association of Military Surgeons of the United States, representing The Military Coalition
- Barbara Cohoon, National Military Families Association, representing The Military Coalition
- John Crum, Medical Professional, Humana Military Healthcare Services, Inc.
- Rance Hutchings, Medical Professional, Uniformed Services Family Health Plan
- Lisa Le Gette, Medical Professional, Express-Scripts, Inc. (by phone)
- Katherine O'Neill-Tracy, Military Officers Association of America, representing The Military Coalition
- Ira Salom, Medical Professional, Clinical Associate Professor, Mt. Sinai School of Medicine
- Marissa Schlaifer, Medical Professional, Academy of Managed Care Pharmacy

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. LTC Stacia Spridgen, the Designated Federal Officer (DFO), called the proceedings to order at 9:00 A.M.

LTC Spridgen said the meeting of the Panel has been convened to review and comment on the recommendations of the Department of Defense (DOD) Pharmacy and Therapeutic (P&T) Committee meeting held May 12 and 13, 2010 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 classes:

    1. Antilipidemic-1s
    2. Alpha Blockers for BPH

- Designated Newly-Approved Drugs:
    1. Narcotic Analgesics – Onsolis (fentanyl transmucosal soluble film)
    2. Triptans – Sumavel Dose Pro (sumatriptan needle-free injection)

- Utilization Management
  1. Quinine sulfate Prior Authorization

- Formulary Status of drugs not in compliance with 2008 NDAA Section 703

Opening Remarks

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

The P&T Committee met for approximately 20 hours to consider the class review recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee

members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DOD P&T Committee meeting minutes and 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 that the minutes accurately reflect relevant facts, regulations or policy.

LTC Spridgen then introduced the individual Panel members and followed by noting the housekeeping considerations pertaining to the meeting.

Private Citizen Comments

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

Chairperson's Opening Remarks

The Panel Chairperson, Ms. Fryar, briefly thanked the Panel members for coming and indicated that the Panel was looking forward to working with the newly-designated DFO, LTC Spridgen. Before beginning the drug class presentations, Ms. Fryar asked the PEC staff to provide the following information for the record:

- An overview of step therapy – what it is, what process is involved and how it works.
- An overview of Prior Authorization (PA) – what it is, what process is involved and how it works.
- How existing prescriptions are affected by Prior Authorizations.

Dr. Dave Meade of the PEC responded to the request with the following information.

He started by reminding the Panel that a drug is classified as either formulary or non-formulary, which is very effective in the Military Treatment Facilities (MTF) for getting market share where the Military Health System (MHS) wants it to be. A second thing looked at is the dosage, to make sure that the patient gets the right amount. The last thing considered is prior authorization, which is used for two different reasons: for safety and to guide therapy. Fentanyl is an example of where a PA used for safety. Fentanyl is a very potent narcotic with potentially fatal, heart-

stopping side effects from overdosing. But the body can get used to it if it is on other drugs before Fentanyl, so the PA requires the patient to be on these other drugs before getting the Fentanyl patch. PAs are also used to guide therapy. The MHS wants the preferred agent to be used for economic reasons. In some drug classes there are similarities between the different agents. In these cases, step therapy comes in as an automated part of the PA process. Prior authorization is the big picture and step therapy is one of the components of the PA process. How it works in mail order and retail is that the computer automatically looks back 180 days. If a patient has had "drug X" during that period, it is in the profile and he or she can get "drug X." If "drug Y" is the preferred agent and the patient isn't doing that well on it, the computer will automatically approve "drug X." If the patient has used either the requested drug or the preferred drug, the request will be approved. If the patient has not used either drug and shows up with a prescription for a drug other than the preferred drug, there will be a blockage. The computer cannot adjudicate that and the pharmacy won't get paid for dispensing the drug. Instead, the pharmacy is directed to the preferred drug agent and the patient has to have a trial of that before he or she can go on to "drug X." In retail and mail order, the process is automated. In the MTFs, the process has to be done manually, and some MTFs are better at that than others. For active prescriptions, the 180 days is really a grandfather period. If a patient is already on the drug they are able to get it again.

Ms. Fryar asked who is responsible for initiating the prior authorization paperwork process when a patient gets a prescription that requires a PA – the physician, the pharmacy or the beneficiary. Dr. Meade replied that ultimately the physician has to sign off on the paperwork, but the pharmacy has a vested interest in making that happen (so they can get paid). Ms. Fryar said she had heard from beneficiaries that they have been notified that they are responsible for walking the paperwork through the system. Dr. Meade said there are multiple ways that it can be handled, including giving the patient a written authorization. For clarification, Ms. Fryar asked if it would be fair to say that, depending on the point of service, it may be the patient's responsibility to handle the paperwork. Dr. Meade agreed, but said it is primarily the provider's responsibility to make sure that the patient has what the process requires.

The Chair then asked to begin the scheduled drug class review presentations.

DRUG CLASS REVIEW PRESENTATIONS

[PEC Script]

(LTC Spridgen): I'm LTC Stacia Spridgen, now wearing my other hat as thePharmacoeconomic Center Director, Joining me today from the PEC are Angela Allerman, one of the PEC clinical pharmacists, and Dave Meade, also a clinical pharmacist, retired Air Force Lieutenant Colonel, and Director of Clinical Operations at the PEC. Also joining us today is Maj Jeremy King, one of the DoD P&T Committee members who will provide the physician perspective and comment on the recommendations made by the Committee. CDR Ellzy, the chairman of the P&T Committee, is here, along with Dr. Kugler, who will be the incoming vice chairman of the P&T committee.

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

review and consideration by the DoD P&T Committee for the Uniform Formulary (UF).

We are here to present an overview of the analyses presented to the DoD P&T Committee. 32 Code of Federal Regulations (C.F.R.) establishes procedures for inclusion of pharmaceutical agents on the Uniform Formulary based upon both relative clinical effectiveness and relative cost effectiveness. The goal of this presentation is not to provide you with the same in-depth analyses presented to the DoD P&T Committee but a summary of the processes and analyses presented to the DoD P&T Committee. These include:

1) A brief overview of the relative clinical-effectiveness analyses considered by the DoD P&T Committee.
2) A brief general overview of the relative cost-effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.
3) The DoD P&T Committee's Uniform Formulary recommendation based upon its collective professional judgment when considering the analyses from both the relative clinical and relative cost-effectiveness evaluations of two Uniform Formulary drug classes – the Antilipidemic-1s drugs and the Alpha Blockers for Begnign Prostatic Hypertrophy; two newly approved drugs – Onsolis oral soluble film and Sumavel injection; and prior authorization for quinine sulfate.
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.

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

I. UNIFORM FORMULARY CLASS REVIEWS — ANTILIPIDEMIC-1 AGENTS

A. ANTILIPIDEMIC-1S — RELATIVE CLINICAL EFFECTIVENESS

(BAP Script) Dr. Angela Allerman

The P&T Committee evaluated the clinical effectiveness of the Antilipidemic-1s, or LIP-1s drug class. The drug class was previously reviewed for UF placement in August 2006. Please turn to Table 1 on page 2 of the handout, where you'll see the table of the drugs in the class. The LIP-1s are all FDA-approved to lower elevated cholesterol levels, and some are also approved to reduce the risk of having a heart attack, stroke or death, in patients with hyperlipidemia, or elevated cholesterol levels.

The class is comprised of 8 statin drugs, two drugs we call add-on therapies (niacin and Zetia), and four drugs that contain a statin combined with niacin (Advicor or Simcor) or Zetia (Vytorin), or a blood pressure drug (Atorvastatin or Lipitor with Norvasc, which goes by the trade name Caduet).

I'd now like you to jump to page 4 of the handout, and look at Table 2. For the LIP-1s, the amount of decrease in the cholesterol level will depend on the dose that you give. We've split the table into the drugs that will give you more than a 45% reduction in low density lipoprotien cholesterol (of LDL cholesterol), and those that give you less than a 45% reduction in LDL cholesterol. The dividing point is shown on the chart by the bolded line in the table.

We primarily focus on LDL cholesterol levels, but there are other types of cholesterol that are important too. HDL cholesterol is sometimes known as the "good cholesterol". For HDL cholesterol, the goal is to increase the levels. Statins do this to some degree, and it also is based on dose, which is similar to what we've seen in Table 2 on page 4. There is another type of cholesterol, called non-HDL, that is also important for patients with elevated cholesterol. The ability of a statin drug to lower non-HDL cholesterol LDL is similar to its ability to lower LDL cholesterol, so the high intensity statins are also the ones that would lower non-HDL to a greater degree.

Now please go back to page 2 and look at Figure 1. This graph shows the utilization for the statins that reduce LDL >45% (we'll call these the high intensity statins). For all three points of service in the Military Health System (MHS), (Military Treatment Facility (or MTF), Mail Order and TRRx, Vytorin has the highest utilization, closely followed by Lipitor, and then Crestor.

Please turn to Figure 2 on page 3 of the handout which has the utilization of the low-to-moderate intensity statins (those that lower LDL levels by less than 45%). Here, for all three points of service, generic simvastatin (Zocor) by far has the highest utilization, followed by Lipitor and then Pravachol. Figure 3 on the bottom of page 3 has the remaining drugs in the class – the utilization for these is lower than the high intensity and low-to-moderate intensity statins. Zetia has the highest utilization here, followed by Niaspan.

In terms of overall expenditures, this class is currently ranked number one in the MHS, with drug class expenditures exceeding $480 million annually.

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

Relative Clinical Effectiveness Conclusion — The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) the following conclusions for the LIP-1s:

1. Across equipotent doses, the statins achieve a similar percentage reduction in low-density lipoprotein (LDL), and a similar percentage increase in high-density lipoprotein (HDL).
2. All statins show a plateau and drop-off in ability to raise HDL at increasing doses.
3. Doubling the dose of a statin provides only an additional 4% to 7% reduction in LDL and 3% to 6 % reduction in non-HDL.
4. There is a strong correlation between the change in LDL and C-reactive protein (CRP). CRP appears to be a strong predictor of coronary heart disease (CHD). It is unclear what

emphasis the upcoming National Heart and Lung Blood Institute Adult Treatment Panel (ATP) IV guidelines will place on CRP in managing patients with hypercholesterolemia.

5. A 1:1 log-linear relationship exists between lowering LDL and non-HDL and reduced relative risk of coronary heart disease. In one mortality study, non-HDL was a stronger predictor of CHD risk than LDL.
6. With respect to the low-to-moderate intensity statins (statins able to reduce LDL levels by $\leq 45\%$):
   - The results of one meta-analysis show Lipitor, Pravachol (pravastatin), and generic Zocor (simvastatin) have similar effects in providing long-term cardiovascular (CV) prevention (which includes reducing death due to all causes, death due to cardiovascular causes, major coronary events (such as heart attack or need for stents), and major cerebrovascular events (such as stroke).
   - There are fewer trials published for generic lovastatin (Mevacor) and Lescol (fluvastatin), but positive outcomes are still shown.
   - Generic simvastatin (Zocor) at doses ≤ 40 mg will remain the DoD-preferred statin.
7. The high-intensity statins (those statins able to reduce LDL levels by >45%) include Lipitor 40 and 80 mg; Vytorin 10/20, 10/40, and 10/80 mg; Crestor 10, 20, and 40 mg; and simvastatin 80 mg.
8. In trials assessing the primary prevention of CHD (which means giving a statin to patients who don't have pre-existing heart disease), statins do not appear to decrease the risk of all-cause mortality. At a dose of 20 mg, Crestor showed a decreased risk of all-cause mortality in the JUPITER trial. The benefit of Crestor in this trial was limited to patients with CRP> 2 and an additional CHD risk factor besides age. When used in the primary prevention of CHD, statins in general decrease the risk of CV events by 22% to 30%.
9. In trials assessing the secondary prevention of CHD (which means giving a statin to patients who already have pre-existing heart disease), statins decrease the risk of mortality and the risk of major CV events 21% to 23%. Similar benefits are conferred among patients with or without diabetes. When used in acute coronary syndrome (another name for heart attacks), Lipitor 80 mg decreases the risk of a second event by 16% to 19%. There are no studies with Crestor assessing the secondary prevention of CHD.
10. Vytorin provides added efficacy in terms of LDL lowering, but still lacks clinical outcomes data showing a reduction in CV events. Positive benefits in reducing CV events have been shown with the simvastatin component of Vytorin in the Heart Protection Study and the Scandinavian Simvastatin Survival Study trials.
11. Zetia lowers LDL 15%–20% by a mechanism distinct from that of the statins.
12. Niaspan lowers LDL 5%–15%, which is lower than the statins. However, Niaspan is required in the MHS, as its primary benefit is to raise HDL by 25%.
13. Since the 2006 review, there is no new compelling data for Advicor, SIMCOR, Caduet, Altoprev, or Lescol XL to change the original conclusion that these drugs do not offer

additional clinical benefits over the other LIP-1s. These drugs have low utilization in the MHS.

14. With regard to safety, there is no evidence that increases in liver function tests or minor adverse events (gastrointestinal disturbances, headaches, rash, itching) are less likely to occur with one statin versus another; these adverse effects are dose-related.

15. Concerns of proteinuria remain with Crestor 40 mg, but the clinical significance of this effect is unknown.

16. The risk of statin-related myotoxicity (or muscle toxicity, including muscle pain) increases with increasing dosages. There is no evidence that one statin is less likely to cause myotoxicity than another. The FDA recently updated the labeling for simvastatin 80 mg, warning of the risk of myotoxicity. The overall incidence of rhabdomyolysis (which is a very severe form of muscle toxicity that also affects the kidneys) is rare with all statins.

17. There is no conclusive data yet to suggest that statin therapy is associated with cognitive decline, behavioral defects, or cancer. However, there is evidence to suggest an increased risk of new onset diabetes with statin therapy (JUPITER trial and Lancet 2010 meta-analysis). The clinical implications of this finding are still unclear.

18. Fluvastatin (Lescol), pitavastatin (a new statin not yet marketed), pravastatin (generic Pravachol), and Crestor do not interact with CYP 3A4 enzymes and have more favorable drug-drug interaction profiles than the other statins. Pravastatin is renally metabolized (in the kidneys instead of the liver) and bypasses the CYP 450 system entirely.

19. The Pharmacy Outcomes Research Team (PORT) analyzed LIP-1s utilization in the MHS during a 7-month period between August 1, 2009, and March 31, 2010. Overall, approximately 1.4 million DoD beneficiaries receive lipid-lowering therapies and about 1.2 million DoD beneficiaries receive statins. The percentage of the study group classified as new statin users was 7%. Women comprised 51% of the entire study group; the mean patient age was 42.4 years (standard deviation 11.8 years).

    The majority of use is statin monotherapy – a statin given alone without any other lipid lowering drugs (882,000 patients). The most common add-on therapy is ezetimibe (Zetia) (194,000), followed by fibrates (123,000) (Fibrates are in the LIP-2 class and include Lopid and Tricor) and niacin (57,000). Zetia is frequently prescribed as Vytorin (73%); only 27% of the study group received Zetia with a statin other than simvastatin. Most niacin is given separately (74%), with only 6,819 patients receiving SIMCOR or Advicor.

    About 29% of all patients receiving statin monotherapy or a statin plus Zetia are receiving high-intensity statins (statins able to reduce LDL levels by >45%); 17% of this group is receiving a high-intensity statin alone; 11% are receiving a high-intensity statin plus Zetia.

    And lastly,

20. To meet the clinical needs of the majority of MHS patients, the UF must include the low-to-moderate intensity statins simvastatin and pravastatin, and at least one high-intensity statin

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

Dr. Meade will now discuss the LIP-1 cost effectiveness conclusion, and Uniform Formulary and Automated Prior Authorization recommendations.

B. ANTILIPIDEMIC-1s — RELATIVE COST-EFFECTIVENESS

(BAP Script) (Dave Meade): The P&T Committee evaluated the relative cost-effectiveness of the LIP-ls in relation to the efficacy, safety, tolerability, and clinical outcomes of the other agents in the class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

***For the Statins*:** A series of cost-effectiveness analyses (CEAs) and budget impact analysis (BIAs) were used to determine the relative cost-effectiveness of agents in the class.

1. The Annual Cost per 1% LDL Decrease Model compared the cost-effectiveness of the high intensity statins based on annual cost per 1% LDL reduction using a decision analytical model.
2. The Annual Cost per Patient Treated to Goal Model compared the cost-effectiveness of these agents based on annual cost per patient successfully treated to Adult Treatment Panel III National Cholesterol Education Program goal using a decision analytical model.
3. The Annual Cost per 1% Non-HDL Decrease Model compared the cost-effectiveness of the high intensity non-HDL lowering agents based on annual cost per 1% non-HDL reduction using a decision analytical model.
4. The Annual Cost per 1% HDL-increase Model compared the cost-effectiveness of the high intensity HDL-increasing agents based on annual cost per 1% HDL increase using a decision analytical model.

***For the Statin combination products and add-on therapies*:** Cost Minimization Analysis (CMA) and BIA were used to evaluate the cost-effectiveness of the statin combination products and add-on therapies.

COMMITTEE ACTION Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

For the statins (14 for, 0 opposed, 0 abstain, 1 absent):

1. For the low-to-moderate intensity agents ($\leq$ 45% LDL reduction) we evaluated generic simvastatin or Zocor (10, 20, and 40 mg), Lipitor 10 and 20 mg, and all strengths of generic pravastatin (Pravachol). The cost-effectiveness of the agents in this class were evaluated using each of the decision analytic models described, above. In pharmacoeconomic terms, simvastatin was considered to be dominant at all equipotent strengths, in terms of cost per LDL reduction, cost per LDL goal attainment, cost per non-HDL reduction, and cost per HDL increase. CEA results showed simvastatin was located along the cost efficiency frontier and considered to be the optimal agent.

Note: Based on low utilization and the conclusions presented at the August 2006 P&T Committee Meeting, the following agents were not evaluated in the models and were not included in the CEA: simvastatin 5 mg, Crestor 5 mg, ezetimibe/simvastatin (Vytorin) 10/10 mg, fluvastatin IR (Lescol), fluvastatin ER (Lescol XL), lovastatin IR (generic Mevacor), and lovastatin ER.

2. For the high-intensity LDL-lowering agents (> 45% LDL reduction), we evaluated: Lipitor 40 and 80 mg, Crestor 10, 20, and 40 mg, simvastatin/ezetimibe (Vytorin) 10/20, 10/40, 10/80 mg, and simvastatin 80 mg. The cost-effectiveness of the agents in this class were evaluated using each of the decision analytic models described, above. In pharmacoeconomic terms, the results of the first three cost-effectiveness analyses showed Lipitor 40 and 80 mg to be the overall most cost-effective high-intensity agents, in terms of cost per % LDL reduction, cost per % LDL goal attainment, and cost per % non-HDL reduction. Crestor 40 mg was more effective but considerably more costly compared to Lipitor at equipotent doses, but not more effective nor less costly than the equipotent dosage of ezetimibe/simvastatin (Vytorin) 10/80 mg. CEA determined Vytorin was not dominant in cost per outcome compared to Lipitor. From a price per % LDL-reduction perspective, Lipitor (all strengths) was more cost-effective than Vytorin. CEA results showed Lipitor 40 and 80mg was located along the cost efficiency frontier and considered to be the optimal agents.

3. BIA was used to assess the potential impact of cost scenarios where selected LIP-1s were designated formulary or nonformulary on the UF. Cost scenarios evaluating the impact of designating agents on the BCF were also considered. Results from the BIA for LIP-1s revealed that the scenarios placing Lipitor at all strengths as the step-preferred product in front of a step-therapy requirement or automated prior authorization and placing all generic statins in front of a step-therapy requirement, were the most cost-effective scenarios.

4. The results of the BIA showed that Lipitor was less costly than the other brand agents Crestor and Vytorin in all scenarios evaluated. All scenarios placing Lipitor in the step-preferred position were less costly than all nonstep-scenarios and less costly than all other scenarios involving multiple step-preferred branded agents.

For the Statin combination products and add-on therapies (13 for, 0 opposed, 1 abstained, 1 absent)**:**

1. The CMA results revealed that SIMCOR (simvastatin/niacin extended release) was the most cost-effective add-on product, based on an analysis of the cost per day of therapy. Cost per day of therapy was calculated using cost per tablet adjusted by daily average consumption (DACON) rates for SIMCOR, Niaspan, Advicor, and Zetia.

2. BIA was used to assess the potential impact of cost scenarios where selected statin combination products and add-on agents were designated formulary or nonformulary on the UF. Scenarios evaluating the impact of designating agents on the BCF were also considered. Results from the BIA revealed the most cost-effective scenario overall was to maintain Niaspan on the UF, add Zetia on the UF, and designate SIMCOR (simvastatin/niacin extended release) and Advicor(lovastatin/niacin

extended release) NF. However, designating SIMCOR NF may result in increased usage of Niaspan and increase overall costs. Sensitivity analyses show no individual scenario was dominant after considering the margin for error present in all cost projections. Therefore, the cost avoidance of the aforementioned most cost-effective scenario was within the margin of error.

C. Antilipidemic-1s — Uniform Formulary Recommendation

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

(1) Ezetimibe/simvastatin (Vytorin), atorvastatin (Lipitor), simvastatin (Zocor, generics), fluvastatin (Lescol), fluvastatin ER (Lescol XL), lovastatin (Mevacor, generics), lovastatin ER (Altoprev), and pravastatin (Pravachol, generics) remain classified as formulary on the UF; and that atorvastatin/amlodipine (Caduet) and rosuvastatin (Crestor) be designated formulary agents on the UF. Prior authorization (PA) for the LIP-1s drug class would require a trial of atorvastatin (Lipitor) and the generic formulations of simvastatin or pravastatin for new patients (12 for, 0 opposed, 2 abstained, 1 absent);

(2) Ezetimibe (Zetia), niacin ER (Niaspan), lovastatin/niacin ER (Advicor), and simvastatin/niacin ER (SIMCOR) remain designated as UF (13 for, 0 opposed, 1 abstained, 1 absent);

(3) As a result of the above recommendations, there are no LIP-1s designated as non-formulary on the UF.

D. ANTILIPIDEMIC-1s – PRIOR AUTHORIZATION CRITERIA—

The Committee recommended (13 for, 1 opposed, 1 abstained, 0 absent) the following PA criteria should apply to the LIP-1s other than generics and Lipitor. The prior authorization would not apply to Zetia, or Niaspan. Coverage would be approved if the patient met any of the following criteria:

(1) Automated PA criteria:

(a) The patient has received a prescription for a preferred agent targeting similar LDL reduction at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

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

(a) The patient has tried the preferred agent and was unable to tolerate treatment due to adverse effects.

(b) The patient is taking a concurrent drug that is metabolized by CYP3A4.

(c) The patient requires >55% LDL lowering.

(d) The patient requires primary prevention with rosuvastatin (Crestor) and is not able to take atorvastatin (Lipitor).

E. ANTILIPIDEMIC-1s — UNIFORM FORMULARY IMPLEMENTATION PLAN

(BAP Script) (Dave Meade) The P&T Committee recommended (13 for, 1 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval of the DoD P&T Committee minutes.

(Dave Meade): Maj King will now give the physician perspective for the LIP-1s

F. ANTILIPIDEMIC-1s — PHYSICIAN PERSPECTIVE

The main reason why the Committee reviewed this class was the generic formulation of Lipitor is expected to be accepted late next year. The Committee last reviewed this class in 2006 just before generic Zocor became available. As already discussed, reduction in LSL levels vary depending on what statin is given, and the greatest LDL reduction is seen with the higher doses of Lipitor, Vytorin and Crestor. Zocor's highest dose also provides a large reduction in LDL cholesterol but this dose may increase the risk of adverse effects, so the Committee focused on high doses of Lipitor, Vytorin and Crestor. None of the drugs in this class were made non-formulary with the Committee agreeing with the recommendations unanimously with 2 abstentions. The Committee felt that having the step therapy would encourage providers to consider using Zocor for those patients who do not need a large reduction an LDL and consider using Lipitor for those who do need to reduce their LDL cholesterol significantly. The Committee also noted that there is a new FDA-approved indication for Crestor and that step therapy would rule out using Crestor for this indication. The FDA indication is quite specific and is based on age: men older than 50 and women older than 60 and the presence of other risk factors, such as hypertension, smoking or heart disease. The step therapy also does not apply to Zetia or lovastatin.

CDR Ellzy noted corrections to the handout for the record.

G. Antilipidemic-1s — BAP Questions and Discussion

The Chair opened the floor to questions and discussion of this drug class. Dr. Crum noted that the handout seems to show substantial numbers of Vytorin and Crestor users who would now require Prior Authorization. He asked how many beneficiaries will be affected by the Prior Authorization recommendation. Dr. Meade replied that many of the beneficiaries shown on the

table referred to will be "grandfathered" in so that only the new users will require a Prior Authorization. Of the new patients, it looks like about 60,000 people will be affected by the step therapy. Of these, 20,000 will be in MTFs, 31,000 in retail and 9,000 in mail order. In response to a follow-up question from Dr. Crum, Dr. Meade said that if the automated profile shows the beneficiary has used a drug requiring Prior Authorization in the last 180 days they will automatically be approved.

Dr. Schlaifer said she doesn't understand the reason why Crestor is remaining on formulary. Dr. Meade said the decision resulted from the scenario of Crestor being made non-formulary plus the clinical decision where we don't really know what CRP means. He went on to explain that step therapy is now the preferred approach in this class where the UF mainly represents availability. For those beneficiaries who really need a particular agent, the UF will have it available.

Mr. Hutchings noted that this is the first time step therapy has been used where there isn't just one step. He asked whether, under this approach, the beneficiaries have to try just one or do they have to try all of the preferred agents before they can get a non-preferred agent. Dr. Meade said that the answer is: one. Ms. Legette confirmed this, saying that once a beneficiary has tried a preferred agent, when the system looks back 180 days and detect the usage. She said on the commercial side, there are two- and three-step step therapies, but not for MHS because of the need to review MTF claims. Dr. Meade said the bottom line is that there won't be more than one step required to get a non-preferred drug.

Mr. Hutchings also asked for clarification regarding the discussion that took place in the Committee concerning one of the PA requirements: item b -- that a patient be taking a concurrent drug that is metabolized by CYP3A4 enzymes. Dr. Allerman said the issue was previously discussed in the 2006 review and again this time. Some statins interact with these enzymes and the purpose of the PA requirement is to allow patients to get used to the complicated interactions.

Without further questioning, the Panel proceeded to vote on the P&T Committee's recommendations in this drug class.

H. Antilipidemic-1s — BAP Vote on UF Recommendations

Ms. Fryar read the P&T Committee's UF recommendations for the record.

In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the Antilipidemic-1s (LIP-1s), the P&T Committee voted to recommend:

(1) Ezetimibe/simvastatin (Vytorin), atorvastatin (Lipitor), simvastatin (Zocor, generics), fluvastatin (Lescol), fluvastatin ER (Lescol XL), lovastatin (Mevacor, generics), lovastatin ER (Altoprev), and pravastatin (Pravachol, generics) remain classified as formulary on the UF; and that atorvastatin/amlodipine (Caduet) and rosuvastatin (Crestor) be designated formulary agents on the UF. Prior authorization (PA) for the LIP-1s drug class would require a trial of atorvastatin (Lipitor) and the generic formulations of simvastatin or pravastatin for new patients ;

(2) Ezetimibe (Zetia), niacin ER (Niaspan), lovastatin/niacin ER (Advicor), and simvastatin/niacin ER (SIMCOR) remain designated as UF;

(3) As a result of the above recommendations, there are no LIP-1s designated as non-formulary on the UF.

Without further discussion the Panel voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

I. Antilipidemic-1s — BAP Vote on Prior Authorization Recommendations

The Chair next read the Prior Authorization recommendations for this drug class.

The Committee recommended the following PA criteria should apply to the LIP-1s other than generics and Lipitor. Coverage would be approved if the patient met any of the following criteria:

(1) Automated PA criteria:

(a) The patient has received a prescription for a preferred agent targeting similar LDL reduction at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

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

(a) The patient has tried the preferred agent and was unable to tolerate treatment due to adverse effects.

(b) The patient is taking a concurrent drug that is metabolized by CYP3A4.

(c) The patient requires >55% LDL lowering.

(d) The patient requires primary prevention with rosuvastatin (Crestor) and is not able to take atorvastatin (Lipitor).

Before voting, several Panel members engaged in discussion. Dr. Schlaifer asked who, if anyone, would be getting a letter if the step therapy is put in place. Dr. Meade said probably nobody would. Dr. Crum referred back to his question about patients already in the non-preferred agent and asked if criterion (1)(a) should read "The patient has received a prescription for a *formulary* preferred agent." Dr. Meade said the answer is not necessarily because right now Crestor is non-formulary. Dr. Crum said the word "Preferred" appears again in criterion (2)(a), where it seems to be referring to Lipitor or generics. Dr. Meade indicated that it is a correct interpretation. Dr. Crum pointed out that means that term "preferred agent" has a different meaning in criterion (2)(a) than it does in (1)(a). Dr. Meade explained that (1)(a) means that if a patients has had Lipitor and wants to go on to a new drug it will be approved. Dr. Crum said he understands the meaning but still has problem with the wording. Dr. Hutchings suggested maybe the criterion should read: "a preferred agent *or that agent*." Dr. Ellzy added that the one thing that criterion (1)(a) does not allow you to do is switch to another non-preferred agent if you are already on a non-preferred agent. If a patient is already on Crestor, he or she could switch to another non-preferred agent, but not if the patient is on a different non-preferred agent. Criterion (1)(a) would block the switch. He also pointed out that a difference with criterion (2)(a) is that the 180-day requirement is absent. Dr. Schlaifer asked about a hypothetical situation whereby she had a patient who was on simvastatin and was well-controlled on that agent but she preferred Crestor

for whatever reason, and decided to push that patient to Crestor. Dr. Meade replied that the system does assume that the provider has a reason for what they are doing. Mr. Hutchings asked whether Caduet would be considered a "preferred" or "non-preferred" agent under the recommended criteria. Dr. Meade answered that Caduet would be considered Lipitor because it is a combination drug so it would be approved. After brief discussion, the Panel agreed to vote on the recommendation as it stands and then offer a comment regarding the wording of criterion (1)(a). Mr. Hutchings said that to avoid confusion about the meaning of the Panel's vote, the members should vote to concur, even if they feel criterion (1)(a) needs to be changed, then offer additional views..

Without further discussion the Panel voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

Panel comment: The Panel agreed that MHS should reconsider the wording of PA criterion (1)(a) to avoid confusion with criterion (2)(a). The suggested wording would be:

> (a) The patient has received a prescription for a preferred *or requested* agent targeting similar LDL reduction at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

J. Antilipidemic-1s — BAP Vote on Implementation Plan Recommendations

Before voting on the implementation plan recommendations for the LIP-1s, Dr. Hutchings said he believes that a shorter time period – he suggested 30 days -- would be fine in this case, especially in view of the fact that so many patients are grandfathered in and there will probably not need to be any patients who need to receive letters.

Without further discussion, Ms. Fryar read the P&T Committee's implementation plan recommendations.

> The P&T Committee recommended an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval of the DoD P&T Committee minutes.

The Panel voted as follows:

Concur: 3 Non-concur: 6 Abstain: 0

Following a brief discussion the Panel agreed on the following comments should be added for the record:

1. The preferred implementation time for this drug class is 30 days instead of 60 days; and
2. Patients don't need to receive a letter.

II. UNIFORM FORMULARY CLASS REVIEWS — ALPHA BLOCKERS FOR BENIGN PROSTATIC HYPERPLASIA (BPH)

A. ALPHA BLOCKERS FOR BPH – RELATIVE CLINICAL EFFECTIVENESS

(BAP Script) Dr. Angela Allerman

The P&T Committee evaluated the relative clinical effectiveness of the alpha blockers used for BPH currently marketed in the United States. Please turn to page 5 of the handout, and look at Table 3 for the drugs in the class. The class is comprised of three non-uroselective agents: terazosin (Hytrin, generics), doxazosin immediate release (IR; Cardura; generics), and doxazosin extended release (Cardura XL); and three uroselective agents: alfuzosin (Uroxatral), tamsulosin (Flomax), and silodosin (Rapaflo). Generic formulations of tamsulosin were launched in March 2010. The BPH alpha blocker drug class was first reviewed in August 2005 and reviewed again in November 2007. The newest agent, Rapaflo, was reviewed in August 2009.

All the alpha blockers are FDA-approved for treating BPH. The clinical evaluation for the BPH alpha blockers included, but was not limited to, the requirements stated in 32 CFR 199.21(e)(1).

There is an existing automated prior authorization process for the uroselective alpha blockers, which requires a trial of Uroxatral as initial therapy.

If you look at Figure 4 on page 5 of the handout, the Alpha Blocker utilization is shown. From the previous review in November 2007, the success of the automated prior authorization process is shown, as the highest utilization in the MHS is with Uroxatral (or Alfuzosin). Flomax (tamsulosin) is next, followed by terazosin (or generic Hytrin).

Current annual expenditures for the BPH alpha blockers are $52 million.

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following clinical effectiveness conclusions regarding the BPH alpha blockers:

1. There are limited head-to-head trials comparing the BPH alpha blockers; the available placebo-controlled trials and meta-analyses were reviewed. Although all the alpha blockers are superior to placebo, variability in study design and demographics preclude the ability to designate one agent as clinically superior.
2. Based on randomized placebo-controlled trials, terazosin (generic Hytrin), doxazosin (generic Cardura IR and branded Cardura XL), tamsulosin (Flomax), alfuzosin (Uroxatral), and silodosin (Rapaflo) produce clinically significant and comparable symptom improvements when compared to placebo.
3. Uroselective agents (Flomax, Uroxatral and Rapaflo) are well tolerated, with a few differences in safety considerations.
4. Uroselective agents appear to be better tolerated than non-uroselective agents, as measured by withdrawals due to adverse events and discontinuation of therapy.
5. Non-uroselective alpha blockers exhibit a higher rate of vasodilatory adverse effects (headache, dizziness, and slowed heart rate) relative to uroselective alpha blockers

6. All agents have similar warnings regarding intraoperative floppy iris syndrome.
7. The PORT analyzed the rejected claims attributable to the existing automated PA process (step-therapy edit) for the BPH alpha blockers from April 16, 2008, to December 31, 2009.
    a) Over the study period, 154,691 patients received uroselective alpha blockers for BPH in the retail or mail points of service; 43% of the patients encountered the step-therapy edit reject. Step therapy was highly effective at causing switches to preferred products; 81% of the patients who received a selective alpha blocker received the preferred product, alfuzosin (Uroxatral), within 90 days. However, a substantial percentage of patients did not receive an alpha blocker within 90 days; 30% of patients did not receive a selective alpha blocker and 26% did not receive any alpha blocker (selective or non-selective). Note that for this particular disease state, some patients discontinue medication therapy and receive surgery instead.
    b) About 7% of the patients affected by the step therapy edit were female. Results for the women were similar to the overall results: 81% of women receiving a selective alpha blocker were switched to alfuzosin (Uroxatral). However, the majority of women (64%) encountering the reject did not receive a selective alpha blocker within 90 days.
    c) When the alpha blocker step-therapy results were compared to previous analyses of UF drugs with step edits, similar results were noted. The percentages for those patients who did not receive a prescription after the step-edit reject were 35% in the newer sedative hypnotics class, and 31% in the proton pump inhibitor class, versus 26%–30% in the alpha blocker class.
8. A review of the clinical literature since the previous UF reviews did not add substantial new information or support changes in clinical practice.
9. The non-uroselective agents terazosin (generic Hytrin), doxazosin IR (generic Cardura IR), and doxazosin ER (Cardura XL) have a low degree of therapeutic interchangeability with alfuzosin (Uroxatral), tamsulosin (Flomax), and silodosin (Rapaflo) in terms of safety and tolerability, due to the higher incidence of discontinuation rates and vasodilatory effects seen with the non-uroselective alpha blockers.
10. Alfuzosin (Uroxatral), tamsulosin (Flomax), and silodosin (Rapaflo) have a high degree of therapeutic interchangeability; any of these drugs could be expected to meet the needs of the majority of MHS BPH patients requiring an uroselective agent.

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

Dr. Meade will now discuss the Alpha Blocker cost effectiveness conclusion, and Uniform Formulary and Automated Prior Authorization recommendations.

B. ALPHA BLOCKERS FOR BPH — RELATIVE COST-EFFECTIVENESS

BAP Script (Dave Meade) The P&T Committee evaluated the relative cost-effectiveness of the alpha blockers used for BPH in relation to the efficacy, safety, tolerability, and clinical outcomes

of the other agents in the class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA and BIA were used to evaluate the cost-effectiveness of the BPH alpha blockers. Currently, there is a national shortage of Cardura XL, resulting in a higher price for some dosage strengths.

Relative Cost-Effectiveness Conclusion Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) the following:

1. CMA results for the non-uroselective agents revealed that generic terazosin (Hytrin) and generic doxazosin IR (Cardura IR) were the most cost-effective agents based on the weighted average cost per day of therapy.

2. CMA results for the uroselective agents revealed that generic tamsulosin (Flomax) was the most cost-effective agent and Rapaflo (silodosin) was the least cost-effective agent based on the weighted average cost per day of therapy.

3. BIA results revealed the scenario that placed generic tamsulosin (Flomax) alone as the step-preferred product in front of a step therapy requirement on the UF and the scenario that included generic tamsulosin and Uroxatral (alfuzosin) on the UF as the step-preferred products in front of a step were the most cost effective.

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

C. ALPHA BLOCKERS FOR BPH – UNIFORM FORMULARY RECOMMENDATION

BAP Script (Dave Meade) Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend (11 for, 3 opposed, 1 abstained, 0 absent) that:

(1) tamsulosin (generic Flomax) and alfuzosin (Uroxatral) be designated as the uroselective UF alpha blockers with Uroxatral or generic tamsulosin as the step-preferred products in front of a step therapy requirement; terazosin (generic Hytrin,) and doxazosin IR (generic Cardura) be maintained as the non-uroselective UF alpha blockers;

(2) silodosin (Rapaflo) remain classified as NF with a PA requiring a trial of alfuzosin or generic tamsulosin for new patients; and

(3) doxazosin ER (Cardura XL) be classified as the NF non-uroselective alpha blocker for BPH

D. ALPHA BLOCKERS FOR BPH –PRIOR AUTHORIZATION CRITERIA

BAP Script (Dave Meade) The automated PA (step therapy) currently in effect requires alfuzosin (Uroxatral) before other NF alpha blockers for BPH, unless there is therapeutic failure, intolerance, or hypersensitivity. The automated PA criteria will now include generic tamsulosin as a preferred BPH alpha blocker, along with alfuzosin (Uroxatral). The P&T Committee voted (13 for, 0 opposed, 2 abstained, 0 absent) to recommend the PA criteria outlined, below, should apply to silodosin (Rapaflo); there is no change to the criteria for silodosin previously in effect. Coverage would be approved if the patient met any of the following criteria:

(1) Automated PA criteria:

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

(2) PA criteria if automated criteria are not met:

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

(b) Treatment with alfuzosin (Uroxatral) or tamsulosin is contraindicated.

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

E. ALPHA BLOCKERS FOR BPH – UNIFORM FORMULARY IMPLEMENTATION PLAN

(Dave Meade) The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval of the DoD P&T Committee minutes.

(Dave Meade) Maj King will now give the physician perspective for the Alpha Blockers

F. ALPHA BLOCKERS FOR BPH — COMMITTEE PHYSICIAN PERSPECTIVE

Maj King provided the BAP with the physician's perspective on the Committee's recommendations in this drug class. He noted that this class was reviewed earlier in 2005 and 2007 – but was re-reviewed now because tamsulosin (Flomax) went generic in March. Overall, there was no information presented that would suggest changing clinical practices. However, a review of the step therapy procedures for alpha blockers showed that the process was very effective in leading practitioners to switch patients to the preferred agent, which has been Uroxatral for the past two years. He said there was some opposition to the recommendations on the Committee. Flomax was previously non-formulary, but now that it has gone generic some Committee members wanted to make it the main preferred agent on the UF. But the majority

agreed to keep Uroxatral as a preferred agent for step therapy along with generic tamsulosin (Flomax). He also said the PA will not apply to the non-uroselective drugs.

G. ALPHA BLOCKERS FOR BPH — BAP QUESTIONS AND DISCUSSION

Dr. Hutchings asked if there is a way to expedite the patient notification process in cases like this. He said he would like to see the step therapy process changes implemented in 30 days, not 60 days. Dr. Allerman and LTC Spridgen said that the process itself just takes some time – more at some points of service than others. Dr. Hutchings asked if the system has to wait the full 60 days or can it be done earlier if that is possible. Ms. Fryar said that 60 days seems to be the most viable way of making the change from the standpoint of continuity across all points of service. Ms. Legette commented that if letters have to be sent, 60 days is an optimal time period because of the time required by the TMA process. But she said the step process for Cardura could occur in 30 days.

H. ALPHA BLOCKERS FOR BPH— BAP VOTE ON UF RECOMMENDATIONS

Ms. Fryar read the P&T Committee's UF recommendations for the alpha blockers for BPH.

In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee voted to recommend:

(1) tamsulosin (generic Flomax) and alfuzosin (Uroxatral) be designated as the uroselective UF alpha blockers with Uroxatral or generic tamsulosin as the step-preferred products in front of a step therapy requirement; terazosin (generic Hytrin,) and doxazosin IR (generic Cardura) be maintained as the non-uroselective UF alpha blockers;

(2) silodosin (Rapaflo) remain classified as NF with a PA requiring a trial of alfuzosin or generic tamsulosin for new patients; and

(3) doxazosin ER (Cardura XL) be classified as the NF non-uroselective alpha blocker for BPH

Without further discussion, the Panel voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

I. ALPHA BLOCKERS FOR BPH— BAP VOTE ON PRIOR AUTHORIZATION CRITERIA

The Chair next read the P&T Committee's recommended Prior Authorization criteria.

There was no Panel discussion of the recommended Prior Authorization criteria.

The automated PA (step therapy) currently in effect requires alfuzosin (Uroxatral) before other NF alpha blockers for BPH, unless there is therapeutic failure, intolerance, or hypersensitivity. The automated PA criteria will now include generic tamsulosin as a preferred BPH alpha blocker, along with alfuzosin (Uroxatral). The P&T Committee voted to recommend the PA criteria outlined, below, should apply to silodosin (Rapaflo); there is no change to the criteria for silodosin previously in effect. Coverage would be approved if the patient met any of the following criteria:

(1) Automated PA criteria:

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

(2) PA criteria if automated criteria are not met:

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

(a) Treatment with alfuzosin (Uroxatral) or tamsulosin is contraindicated.

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

The Panel voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

J. ALPHA BLOCKERS FOR BPH — BAP VOTE ON IMPLEMENTATION PLAN RECOMMENDATIONS

Ms. Fryar read the implementation plan recommendations for this drug class.

The P&T Committee recommended 1) an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval of the DoD P&T Committee minutes.

Without further discussion, the Panel voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

Mr. Hutchings commented for the record that in his opinion letters should not be sent to Flomax patients, only to Cardura patients.

III. NEWLY APPROVED DRUGS — NARCOTIC ANALGESICS

A. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) - RELATIVE CLINICAL EFFECTIVENESS

(BAP Script) (Angela Allerman) Fentanyl citrate transmucosal soluble film (Onsolis) is classified as part of the Narcotic Analgesic drug class, which was first reviewed for Uniform Formulary placement in February 2007. The clinical evaluation for Onsolis included, but was not limited to, the requirements stated in 32 Code of Federal Regulations (CFR) 199.21(e)(1).

Onsolis is a pure opioid agonist available in a new transmucosal delivery system. It is FDA-approved for the treatment of breakthrough pain in adults with cancer who are opioid tolerant. Onsolis contains the same active drug (fentanyl) via the same route of administration (oral mucosa) as the UF products Actiq (fentanyl transmucosal lozenge; generics) and Fentora (fentanyl transmucosal tablet). It differs from Actiq and Fentora as fentanyl is delivered through a soluble film that adheres to the mucosal membrane and provides protection from the saliva. The film dissolves completely over 15–30 minutes.

If you turn to table 4 on pages 6 to 7 of the handout, you'll see the list of the Narcotic Analgesic drugs. Onsolis falls into the category of a short-acting agent with a duration of action that is less than 12 hours. The utilization of some of the Narcotic Analgesics is found on page 7, in Figure 5. Overall, the short-acting fentanyl products (Actiq and Fentora) have low utilization compared to the long acting fentanyl patch (Duragesic) and morphine sulfate. For Figure 5, the highest utilization is with morphine sulfate tablet, followed by the generic fentanyl patch; the third highest utilization is with morphine sulfate oral solution, followed by the Actiq lozenge on a stick. Not shown in the chart is the utilization for the short-acting fentanyl. For the past 3 years, the generic Actiq lozenge on a stick had the highest MHS utilization, with about 35,000 Rxs per month, followed by Fentora buccal tablets at 20,000 Rxs per month, and then branded Actiq lozenge (at 5,000 Rxs per month),.

There are no direct comparative clinical trials between Onsolis and the other transmucosal fentanyl products. Onsolis is not bioequivalent with other transmucosal fentanyl products. The safety and tolerability profile for Onsolis appears comparable to other transmucosal fentanyl products. The new delivery system offers more efficient absorption with less swallowing of the drug, which could possibly result in less gastrointestinal (GI) adverse effects. Other potential benefits of the new delivery system include reduced ability for diversion and less risk of dental caries.

Onsolis has a restricted distribution risk evaluation and mitigation strategy (REMS) program that requires enrollment by both the physician and patient, limits dispensing to a single retail pharmacy, and provides delivery of the drug via traceable courier. The FDA is requiring, but has not determined an effective date, for similar REMS programs for Actiq and Fentora.

- *Relative Clinical Effectiveness Conclusion*—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the plausible, yet unproven, benefits of the transmucosal fentanyl buccal film (Onsolis) new delivery system include less GI side effects, less risk of diversion, and less risk of dental caries, compared to other UF transmucosal fentanyl products. The clinical relevance of the proposed advantages is unclear at this time. The FDA-mandated REMS

program will ensure use is limited to opioid-tolerant patients.

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

B. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) - RELATIVE COST EFFECTIVENESS

(BAP Script) (Dave Meade) The P&T Committee evaluated the cost of fentanyl citrate transmucosal soluble film (Onsolis) in relation to the efficacy, safety, tolerability, and clinical outcomes of the other currently available narcotic analgesics. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the relative cost-effectiveness of the agent. Results from the CMA showed the projected weighted average cost per day for Onsolis is higher than other formulary narcotic analgesics, except the branded drug Actiq.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 0 abstained, 0 absent) that fentanyl citrate transmucosal soluble film (Onsolis) is more costly than generic fentanyl products in the narcotic analgesic drug class. In comparison to generics in this class, the P&T Committee determined that the higher daily cost for Onsolis was offset by its unique delivery system and the strict REMS program, which will limit inappropriate prescribing.

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

C. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) — UNIFORM FORMULARY RECOMMENDATION

(BAP Script) (Dave Meade) Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (12 for, 2 opposed, 1 abstained, 0 absent) fentanyl citrate transmucosal soluble film (Onsolis) be designated as formulary on the UF.

D. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) — UNIFORM FORMULARY IMPLEMENTATION PLAN – NOT APPLICABLE

(BAP Script) (Dave Meade) : Maj King will now give the physician perspective for Onsolis.

E. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) — COMMITTEE PHYSICIAN PERSPECTIVE

Maj King said the Committee agreed with the analysis and recommendations by the PEC. The agent contains the same active ingredient as the Fentanyl tablet but it may have some unique applications because it is a new delivery system. The Committee was comfortable with this recommendation, although two members felt that it should be non-formulary because of the cost and because it offers no overwhelming advantages compared to Actiq and Fentora. The drug should have limited use because of the REMS program.

F. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) — BAP QUESTIONS AND DISCUSSION

Dr. Schlaifer asked if patients on other Fentanyl products, such as Actiq, could automatically be moved to Onsolis or would a Prior Authorization be required. The answer was that this product will require a Prior Authorization. Dr. Hutchings noted that the REMS program isn't a true Prior Authorization. Under the REMS program, the patient will get a rejection notice every single time. Further Panel discussion indicated that the REMS program also doesn't say what to look for in terms of prior patient use. Dr. Schlaifer said she thinks the program only requires registration. Dr. Hutchings said it just seems like duplication of work.

Ms. Cohoon asked how the program will work overseas, for patients in theater, for example. Dr. Allerman said that they had already been asked about shipping the product to patients in Germany and had been told that it can't be shipped overseas. The product appears to be stable, but there has been no real discussion about in theater use. That would have to be discussed with the company because of FDA requirements. Ms. Cohoon said she knows about the lollipop agent, but hasn't heard about this one in terms of how to store it and other things. Dr. Meade said that because of the REMS program this drug probably won't be available in theater unless some arrangement can be made with the company. Dr. Schlaifer commented that once the FDA sets up a REMS program that may change whether the lollipop is available. She suggested that someone at DoD might want to consider making that comment to the FDA. Ms. Fryar added that the comments about some products not being available in theater are well taken.

G. NARCOTIC ANALGESICS—FENTANYL CITRATE TRANSMUCOSAL SOLUBLE FILM (ONSOLIS) — BAP VOTE ON UF RECOMMENDATIONS

The Chair read the P&T 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 fentanyl citrate transmucosal soluble film (Onsolis) be designated as formulary on the UF.

Without further discussion the BAP voted as follows:

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

The non-concurring Panel member commented that his vote was based on Onsolis having no proven benefits compared to Actiq.

The Chair noted that the implementation plan doesn't apply to this drug.

IV. RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS — TRIPTANS

A. SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO)

(BAP Script) (Angela Allerman) The second new drug we have to discuss is a triptan drug. Sumatriptan needle-free injection (Sumavel DosePro) is a new single-use delivery system for administering sumatriptan subcutaneously. Sumatriptan (Imitrex) is available in oral tablets, a nasal spray, and a traditional needle-containing injection device; all are available in generic formulations. The triptans drug class was last reviewed for UF placement in June 2008. Sumatriptan oral tablets and injection (Imitrex STATdose; generics) are currently included on the BCF. The clinical evaluation for Sumavel DosePro included, but was not limited to, the requirements stated in 32 CFR 199.21(e)(1).

If you turn to page 8 of the handout and look at table 5, the triptan drugs are listed. The utilization is at the bottom of the page, in Figure 6. Sumatriptan has the highest utilization in the MHS, followed by rizatriptan (Maxalt) and zolmitriptan (Zomig). Not shown in the figure is a breakdown of the sumatriptan utilization, by dosage strength. Sumatriptan tablets account for about 25,000 Rxs per month in the MHS, followed by the Sumatriptan injection at 5,000 Rxs per month (which is about 20% of the usage of sumatriptan, and 4% of the overall triptan market basket).

Sumavel DosePro is FDA-approved for treating migraines and cluster headaches. The sumatriptan dose is delivered by a high pressure burst of nitrogen gas, which propels the drug through the subcutaneous space. Pharmacokinetic studies comparing Sumavel DosePro with Imitrex STATdose demonstrated bioequivalence between the two products. Sumavel DosePro obtained FDA approval via section 505(b)(2) of the Federal Food, Drug, and Cosmetic (FDC) Act using data submitted from the original Imitrex STATdose submission. Thus, there are no clinical trials with Sumavel DosePro that measure efficacy for providing pain relief from migraine headaches.

Following administration, initially there is a higher incidence of bleeding, swelling, and bruising with Sumavel DosePro than with Imitrex STATdose; these adverse effects dissipate, and show no difference in severity with Imitrex STATdose 8 hours after administration.

Potential benefits of Sumavel DosePro compared to sumatriptan needle-containing injection include that the device is easy to use, it provides an alternative injection option to patients with severe needle phobia, and it does not require special biohazard disposal (e.g., disposal in household refuse).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed,

0 abstained, 1 absent) that although sumatriptan needle-free injection (Sumavel DosePro) is easy to use, particularly for patients with dexterity issues, and can be disposed of without special precautions, it does not have a significant, clinically relevant therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to the existing UF product, sumatriptan needle-containing injection

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

B. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) RELATIVE COST EFFECTIVENESS

(BAP Script) (Dave Meade) The P&T Committee evaluated the cost of sumatriptan needle-free injection (Sumavel DosePro) in relation to the efficacy, safety, tolerability, and clinical outcomes of the other non-oral sumatriptan formulations included in the triptans drug class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the relative cost-effectiveness of Sumavel DosePro relative to other non-oral UF sumatriptan agents. Results from the CMA showed the projected weighted average cost per day for Sumavel DosePro is higher than other non-oral sumatriptan formulary agents, with the exception of the Imitrex STATdose proprietary formulation.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 0 abstained, 0 absent) that sumatriptan needle-free injection (Sumavel DosePro) is more costly compared to current UF agents except the Imitrex STATdose proprietary formulation.

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

C. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) UNIFORM FORMULARY RECOMMENDATION

(BAP Script) (Dave Meade) Taking into consideration the conclusions from the relative clinical effectiveness, 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) sumatriptan needle-free injection (Sumavel DosePro) be designated nonformulary (NF) on the UF.

D. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) UNIFORM FORMULARY IMPLEMENTATION PLAN

(BAP Script) (Dave Meade) The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at Military Treatment Facilities (MTFs) no later than a 60-day implementation period; and 2) TMA

send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval of the DoD P&T Committee minutes.

Major King will now give the physician perspective for Sumavel.

E. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) — COMMITTEE PHYSICIAN PERSPECTIVE

Maj King provided the P&T Committee physician's perspective on these recommendations. He said most patients with migraine headaches are given oral tablets; only a small percentage require the Imitrex injection. Sunavel is easier to use than the injection, especially for patients with manual dexterity problems. But it is a new technology that has only been available for a couple of months, so it isn't clear if there will be any real benefits. The main reason why Sumavel was made non-formulary came down to the high cost relative to the generic Imitrex and the fact that there would be a limited MHS population needing it.

F. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) — BAP QUESTIONS AND DISCUSSION

The Chair indicated that four letters had been received from practitioners regarding this agent and she read the letters for the record.

Letter #1

Date: 6/18/2010

TRICARE Beneficiary Advisory Panel
Attention: Pharmaceutical Operations Directorate
5111 Leesburg Pike
Skyline 5 -Suite 810
Falls Church, VA 22041~3206

This letter is to support the use of Sumavel DosePro for migraine treatment. I am Director of The Headache Center of Southern California, which is the largest facility of this type in Southern California. As part of this, I see a large number of patients who suffer with migraine. I frequently use triptan medications to help reduce the disability of their attacks. Imitrex has been one of the standard choices for many years. Imitrex STATdose has been used frequently; however, there are limitations due to needle phobia and ease of use. Sumavel DosePro allows patients to deliver sumatriptan subcutaneously without the need for a needle and without the need for a complicated assembly of the injectable substance. A large percentage of my patients suffer with needle phobia, and, thus, have been resistant to using Imitrex stat dose. Subcutaneous sumatriptan is a very effective method for decreasing the duration and intensity of an

individual's migraine attack. A large number of patients will have vomiting, which makes use of oral sumatriptan problematic. Furthermore, some patients' attacks rapidly escalate, or they can awake from sleep in the midst of an attack. As a result, oral formulations are not ideal.
In some cases, patients' headaches persist beyond a 24~hour period, and rescue treatment is required. In these cases, subcutaneous sumatriptan is also ideal. Because of all of these factors, I would support maintaining Sumavel DosePro on the uniform formulary,

If you have any additional questions please contact me at xxx-xxx-xxxx.

Sincerely,

Andrew M. Bumenfeld, M.D.
Diplomate, American Board of Psychiatry and Neurology

Letter #2

June 18, 2010

Tricare Beneficiary Advisory Panel
Fax: 703-681-4504
Re: Sumavel DosePro

To Whom it May Concern:

I have been informed that the Sumavel DosePro is under review within the Tricare network. At this time I have been active in the current trial period and have been pleased with my patient results. This letter is to inform you that I support the extension of the trial period for the Sumavel DosePro.

If you have any questions please feel free to contact me at xxx-xxx-xxxx. Thank you.

Sincerely,

Dr. Nanda N. Kumar

Letter #3

June 18, 2010

TRICARE Beneficiary Advisory Panel
Att: Pharmaceutical Operations Directorate
5111 Leesburg Pike
Skyline 5- Suite 810

Falls Church, VA 22041-3206

Dear BAP:

I was asked to communicate my thoughts in regard to the use of Sumavel DosePro (SDP) and my support of Sumavel DosePro remaining on the "Uniform Formulary" on tier 2 and being available to TRICARE patients for a $9 co-pay as well as my experience with the formulation to date.

I have prescribed the original formulation since its introduction in the United States in 1993 for both migraine (for severe attacks, those attacks already in progress on awakening, attacks with rapid peak to maximal intensity and for episodes associated with severe nausea and vomiting) as well as for cluster headache where rapid relief is of paramount necessity.

The SDP formulation has identical pharmacokinetic properties with a T_{max} of ten minutes explaining its rapid onset and in fact the fastest onset versus any other formulation whatever the triptan. As someone who has worked and written extensively on the SC formulation in regard to having the most impressive onset, efficacy vs. placebo regarding both pain relief and pain freedom, I have been impressed by the novel needleless SC delivery provided by this new formulation. In addition, I have also been working in regard to Post-traumatic Headache/mTBI in our deployed and post-deployed soldiers involved in OIF/OEF. Its simplicity of use and convenience, in my opinion, give it an advantage (especially in combat situations) over the older traditional formulation while also delivering the branded sumatriptan moiety.

My personal clinical experience with the civilian population demonstrates to me that in Sumatriptan SC naïve patients, demonstrating both formulations shows the SDP to be preferred. In experienced users they do prefer the convenience and ease of use and for those that are needle phobic, they don't have to think twice about using it.

I do hope this information is helpful to you and will be considered in your decision making process.

Sincerely yours,

Fred Sheftell, MD
Director and Founder
New England Center for Headache
Stamford, CT

Clinical Assistant Professor
Departments of Neurology and Psychiatry and Behavioral Sciences
Albert Einstein College of Medicine
Bronx, NY

Letter #4

June 18, 2010

TRICARE Beneficiary Advisory Panel
Attn: Pharmaceutical Operations Directorate

To Whom It May Concern:

I, Peter G. Berna, M.D., am writing this letter as a request for a trial period extension for Sumavel DosePro. I am a TRICARE provider, and 60% of my patients are TRICARE beneficiaries. So far the response from patients have been positive, but this extension would allow me to get further experience with Sumavel DosePro, and get as much feedback as possible from patients. For many of these patients the benefits of this medication exceeds the cost and would tremendously improve their quality of life. Thank you for your consideration. My Nurse Practitioner and I sincerely hope that TRICARE patients will continue to benefit from Sumavel Dose Pro.

If you have any questions please feel free to call me at xxx-xxx-xxxx.

Sincerely,

Peter G. Berna, M.D., M.P.H., F.A.C.P.
Janelle A. Hibson, FNP-BC

The Chair then opened the floor to questions and comments from the Panel.

In response to a question from Dr. Hutchings, LTC Spridgen said that even if a drug is classified non-formulary patients still have access to it through the retail and mail order networks. Ms. Fryar verified that the agent would be delivered in a timely manner through mail order.

G. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) — BAP VOTE ON UF RECOMMENDATION

The Chair then read the P&T Committee's UF recommendation for this product.

> Taking into consideration the conclusions from the relative clinical effectiveness, relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended sumatriptan needle-free injection (Sumavel DosePro) be designated nonformulary (NF) on the UF.

Without further discussion the BAP voted as follows:

Concur: 6 Non-concur: 3 Abstain: 0

Panel comments regarding the non-concur votes were: (1) the product should be made available to everyone; (2) the product has only been available for two months and would have a Prior Authorization requirement anyway; (3) the input received sounds like the product is quite beneficial to some patients; (4) practitioner experience indicates that having another option available for patients with needle phobia would be very useful, especially for caregivers who are providing the medication; (5) this delivery mechanism, unlike needles, doesn't present a biohazard; (6) the letters seemed to emphasize that this medication has been beneficial to the beneficiaries and were helpful for Panel members. However, one panel member did note that one of the letters had indicated that it had been solicited.

H. TRIPTANS—SUMATRIPTAN NEEDLE-FREE INJECTION (SUMAVEL DOSEPRO) — BAP VOTE ON IMPLEMENTATION PLAN

The Chair then read the Committee's implementation plan recommendations.

> The P&T Committee recommended an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at Military Treatment Facilities (MTFs) no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval of the DoD P&T Committee minutes.

Without further discussion the BAP voted as follows:

Concur: 8 Non-concur: 1 Abstain: 0

The non-concurring Panel member stated that her vote was based on earlier non-concurrence with the UF recommendation.

V. UTILIZATION MANAGEMENT — QUININE SULFATE (QUALAQUIN)

A. UTILIZATION MANAGEMENT — QUININE SULFATE (QUALAQUIN) - BACKGROUND

(BAP Script) (Angela Allerman) Next, we'd like to discuss recommendations made by the Committee for a new prior authorization for a new drug, which is really an old drug, quinine sulfate. Quinine sulfate has been used off-label for years to treat nocturnal leg cramps. The only quinine product approved by the FDA (marketed under the trade name Qualaquin) is only approved for treating malaria; however, the FDA recognizes that the majority of its use is for leg cramps. All over-the-counter quinine products were removed from the market a few years ago, and once Qualaquin was approved by the FDA in 2005, all other prescription quinine products

were also removed from the market.

We have some data on quinine utilization. In the MHS, between April 1, 2009, and March 31, 2010, over 10,300 patients were prescribed quinine, with over 70% of the prescriptions dispensed from the retail network. The majority of patients receiving quinine sulfate prescriptions are older than 45 years. The current MHS usage is 80% lower than that reported in a DoD P&T Committee analysis from 2004. Results from an analysis of MHS quinine prescriptions during fiscal year 2009 found that out of 11,341 patients, 24% had one or more a diagnosis code (ICD-9 code) associated with leg cramps and 0.1% had ICD-9 codes associated with malaria; 76% of patients did not have ICD-9 codes for either malaria or leg cramps.

Meta-analyses and professional guidelines conclude that quinine is likely effective in reducing the frequency of muscle cramps, but the magnitude of benefit is small. No drug is currently FDA-approved for leg cramps, and there are no clearly effective pharmacological or nonpharmacological alternatives. A 2006 post-marketing FDA surveillance study reported that since 1969 there have been 665 reports of adverse events involving quinine sulfate, including 93 deaths. Serious adverse events reported with quinine sulfate include thrombocytopenia (a deficiency of platelets which increases the bleeding risk), hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS-TTP), chronic renal impairment associated with HUS-TTP, hypersensitivity reactions, and QT prolongation. The product labeling for Qualaquin was updated in 2009 to state that the risk associated with quinine sulfate when used for nocturnal leg cramps outweighs any potential benefit.

Dave Meade will give the recommendations from the Committee.

B. PRIOR AUTHORIZATION RECOMMENDATION — QUININE SULFATE (QUALAQUIN)

BAP Script) (Dave Meade) COMMITTEE ACTION: Due to continued safety concerns and FDA advisories recommending against use of quinine sulfate for leg cramps, the P&T Committee recommended (13 for, 1 opposed, 1 abstained, 0 absent) a PA be required for quinine sulfate (Qualaquin) that limits use to the FDA-approved indication of malaria. The PA would apply to both existing and new users of quinine sulfate. Updated estimates on the numbers of patients who would be affected by the PA are 6,600 patients, based on the numbers of users in the past 120 days.

C. PRIOR AUTHORIZATION IMPLEMENTATION PLAN — QUININE SULFATE (QUALAQUIN)

BAP Script) (Dave Meade) COMMITTEE ACTION: The P&T Committee voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend the quinine sulfate PA should have an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at the MTFs, no later than a 60-day implementation date. The implementation period will begin immediately following the approval by the Director, TMA.

Dr. Ellzy will now give the physician perspective for the quinine Prior Authorization recommendation.

D. QUININE SULFATE PRIOR AUTHORIZATION AND IMPLEMENTATION PLAN — PHYSICIAN PERSPECTIVE

Dr. Ellzy said that use of this drug for leg cramps is an off-label use. The recommendation is to ensure that quinine is used only for malaria and the reason for a PA is to make sure that the drug is safe for the beneficiary. There is no other drug for leg cramps.

E. QUININE SULFATE PRIOR AUTHORIZATION AND IMPLEMENTATION PLAN — BAP QUESTIONS AND DISCUSSION

The Panel had no questions or comments regarding this recommendation.

F. QUININE SULFATE PRIOR AUTHORIZATION AND IMPLEMENTATION PLAN — BAP VOTE ON PA RECOMMENDATIONS

Ms. Fryar read the Committee's PA recommendations for quinine sulfate.

> Due to continued safety concerns and FDA advisories recommending against use of quinine sulfate for leg cramps, the P&T Committee recommended a PA be required for quinine sulfate (Qualaquin) that limits use to the FDA-approved indication of malaria. The PA would apply to both existing and new users of quinine sulfate.

Without further discussion the BAP voted as follows:

> Concur: 9 Non-concur: 0 Abstain: 0

G. QUININE SULFATE PRIOR AUTHORIZATION AND IMPLEMENTATION PLAN — BAP VOTE ON IMPLEMENTATION PLAN RECOMMENDATIONS

The Chair then read the quinine sulfate PA implementation plan recommendation:

> The P&T Committee voted to recommend the quinine sulfate PA should have an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the retail network and mail order, and at the MTFs, no later than a 60-day implementation date. The implementation period will begin immediately following the approval by the Director, TMA.

One Panel member asked if letters would be sent on this PA. The answer was that they will.

Another member asked whether it could be implemented in 30 days since there is a safety concern. The answer was probably not.

The BAP implementation plan vote was as follows:

Concur: 9 Non-concur: 0 Abstain: 0

The Panel made a formal comment to the effect that MHS should ensure that letters are sent to affected beneficiaries before implementing this PA.

VI. NATIONAL DEFENSE AUTHORIZATION ACT, SECTION 703—INCLUSION OF TRICARE RETAIL PHARMACY PROGRAM IN FEDERAL PROCUREMENT OF PHARMACEUTICALS UPDATE

(BAP Script) (Dave Meade)

The P&T Committee reviewed drugs that have been established on a DoD Retail Refund Pricing Agreement; these drugs are now compliant with Fiscal Year 2008 National Defense Authorization Act, Section 703. By law, these drugs were designated NF on the UF and subject to pre-authorization prior to use in the retail point of service (POS) and medical necessity in MTFs. These drugs are now eligible to return to their previous formulary status without a pre-authorization requirement. Drugs with pricing agreements were systematically classified according to therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification.

The DoD P&T Committee recommended the following:

A. The P&T Committee recommended by consensus the drugs listed on pages 25-26 of the BAP background information document, return to formulary status on the UF.

Table 1.

Product Name	Subclass	Manufacturer
DEPAKENE	Anticonvulsants	ABBOTT LABS
OMNICEF	3rd gen cephalosporins	ABBOTT LABS
PCE	Macrolide	ABBOTT LABS
DIPENTUM	Medications for inflammatory bowel disease	ALAVEN PHARMA
KADIAN	Higher potency single analgesic agents	ALPHARMA BPD
ALLEGRA	2nd gen antihistamines & combos	AVENTIS PHARM
CYTOXAN	Alkylating agents	BMS ONCO/IMMUN
CATAPRES	Sympatholytics	BOEHRINGER ING.
EVOXAC	Parasympathetic agents	DAIICHI SANKYO
FLOXIN	Otic medications, anti-infective	DAIICHI SANKYO
BANZEL	Anticonvulsants/antimania medications	EISAI INC.
FRAGMIN	Anticoagulants	EISAI INC.
SALAGEN	Parasympathetic agents	EISAI INC.
ZONEGRAN	Anticonvulsants	EISAI INC.
CETROTIDE	LHRH (GNRH) antagonist, pituitary suppressant agent	EMD SERONO, INC
LUVERIS	Luteinizing hormones	EMD SERONO, INC
SEROSTIM	Growth hormone	EMD SERONO, INC
ZORBTIVE	Growth hormone	EMD SERONO, INC

BRAVELLE	FSH/LH fertility agents	FERRING PH INC
ENDOMETRIN	Pregnancy facilitating/maintaining agent	FERRING PH INC
REPRONEX	FSH/LH fertility agents	FERRING PH INC
LAMICTAL ODT	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL ODT (BLUE)	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL ODT (GREEN)	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL ODT (ORANGE)	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
LAMICTAL XR	Anticonvulsants/antimania medications	GLAXOSMITHKLINE
DERMA-SMOOTHE-FS	Topical corticosteroids	HILL DERM
PERANEX HC	Topical corticosteroids/immune modulators	KENWOOD LAB
FLEXERIL	Skeletal muscle relaxants	McNEIL CONS
UROCIT-K	Urinary agent	MISSION
LITHOSTAT	Ammonia inhibitors	MISSION PHARM
TINDAMAX	Antiprotozoal	MISSION PHARM
LINDANE	Misc topical anti-infectives	MORTON GROVE PH
ERGOLOID MESYLATES	Misc cardiovascular medications	MUTUAL PHARM CO
KERAFOAM	Keratolytics	ONSET THERAPEUT
OPTASE	Misc topical agents	ONSET THERAPEUT
SALKERA	Keratolytics	ONSET THERAPEUT
PROCRIT	RBC stimulants	ORTHO BIOTECH
METANX	Vitamin B preparations	PAN AMERICAN
DILANTIN	Anticonvulsants/antimania medications	PFIZER US PHARM
OGEN	Estrogens & estrogen/androgen combos	PHARMACIA/UPJOHN
TENEX	Sympatholytics	PROMIUS PHARMA
MS CONTIN	Higher potency single analgesic agents	PURDUE PHARMA L
DORAL	Sedative/hypnotics II	QUESTCOR
RIOMET	Biguanides	RANBAXY BRAND D
ANAPROX	NSAIDs	ROCHE LABS
ANAPROX DS	NSAIDs	ROCHE LABS

Table 1 continued

Product Name	Subclass	Manufacturer
KLONOPIN	Anticonvulsants	ROCHE LABS
KYTRIL	5HT3 antiemetics	ROCHE LABS
VALIUM	Anxiolytics	ROCHE LABS
VESANOID	Misc antineoplastics	ROCHE LABS
VIMPAT	Anticonvulsants/antimania medications	SCHWARZ PHARMA
AGRYLIN	Platelet reducing agents	SHIRE US INC.
CARBATROL	Anticonvulsants	SHIRE US INC.
FOSRENOL	Phosphate binders	SHIRE US INC.
LIALDA	Medications for inflammatory bowel disease	SHIRE US INC.
PENTASA	Medications for inflammatory bowel disease	SHIRE US INC.
PROAMATINE	Adrenergic vasopressors	SHIRE US INC.
NEOBENZ MICRO	Keratolytics	SKINMEDICA
ELDEPRYL	Parkinson's medications	SOMERSET PHARM
LOCOID	Topical corticosteroids	TRIAX PHARMACEU
MINOCIN	tetracyclines	TRIAX PHARMACEU
SULFAMYLON	Topical sulfonamides	UDL
ANDROID	Androgens/anabolic steroids	VALEANT
OXSORALEN	Hyperpigmentation agents	VALEANT
TESTRED	Androgens/anabolic steroids	VALEANT
QUIXIN	Ophthalmic antibiotics, quinolones	VISTAKON PHARMA

MUSE	Prostaglandins for ED	VIVUS
FIORICET	Analgesic combos	WATSON PHARMA
MYAMBUTOL	Antitubercular medications	X-GEN PHARMACEU

B. The P&T Committee recommended by consensus the drugs listed, below, maintain NF status but not be subject to preauthorization:

Daytrana, Kapidex, Saizen, Azor, Welchol, Cardene SR, and Vyvanse

C. The P&T Committee recommended by consensus the following Factor VIII and Factor IX drugs be returned to formulary status on the UF upon execution of the DoD Retail Refund Pricing Agreement

Human Factor VIII: Humate-P, Monoclate-P

Recombinant Factor VIII: Helixate FS

Human Factor IX: MonoNine

SECTION 703 RECOMMENDATIONS — BAP QUESTIONS AND DISCUSSION

The Panel members had no questions or comments regarding the Section 703 recommendations.

SECTION 703 RECOMMENDATIONS — BAP VOTE ON DRUGS RECOMMENDED FOR RETURN TO THE UF

The Chair read the Committee's recommendations.

A. The P&T Committee recommended by consensus the drugs listed on pages 25-26 of the BAP background information document, return to formulary status on the UF.

Depakene, Omnicef, PCE, Dipentum, Kadian, Allegra, Cytoxan, Catapres, Evoxac, Floxin, Banzel, Fragmin, Salagen, Zonegran, Cetrotide, Luveris, Serostim, Zorbtive, Bravelle, Endometrin, Repronex, Lamictal ODT, Lamictal ODT (Blue), Lamictal ODT (Green), Lamictal ODT (Orange), Lamictal XR, Derma-Smoothe FS, Peranex HC, Flexiril, Urocit-K, Lithostat, Tindamax, Lindane, Ergoloid Mesylates, Kerafoam, Optase, Salkera, Procrit, Metanx, Dilantin, Ogen, Tenex, MS Contin, Doral, Riomet, Anaprox, Anaprox DS, Klonopin, Kytrikl, Valium, Vesanoid, Vimpat, Agrylin, Carbatrol, Fosrenol, Lialda, Pentasa, Proamatine, Neobenz Micro, Eldepryl, Locoid, Minocin, Sulfamylon, Android, Oxsoralen, Testred, Quixin, Muse, Fioricet, Myambutol.

Without further discussion the BAP voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

SECTION 703 RECOMMENDATIONS — BAP VOTE ON DRUGS RECOMMENDED FOR NF STATUS BUT SUBJECT TO PRIOR AUTHORIZATION

The Chair read the Committee's recommendations in this category.

B. The P&T Committee recommended by consensus the drugs listed, below, maintain NF status but not be subject to preauthorization:

Daytrana, Kapidex, Saizen, Azor, Welchol, Cardene SR, and Vyvanse

Without further discussion the BAP voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

SECTION 703 RECOMMENDATIONS — BAP VOTE ON DRUGS RECOMMENDED FOR RETURN TO FORMULARY STATUS UPON EXECUTION OF THE DoD RETAIL REFUND PRICING AGREEMENT

The Chair read the Committee's recommendations in this category.

C. The P&T Committee recommended by consensus the following Factor VIII and Factor IX drugs be returned to formulary status on the UF upon execution of the DoD Retail Refund Pricing Agreement

Human Factor VIII: Humate-P, Monoclate-P

Recombinant Factor VIII: Helixate FS

Human Factor IX: MonoNine

Without further discussion the BAP voted as follows:

Concur: 9 Non-concur: 0 Abstain: 0

CLOSING REMARKS

The DFO thanked the participants and announced that the next BAP meeting will take place September 23, 2010, at the Naval Heritage Center. LTC Spridgen then adjourned the meeting at 11:30 A.M.

Brief Listing of Acronyms Used in This Summary

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

- AE — Adverse event
- APR — Automated Profile Review
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- BP — Blood pressure
- BPA — Blanket Purchase Agreement
- BPH — Benign Prostatic Hyperplasia
- CEA — Cost-effectiveness analysis
- C.F.R — Code of Federal Regulations
- CHD — Coronary heart disease
- CMA — Cost-Minimization Analysis
- CR — Controlled Release (a drug formulation)
- CRP — C-reactive protein
- CV — Cardiovascular
- CYP3A4 — Cytochrome $P_{450}3A4$ (an enzyme)
- DACON — Daily average consumption
- DEA — U.S. Drug Enforcement Administration
- DFO — Designated Federal Officer
- DoD — Department of Defense
- ECF — Extended Core Formulary
- ER — Extended Release (a drug formulation)
- ESI — Express-Scripts, Inc.
- FACA — Federal Advisory Committee Act
- FCP — Federal Ceiling Price
- FDA — U.S. Food and Drug Administration
- HDL — High-density lipoprotein
- IR — Immediate Release (a drug formulation)
- IV — Intravenous
- LIP-1 — Antilipidemics (a drug class)
- LDL — low-density lipoprotein
- MHS — Military Health System
- MN — Medical Necessity
- MTF — Military Treatment Facility

- NDAA — National Defense Authorization Act
- NF — Non-formulary
- NIH — National Institutes of Health
- NNH — Number Needed to Harm
- NNT — Number Needed to Treat
- OTC — Over the counter
- PA — Prior Authorization
- 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)
- SQ — Subcutaneously
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TPHARM — TRICARE Pharmacy Program
- TRRx — TRICARE Retail Pharmacy Program
- UF — DOD Uniform Formulary
- U.S.C. — United States Code
- VA — U.S. Department of Veterans Affairs
- VARR — Voluntary Agreement on Retail Rebates