Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary
September 17, 2008
Washington, D.C.

Panel Members Present:

- Deborah Fryar, National Military Family Association, Chairperson
- Morgan Brown, National Military and Veterans Alliance
- Kathryn Buchta, Health Net Federal Services
- Barbara Cohoon, National Military Family Association
- John Class, Military Officers Association of America
- John Crum, Humana Military Healthcare Services, Inc.
- Rance Hutchings, Uniformed Services Family Health Plan
- Lisa Le Gette, Express-Scripts, Inc.
- Kimberly Owens, National Military and Veterans Alliance
- Charles Partridge, National Military and Veterans Alliance
- Marissa Schlaifer, Academy of Managed Care Pharmacy
- Robert Washington, Fleet Reserve Association

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. LTC Travis Watson, the Alternate Designated Federal Officer (DFO), called the proceedings to order at 8:00 A.M. LTC Watson stated that he is serving as the DFO for this meeting only and has been duly appointed by the DoD Designated Federal Officer to serve during his absence.

LTC Watson said this 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 in August 2008 in San Antonio, TX.

Agenda

The agenda for this meeting of the Panel is:

- Opening remarks
- Public citizen comments
- Review and discussion of P&T Committee recommendations for drugs in the following therapeutic classes:
  - Self-Monitoring Blood Glucose System Test Strips
  - Overactive Bladder Drugs
  - Designated Newly Approved Drugs
- Wrap-up comments

Opening Remarks

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

10 U.S.C. section 1074g (subparagraph d) also requires the Secretary to establish a Uniform Formulary Beneficiary Advisory Panel (BAP) to review and comment on the development of the Uniform Formulary. The Panel includes members that represent non-governmental organizations and associations that represent the views and interests of a large number of eligible covered beneficiaries. Comments of the Panel must be considered by the Director, TRICARE Management Activity (TMA) before implementing changes to the Uniform Formulary. 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 Uniform Formulary and subsequent recommended changes. Comments to the Director, TMA, regarding recommended formulary status, pre-authorizations, and the effective dates for changing drugs from "formulary" to "non formulary" status must be considered by the Director before making a final decision.
- To hold quarterly meetings in an open forum. The Panel may not hold meetings except at the call of or with the advance approval of the Chairman of the Panel.
- To prepare minutes of the proceedings and prepare comments for the Secretary or his designee regarding the Uniform Formulary or changes to the Formulary. The minutes will be available on the website and comments will be prepared for the Director, TMA (Dr. Casscells).

As guidance to the Panel regarding this meeting, LTC Watson said the role of the BAP is to comment on the Uniform Formulary 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 chartered functions 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 Dr. Cassscells's decisions will be available on the TRICARE website in approximately four – six weeks.

LTC Watson next provided the ground rules for conducting the meeting:

- All discussion takes 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 Watson briefly reviewed housekeeping considerations pertaining to the meeting then introduced Pharmacoeconomic Center (PEC) Director LTC Stacia Spridgen and her staff, RADM Tom McGinnis, Chief of the Pharmaceutical Operations Directorate and CDR James Ellzy, Deputy Medical Director, TMA and the individual members of the BAP.

Private Citizen Comments

The DFO opened the meeting for private citizen comments. There was no response from individuals present at the meeting.

Chairperson's Opening Remarks

Panel Chair Deborah Fryar thanked LTC Watson for agreeing to serve as the Designated Federal Officer for this meeting and also thanked the Panel members for their attendance at today's meeting.

Presentation of Drug Class Reviews

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

[Insert script, page 1]

REVIEW OF THE SELF-MONITORING BLOOD GLUCOSE SYSTEM TEST STRIPS (SMBGS) DRUG CLASS

Clinical Effectiveness Review

Dr. Angela Allerman provided the BAP with a summary of the P&T Committee's clinical effectiveness review of blood glucose test strips.

[Insert script, pages 2 and 3]

Cost Effectiveness Review

Dr. Eugene Moore next provided the Panel with the results of the cost-effectiveness review.

[Insert script, page 4]

P&T Committee Action and Recommendations

Dr. Allerman discussed the P&T Committee's formulary recommendations, justification and implementation plan.

[Insert script, page 5]

Committee Physician Perspective

COL Doreen Lounsberry, Vice Chair of the DoD P&T Committee, provided the Panel with a physician's perspective on the recommendations in this drug class. She informed the Panel that the Committee did a "hands on" demonstration of the meters associated with the test strips to see if they could figure them out and to make sure that they were easy to use. They also made sure that at least one meter with a larger digital read out would be available. The Committee discussed minor matters, such as how many blood glucose readings were held in storage, in addition to the major details discussed by Dr. Allerman. Coding was also considered to be a big deal — some patients wouldn't do well with coding — as well as packaging options. In addition, all of the test strips selected for the Uniform Formulary have a 1-800 toll-free number for patients to call and get answers to questions. She said there were two votes against the recommendations, both of them in favor of adding additional items, but the deciding factor was the cost-effectiveness analysis.

Panel Questions

Mr. Crum asked about the likelihood that the average retail pharmacy would have the required quantities of test strips. Dr. Allerman replied that the test strips selected for the formulary are already very popular and large retail establishments such as CVS have ample supplies. Smaller local drug stores may not have as many choices available.

Mr. Hutchings asked about the factors included in the cost effectiveness analysis and also asked why True Track had been included on the third tier. Dr. Moore replied that the product had the fewest clinical attributes of any of the products that met the Committee's clinical specifications. There were also pricing issues that lowered its cost effectiveness ranking. Dr. Allerman added that the company recently added a new test strip that will be reviewed at a future P&T Committee meeting, probably in February. Mr. Partridge asked whether the 10-second response time was the reason for True Track's exclusion from the UF. COL Lounsberry said that it was one factor but that it also takes more blood than the other strips.

Mr. Partridge asked whether the Precision Ultra test strips are the only ones that are individually foil wrapped and whether this was important for kids. The answer was that they are the only strips so packaged and that it is useful when kids have to take the strips to school because it keeps them from becoming degraded. But the foil wrapping also presents problems for older patients.

Ms. Owens asked about the adequacy of the recommended 120-day implementation period and what would be done to make sure that pharmacies would have an adequate supply of meters in advance. An extended discussion of this matter ensued. Nearly every member of the Panel commented or expressed concern about the implementation period. The primary concern expressed was that the 120-day time frame would not be sufficient to allow manufacturers to fulfill the requirements — both for meters and for test strips — of the number of beneficiaries, particularly those using retail pharmacies, who would be transitioning because of formulary changes. Of special concern were beneficiaries who would be newly diagnosed during the transition period, given a prescription for a non-formulary agent and then be required to change almost immediately. Ms. Buchta asked if the implementation period vote could be deferred until after the manufacturers had provided MHS with specific plans showing that they were able to meet the requirements. Mr. Crum agreed with the desirability of having a good operational plan in place for the changeover. Mr. Class asked what would happen at the retail pharmacy level after the change when newly-diagnosed beneficiaries showed up with prescriptions for non-formulary test strips. He also asked whether it would be possible to send letters advising newly-diagnosed beneficiaries of the changes far enough in advance of the implementation date to avoid transition problems and whether pharmacies would be able to just make the switch. Mr. Hutchings commented that the maximum of 180 days would be best for his organization because the organization serves a number of older patients and will have training to do once the new meters are sent out.

Ms. Owens said she would like to see multiple sets of letters sent out, both to beneficiaries and especially to pharmacies. After the initial 180-day notification, she would like to see reminder notices sent out 60 days before implementation and 30 days before implementation. This would help to ensure that patients don't find themselves without their needed diabetes supplies. She said the intent is to make sure that pharmacies have what they need to meet patient needs in advance of the implementation date so patients won't have to buy extra supplies at non-formulary prices while they are waiting for supplies at formulary prices. She noted that diabetes patients need both the

right meters and the right strips at the same time. She also said that the letters that go out to beneficiaries can easily be lost.

The PEC representatives replied that they had anticipated concerns about supply adequacy and had invited all of the manufacturers to present plans for how they would handle the issue. The current system is that patients buy their meters and test strips at the pharmacy and get reimbursed for them. Now, all of the systems included in the UF will have toll-free (1-800) numbers that beneficiaries can call and arrangements have been made for overnight shipping if required. Moreover, some companies will provide a dedicated government line that DoD beneficiaries can call. Additionally, after today's meeting, manufacturers will be contacted by TMA and asked to provide specific plans. Manufacturers of agents on the UF also have contracts with ESI that will allow beneficiaries to receive meters at no cost and there has also been talk of mailing rebate coupons to patients.

Mr. Class also asked about the clinical criteria for inclusion in the Uniform Formulary that had been used by the P&T Committee in making its recommendations and whether the number of people required to switch agents had been included in the cost analysis. Dr. Moore replied that most of the agents being designated as non-formulary did not meet the clinical criteria established in advance by the P&T Committee. Combined, they represent less than one percent of the utilization in DoD. Only two of the agents that met the clinical criteria were designated as non-formulary and those were based on the cost effectiveness analysis. The costs of re-training and changeover were included in the model. COL Lounsberry added that the clinical parameters were set in advance of the Committee meeting. There may also have been contracting issues.

One Panel member asked about the period of time during which beneficiaries would be provided with free meters. The answer given was that meters would be provided free for the duration of the contract with the manufacturer. Moreover, manufacturers often upgrade their machines and these also would be supplied free to beneficiaries.

Mr. Class asked about how the process would work at the MTFs. COL Lounsberry replied that it is much easier there. Physicians write the prescriptions for the machine and the strips and the patient goes and picks them up. Part of the process is making sure that manufacturers have the ability to convert large numbers of MTF patients.

Mr. Class asked about the requirements for wireless insulin pumps and downloading test results to computers. Dr. Allerman said that all of the formulary meters can be downloaded. Wireless wasn't a requirement as it affects such a small percentage of the population.

Panel members said they appreciated the consideration of potential solutions but continued to express concern about implementing a plan in which so many details would be worked on later on. TMA staff noted that decisions concerning formulary placement are required before any of the details can be worked out.

Panel Discussion of P&T Committee Formulary Recommendations for Self-Monitoring Blood Glucose System Test Strips (SMBGS)

The Panel Chair, Ms. Fryar, read the recommendations of the P&T Committee regarding Uniform Formulary placement of Self-Monitoring Blood Glucose System Test Strips (SMBGS):

> "In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Self-Monitoring Blood Glucose System Test Strips (SMBGS), and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that:
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> 1) Accu-chek Aviva, Precision Xtra, Freestyle Lite, and the Ascensia Countour SMBGS test strips be designated as formulary on the Uniform Formulary.
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> 2) One Touch Ultra, True Track, Accu-chek Comfort Curve, Accu-Check Compact Plus, Accu-check Simplicity, Ascensia Autodisc, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle Test Strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check, and all store/private label Brands not specified as formulary in "1" above be designated as non formulary on the UF."

There was no further Panel discussion.

Panel Vote on P&T Committee Formulary Recommendations for Self-Monitoring Blood Glucose System Test Strips (SMBGS)

The BAP vote on the SMBGS formulary recommendations was:

9 concur; 3 non-concur.

Panel Discussion of P&T Committee Implementation Plan Recommendations for Self-Monitoring Blood Glucose System Test Strips (SMBGS)

The Chair then read the implementation plan recommendations:

> "The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 120-day implementation period in

the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Network Pharmacy Program (TRRx). The implementation period will begin immediately following the approval by the Director, TMA."

The question was asked whether there was a mechanism by which the Panel could abstain from voting on the implementation plan recommendation. The answer given was that the BAP is required to take action on the recommendation submitted to it. LTC Watson advised the Panel that it could propose its own operational plan for consideration by Dr. Casscells.

Panel Vote on P&T Committee Implementation Plan Recommendations for Self-Monitoring Blood Glucose System Test Strips (SMBGS)

The BAP vote on the SMBGS formulary recommendations was:

0 concur; 12 non-concur.

Panel Comment on P&T Committee Formulary Recommendations for Self-Monitoring Blood Glucose System Test Strips (SMBGS)

The Beneficiary Advisory Panel recommended a 180-day implementation plan for the recommendations in this class.

The Panel also recommended that necessary steps be taken to ensure that pharmacies have adequate supplies of both test strips and meters in advance of the implementation date and that beneficiaries will be supplied with meters overnight if required. For the future, the Panel affirmed its recommendation that good preliminary implementation plans be available before formulary recommendations are approved, especially when the recommendations will play out primarily at the retail pharmacy level. The Panel further recommended that two sets of letters be sent to beneficiaries in this case, one 60 days before implementation and another 30 days before implementation and that pharmacies be notified of the pending change at the same time.

Additional Discussion

In response to the comments, the PEC staff noted that it can not take actions that might be viewed as promoting particular products or manufacturers. But they do have mechanisms for communicating to and with manufacturers. The mechanisms that will be used in this case will involve sending beneficiaries a coded list of available products from which the patient is expected to make a choice then call the manufacturer with the code.

Mr. Hutchings also asked if there is a possibility of implementing "grandfathering" for current users. If this could be done, it would allow very short implementation times for formulary changes while allowing current users to continue at their current co-pay for a longer period of up to180 days. LTC Watson answered that the co-pay does not change until the actual implementation date, but new users can't be implemented earlier under

the regulations. The General Counsel commented that there can't be overlap: an item is either on formulary or it's not. She doesn't see any way the system could be changed to waive the higher co-pay for current users after an agent becomes non-formulary. However, she will look into the matter. Mr. Hutchings said he would discuss the issue further with General Counsel after the session.

REVIEW OF THE OVERACTIVE BLADDER (OAB) DRUG CLASS

Clinical Effectiveness Review of OAB Agents

Dr. Allerman next presented the results of P&T Committee's review of Overactive Bladder (OAB) drug agents.

[Insert script, pages 6 and 7]

Cost Effectiveness Review of OAB Agents

Dr. Moore provided the Panel with an overview of the relative cost effectiveness of agents in the OAB drug class.

[Insert script, page 8, section titled "OAB Agents – Relative Cost Effectiveness]

P&T Committee Recommendations and Justification – OAB Aents

Dr. Moore next informed the Panel of the P&T Committee's recommendations regarding agents in the Overactive Bladder drug class.

[Insert script, page 8, section titled "OAB Agents – Uniform Formulary Recommendations" through page 9, section titled "OAB – Implementation Plan."]

Physician's Perspective – OAB Drug Class Review

COL Lounsberry commented on the P&T Committee's recommendations from a physician's perspective. She pointed out that this was the Committee's second look at agents in this drug class, it having been reviewed previously in 2006 when Vesicare, Sanctura Immediate Release and Enablex hit the market. Because there was not a lot of information available about them at that time, the Committee decided to look at them again. The Committee found that there are really no clinical differences and no differences in side effects. The main differences are in the side effects of the immediate versus the longer-acting drugs. The persistence rates were the same or a little better than the literature suggests. Many patients only take these drugs on an "as needed" basis because of their side effects. All of the longer-acting drugs were put on the formulary. The two immediate release drugs that were made non-formulary were placed there because of their higher cost. They have very little use in DoD. One immediate release

formulation is still on formulary (as a syrup). There were no controversies about the recommendations in this category.

Panel Questions

Mr. Hutchings noted that after the first review the Oxytrol patch was found to be less effective and was made non-formulary. It is now being put on the UF, which is the only change from the previous review of this drug class. He questioned why an implementation period would be needed for that.

The answer given was that Sanctura XR is also being added to the formulary, so 90 days is being allowed for the two changes. Regarding the effectiveness of Oxytrol, Dr. Moore said that the manufacturer came in with a more favorable price this time, which changed its relative cost effectiveness.

Panel Discussion of P&T Committee Formulary Recommendations for the Overactive Bladder (OAB) Drug Class

The Chair read the P&T Committee's formulary recommendations for agents in the Overactive Bladder (OAB) drug class:

> "In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Overactive Bladder Drugs, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted to recommend that:
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> 1) Oxybutinin IR (Ditropan, generics), Oxybutinin ER (Ditropan XL, generics), oxybutinin patch (Oxytrol), tolterodine ER (Detrol LA), solefenacin (Vesicare), trospium ER (Sanctura XR), and darifenacin (Enablex) be classified as formulary on the UF; and
>
> 2) Tolterodine IR (Detrol) and trospium IR (Sanctura) be designated as non-formulary under the UF, based on cost effectiveness.

There was no further Panel discussion of the formulary recommendations.

Panel Vote on P&T Committee Formulary Recommendations for Overactive Bladder (OAB) Drug Agents

The Panel vote on the OAB formulary recommendations was:

12 concur; 0 non-concur.

Panel Discussion of P&T Committee Implementation Plan Recommendations for the Overactive Bladder (OAB) Drug Class

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

> "The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed following a 90-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following the approval by the Director, TMA."

There was no additional Panel discussion of the implementation plan recommendations.

Panel Vote on P&T Committee Implementation Plan Recommendations for the Overactive Bladder (OAB) Drug Class

The Panel vote on the OAB implementation plan recommendations was:

11 concur; 1 non-concur.

Mr. Hutchings commented that the reason for his non-concurrence is that he sees no reason to charge a patient a $22 co-pay for three months for a drug that is being moved from non-formulary to formulary status.

REVIEW OF NEWLY-APPROVED DRUGS IN PREVIOUSLY APPROVED DRUG CLASSES

Desvenlafaxine (Pristiq)

Dr. Allerman presented the Committee's recommendations on newly-approved drugs.

Clinical Effectiveness Review of Desvenlafaxine (Pristiq)

[Insert script, page 10]

Cost Effectiveness Review of Desvenlafaxine (Pristiq)

Dr. Moore presented the relative cost effectiveness review.

[Insert script, page 11, section titled "Pristiq – Relative Cost Effectiveness"]

Pristiq Uniform Formulary Recommendation and Justification; Implementation Plan Recommendation

Dr. Moore also provided the Panel with the Committee's recommendations.

[Insert script, page 11, sections titled "Pristiq – Uniform Formulary Recommendation," "NF Justification," and "Pristiq – Implementation"]

Physician's Perspective on P&T Committee Review of Pristiq

COL Lounsberry told the Panel that Pristiq was neither more efficacious clinically nor more cost effective than other drugs in this class and it costs more. That's what the decision was based on. Additionally, Effexor is expected to go generic in a couple of years.

Panel Questions

Ms. Owens asked why one Committee member abstained from voting on this recommendation. The answer provided was that the Committee has a VA Member on it by rule and that the VA General Counsel has recommended that the member not vote on certain things.

Mr. Partridge asked whether the 60-day implementation period poses any problems for physicians. COL Lounsberry said that right now there are very few patients using this drug. The number of patients affected, especially on the retail side, will increase with time, but 60 days doesn't pose much of a problem.

Panel Discussion of P&T Committee Formulary Recommendations for Pristiq

The Chair read the P&T Committee's Uniform Formulary recommendations for the newly-approved drug, Pristiq:

> "The P&T Committee, based on its professional judgment, voted to recommend that desvenlafaxine (Pristiq) be classified as non-formulary on the Uniform Formulary."

There was no additional Panel discussion of the recommendation.

Panel Vote on P&T Committee Formulary Recommendation for Pristiq

The Panel vote on the Pristiq formulary recommendation was:

11 Concur; 0 Non-Concur; 1 absent.

Panel Discussion of P&T Committee Implementation Plan Recommendation for Pristiq

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

> "The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed following a 60-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following the approval by the Director, TMA."

There was no Panel discussion of the implementation plan recommendation.

Panel Vote on P&T Committee Implementation Plan Recommendation for Pristiq

The Panel vote on the Committee's implementation plan recommendation was:

11 Concur; 0 Non-Concur; 1 absent.

Nisoldipine Geomatrix (Sular Geomatrix)

Dr. Allerman presented the Committee's recommendations on Sular Geomatrix.

Clinical Effectiveness Review of Sular Geomatrix

[Insert script, page 12]

Cost Effectiveness Review of Sular Geomatrix

Dr. Moore presented the relative cost effectiveness review.

[Insert script, page 13]

Pristiq Uniform Formulary Recommendation and Justification; Implementation Plan Recommendation

Dr. Allerman presented the Committee's recommendations on Sular Geomatrix.

[Insert script, page 14]

Physician's Perspective on P&T Committee Review of Pristiq

COL Lounsberry said the DoD already had a drug in this class on the formulary. This one offered no real advantages and it cost more.

Panel Questions

The Panel had no questions for the presenters about this recommendation.

Panel Discussion of P&T Committee Formulary Recommendations for Sular Geomatrix

The Chair read the recommendation:

"The P&T Committee, based on its professional judgment, voted to recommend that nisoldipine geomatrix (Sular geomatrix) be classified as non-formulary on the Uniform Formulary."

There was no discussion of the recommendation.

Panel Vote on P&T Committee Formulary Recommendation for Sular Geomatrix

The Panel vote on the formulary recommendation was:

11 Concur; 0 Non-Concur; 1 absent.

Panel Discussion of P&T Committee Implementation Plan Recommendation for Pristiq

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

"The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed following a 60-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following the approval by the Director, TMA."

There was no discussion of the implementation plan recommendations.

Panel Vote on P&T Committee Implementation Plan Recommendation for Sular Geomatrix

The Panel vote was:

11 Concur; 0 Non-Concur; 1 absent.

Closing Remarks

The Chair asked about the educational effort that would be associated with the items classified as non-formulary. She said the Panel has been concerned that every effort be made to contact beneficiaries about formulary changes that will affect them. Ms. Owens commented that it would be beneficial to TRICARE Standard members and those without ready access to MTF if official communications would direct them to the ESI website or the PEC website for information about what's going on.

Ms. Fryar concluded the meeting by thanking the presenters and staff members for a lively discussion and again thanked the Panel members for their attendance.

LTC Watson announced that the next meeting will be January 8, 2009 at the Naval Heritage Center.

The meeting was adjourned at 10:30 A.M.

Appendix 1

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.

- ABAs — Adrenergic Blocking Agents (a drug class)
- ABs — Alpha blockers
- ACE inhibitors — Angiotensin-converting Enzyme inhibitors (a drug class)
- AD-1 — Antidepressant-1 (a drug class)
- APR — Automated Profile Review
- ARB — Angiotensin Receptor Blocker (a drug class)
- BAP — Uniform Formulary Beneficiary Advisory Panel (the "Panel" referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- BMD — Bone Mineral Density
- BPA — Blanket Purchase Agreement
- CCBs — Calcium Channel Blockers (a drug class)
- CEA — Cost-effectiveness analysis
- C.F.R — Code of Federal Regulations
- CMA — Cost-Minimization Analysis
- CR — Controlled Release (a drug formulation)
- DEA — U.S. Drug Enforcement Administration
- DFO — Designated Federal Officer
- DHP — Dihydropyridine
- 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
- GDH — Glucose dehydrogenase
- HCTZ — Hydrochlorothiazide
- HMO — Health Maintenance Organization
- IR — Immediate Release (a drug formulation)
- IV — Intravenous
- LIP-2 — Antilipidemic agents (a drug class)

- LM — Leukotriene Modifiers (a drug class)
- MHS — Military Health System
- MN — Medical Necessity
- MTF — Military Treatment Facility
- NA — Newer Antihistamines (a drug class)
- NIH — National Institutes of Health
- NNH — Number Needed to Harm
- NNT — Number Needed to Treat
- OAB — Overactive Bladder drugs (a drug class)
- OTC — Over the counter
- PA — Prior Authorization
- P&T Committee — DOD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DOD Pharmacoeconomic Center
- POS — Point of Service
- PTH — Parathyroid Hormone (a drug class)
- RAAs — Renin Angiotensin Antihypertensives (a drug class)
- RCTs — Randomized Control Trials
- SMBGS — Self-Monitoring Blood Glucose Test Strips (a drug class)
- SNRI — Serotonin norepinephrine re-uptake inhibitor
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- TNF — Tumor necrosis factor
- TRRx — TRICARE Retail Pharmacy Program
- UF — DOD Uniform Formulary
- U.S.C. — United States Code
- VA — U.S. Department of Veterans Affairs
- VARR — Voluntary Agreement on Retail Rebates

17 SEPTEMBER 2008 BENEFICIARY ADVISORY PANEL MEETING

Script

(LTC Spridgen): I'm LTC Stacia Spridgen, the PEC Director. Joining me today from the PEC Clinical Operations staff is Dr. Eugene Moore, and Dr. Angela Allerman, civilian clinical pharmacists. Also joining us today is CDR James Ellzy, the Vice DoD P&T Committee chair, and COL Doreen Lounsbery, who will provide the physician perspective and comment on the recommendations made by the Committee.

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

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

1) A brief overview of the relative clinical-effectiveness analyses considered by the DoD P&T Committee.
2) A brief general overview of the relative cost-effectiveness analyses. This overview will be general in nature since we are unable to disclose the actual costs used in the economic models. This overview will include the factors used to evaluate the costs of the agents in relation to the safety, effectiveness, and clinical outcomes.
3) The DoD P&T Committee's Uniform Formulary recommendation based upon its collective professional judgment when considering the analyses from both the relative clinical and relative cost-effectiveness evaluations of the Self-Monitoring Blood Glucose test strips, the Overactive Bladder Agents, and two new drugs in previously reviewed classes.
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. As usual, 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.

Angela will now present the blood glucose test strips relative clinical effectiveness evaluation.

SELF-MONITORING BLOOD GLUCOSE SYSTEMS TEST STRIPS – RELATIVE CLINICAL EFFECTIVENESS

(Angela Allerman) – Background - Please turn to the handout on page 2, and look at Table 1. I'll refer to the Self-Monitoring Blood Glucose Systems test strips as the blood glucose test strips from now on. This class is different from the other Uniform Formulary drug class reviews previously reviewed by the DoD P&T Committee, in that the test strips are considered medical devices, and not drugs, and there were some additional regulations that had to be followed.

The primary goal for the UF recommendation is to ensure uniform availability of quality test strips across the MHS (MTF, TRRx, and TMOP points of service). The blood glucose meters are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review; however provisions have been made to provide blood glucose meters at no cost to MHS beneficiaries.

Since the FDA classifies the test strips and meters as medical devices, rather than drugs, the focus of the clinical effectiveness review centered on differences in the technical aspects/attributes among the products. The P&T Committee had previously determined that test strips considered for inclusion on the UF must meet minimum technical standards relating to accuracy, blood sample size, availability of testing sites other than the fingertips, result time, memory capacity, ease of use (e.g., calibration and coding, large visual display), manufacturer customer support services, downloading capabilities, availability of data management software, and size.

Utilization - The test strips included in the blood glucose test strip class were those products approved by the FDA and available in the marketplace as of May 2008. Due to the complexity of evaluating the more than 40 commercially marketed test strip brands, the number of test strips eligible of inclusion on the UF was determined by DoD P&T Committee minimum technical requirements, operational limitations of the existing TMOP and TRRx contract, and Federal Government contracting regulations.

Please turn to page 3 of the handout, and look at Figure 1, which shows the test strip utilization in the MHS. The market leader is the Precision brand of test strips, followed by the One Touch strip in 2nd place, with the Aviva strips coming in third, and the Contour strips coming in 4th. If you notice the orange line at the very bottom, it shows the utilization of all the other strips combined, which makes up less than 1% of the overall MHS test strip utilization. In terms of expenditures, which isn't shown, the MHS spends about $73 million dollars a year on the test strips at all three points of service.

Relative Clinical Effectiveness Conclusion – It might be helpful to turn to Table 2 on pages 4-5 of your handout, which provides pictures of the test strips, blood glucose meters, and the some of the technical aspects considered by the Committee.

a) With regard to efficacy, all meters that are approved by the FDA for licensing in the USA must meet the FDA standard of accuracy, which is a total analytical error of <5%. The International Organization for Standardization (ISO) also has standards. All the SMBGS test strips meeting the minimum technical requirements for inclusion on the UF met both FDA and ISO standards. There was insufficient published clinical trial data to determine if there were clinically relevant differences between the

SMBGS test strips with regard to accuracy. The most common cause of inaccurate SMBGS test results is operator error.

b) With regard to calibration and coding, the SMBGS test strips with the lowest risk of coding/calibration errors (as they do not require coding) are the Ascensia Contour and Freestyle Lite test strips. The Accu-chek Aviva, Precision Xtra, and TrueTrack test strips require insertion of a coding chip or strip. The One Touch Ultra test strip requires manual coding.

c) With regard to blood sample size, the Freestyle Lite test strip requires 0.3 microliter (μL) blood; the Accu-check Aviva, Ascensia Contour, and Precision Xtra require 0.6 μL; and the One Touch Ultra and TrueTrack test strips require 1 μL blood.

d) With regard to alternate site testing, the Accu-chek Aviva and Freestyle Lite strips are FDA-approved for testing at 5 alternate sites other than the fingertips, the Ascensia Contour strip is approved for 4 alternate sites, the Precision Xtra and One Touch Ultra strips are approved for 3 alternate sites, and the TrueTrack strip is approved for one alternate testing site other than the fingertips.

e) With regard to test result time, the Accu-chek Aviva, Ascensia Contour, Freestyle Lite, Precision Xtra, and One Touch Ultra provide test results within 5 seconds, while the TrueTrack strips provide test results in 10 seconds.

f) With regard to SMBGS test strip degradation due to heat and humidity, the Precision Xtra test strips are individually foil-wrapped; however patients with dexterity problems may have difficulty opening the foil wrappers.

g) With regard to safety, the Accu-chek Aviva and Freestyle Lite SMBGS test strips employ technology using glucose dehydrogenase (GDH) pyrroloquinolinequinone, which may cause falsely elevated blood glucose readings in patients receiving concomitant therapy with icodextrin-containing substances (Extrarenal peritoneal dialysis solution and the IV immunoglobulin product Octagam). SMBGS strips using GDH nicotinamide adenine dinucleotide [Precision Xtra], GDH flavin adenine dinucleotide [Ascensia Contour] or glucose oxidase technology [One Touch Ultra and TrueTrack] do not interfere with Extrarenal or Octagam.

h) With regard to special populations, those patients requiring intensive blood glucose monitoring (e.g., women with gestational diabetes, Type 1 diabetics, children and adults using insulin pumps) may prefer SMBGS test strips used in certain meters that can communicate wirelessly with insulin pumps.

i) With regard to provider opinion, a survey of MTF providers reported that accuracy and small blood sample size were the two technical requirements considered most important when comparing SMBGS.

j) With regard to therapeutic interchangeability, there is a high degree of therapeutic interchangeability between the SMBGS test strips meeting the DoD P&T Committee minimum technical requirements and contracting requirements.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusion stated above.

SELF-MONITORING BLOOD GLUCOSE SYSTEM TEST STRIPTS– RELATIVE COST EFFECTIVENESS

(Eugene Moore) In considering the relative cost-effectiveness of pharmaceutical agents in the blood glucose test strip class, the P&T Committee evaluated the costs of the agents 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).

Relative Cost Effectiveness Conclusion:

The relative clinical effectiveness evaluation concluded that for those blood glucose test strips meeting the minimum technical criteria, there were no clinically relevant differences between the agents. As a result, a cost minimization analysis (CMA) and budget impact analysis (BIA) were conducted. Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

a) Results from the CMAs for the condition sets for both the 3 or less and 4 or more included on the UF revealed that Ascensia Contour was the most cost effective SMBG system while One Touch Ultra was the least cost effective. The ranking of most to least cost effective SMBGS test strips based on prices submitted for each condition set was: Ascensia Contour >TrueTrack > Freestyle Lite > Precision Xtra > Accu-chek Aviva > OneTouch Ultra.

b) The BIA evaluated the potential impact of scenarios with selected SMBGS products designated formulary or non-formulary on the UF. The BIA results showed that the scenario that designated the One Touch Ultra and True Track self SMBGS as non-formulary on the UF was more favorable to the MHS.

COMMITTEE ACTION: The P&T Committee voted (14 for, 0 opposed, 1 abstained, 0 absent) to accept the cost effectiveness conclusion.

BLOOD GLUCOSE TEST STRIPS –UF RECOMMENDATION

(Angela Allerman) In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the test strips, and other relevant factors, the P&T Committee voted (12 for, 2 opposed, 0 abstained, 1 absent) to recommend that:

1) Accu-chek Aviva, Precision Xtra, Freestyle Lite, and the Ascensia Contour SMBGS test strips be designated as formulary on the Uniform Formulary.
2) That the following strips found in Table 1 on page 2 of the handout be designated as non-formulary on the UF: One Touch Ultra, TrueTrack, Accu-chek Comfort Curve, Accu-chek Compact Plus, Accu-chek Simplicity, Ascensia Autodisc, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle Test Strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check, and all store/private label brands not specified as formulary in "1".

The SMBGS test strips are a medical device and subject to wholesale acquisition cost, rather than Federal Ceiling Price (FCP) pricing.

NON-FORMULARY JUSTIFICATION:

The P&T Committee recommended that the test strips agents listed as non-formulary on Table 1 on page 2 of the handout be classified as non formulary under the UF. The Committee's recommendation was based on the following:

1) Results of the clinical effectiveness evaluation did not support clinically significant advantages to the test strips designated as non-formulary when compared to those designated as formulary, plus some of the test strips designated as non-formulary did not meet the minimum technical requirements, or operational limitations of the existing TMOP and TRRx contract, and Federal Government contracting regulations

2) These test strips were not cost effective relative to the other blood glucose test strips.

SELF-MONITORING BLOOD GLUCOSE TEST STRIPS – IMPLEMENTATION PLAN

(Angela Allerman) The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday following a 120-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) program and in the TRICARE Retail Network Pharmacy Program (TRRx), and at the MTFs no later than a 120-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA. *And now COL Lounsbery will provide the DoD P&T Committee physician member perspective.*

BLOOD GLUCOSE SYSTEM TEST STRIPS – COMMITTEE PHYSICIAN PERSPECTIVE - *(COL Lounsbery).* *(BAP Discussion comes next)*

OVERACTIVE BLADDER AGENTS (OAB) RELATIVE CLINICAL EFFECTIVENESS

(Angela Allerman) - Background - The Overactive Bladder Agents, or OAB, clinical effectiveness review was conducted by Lt Col James McCrary, the Air Force physician at the PEC. This class was first reviewed for the UF in February 2006. If you'll turn to page 6 of the handout, Table 3 shows that the P&T Committee evaluated the relative clinical effectiveness of the nine marketed OAB drugs in the US. darifenacin (Enablex), oxybutynin immediate release (IR) (Ditropan, generics), oxybutynin extended release (ER) (Ditropan XL; generics), oxybutynin transdermal (Oxytrol patch) solifenacin (Vesicare), tolterodine IR (Detrol), tolterodine ER (Detrol LA), trospium IR (Sanctura) and trospium ER (Sanctura XR). Only oxybutynin IR and ER are available in generic formulations.

All of these drugs are FDA approved for the treatment of OAB with symptoms of urge incontinence, urgency and urinary frequency. Other indications were not evaluated by the committee, such as urinary problems associated with neurological conditions including spina bifida.

Utilization: If you turn to Figure 2 found on page 7 of the handout, you'll see the utilization for the OAB class. Military Health System expenditures for the OAB class exceeded $74 million from July 07 to June 08. For utilization, Detrol LA has the highest utilization for all three points of service at about 1.5 million capsules dispensed monthly, followed by generic Ditropan immediate release, and generic Ditropan XL. .

Relative Clinical Effectiveness Conclusion

a) With regard to efficacy, evaluation of clinically relevant differences in efficacy of the OAB agents at relieving urinary symptoms is hampered by the high placebo response rate (30-50%), varying use of non-pharmacologic measures such as bladder training and behavioral modification, and differing outcome measures used in clinical trials.

b) With regard to efficacy at reducing the number of urge incontinent episodes, urgency episodes, and micturition frequency, the available evidence does not support clinically relevant differences between generic Ditropan IR, generic Ditropan XL, the Oxytrol patch, Detrol IR, Detrol LA, Sanctura IR, Sanctura XR, Vesicare, and Enablex.

c) With regard to safety and tolerability, the following conclusions were made:

- There are no differences between the OAB drugs in terms of black box warnings listed in the package inserts, including acute urinary or gastric retention, acute angle-closure glaucoma, and myasthenia gravis.
- Generic Ditropan IR had higher rates of withdrawals of therapy due to adverse events and occurrence of dry mouth than the other OAB agents, but no single agent has shown a clearly superior profile.
- The incidence of adverse events including dry mouth, and constipation, overall was lower with extended release preparations compared with immediate release formulations of the agents. The Oxytrol patch has been associated with pruritis and rash.

- The newer agents Sanctura IR, Sanctura XR, Vesicare and Enablex do not appear to have a significantly lower incidence of dry mouth or constipation compared to extended-release forms of the older agents generic Ditropan XL and Detrol LA.
- All the OAB agents may cross the blood brain barrier and result in significant central nervous system effects, although this may be less likely with Sanctura IR and Sanctura XR.
- Drug-drug interactions are less likely with Sanctura IR and XR than the other agents.

d) With regard to tolerability and persistence rates, persistence rates for OAB medications reported in the medical literature are less than 10%. A 2006 PEC analysis reported that only about 11% of MHS patients continued to obtain prescriptions for OAB medications on a regular basis after 1 year. When the analysis was updated for the August 2008 DoD P&T meeting, the persistence rate had increased only slightly, to 14%. Generally higher persistence was seen for patients receiving newer agents and extended release versions of older agents, compared to those receiving immediate release versions of Detrol and generic Ditropan. About 28% of patients who were considered to be non-persistent continued to occasionally obtain prescription refills, consistent with use on an "as needed" rather than routine basis.

e) With regard to special populations, only generic Ditropan Ir and generic Ditropan XL are approved for use in children ages 6 years and older. For pregnancy, generic Ditropan IR and XL and the Oxytrol patch are labeled as category B drugs, while the other OAB drugs are labeled as category C drugs.

f) With regard to therapeutic interchangeability, there is a high degree of therapeutic interchangeability between the OAB drugs.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusion.

OAB AGENTS– RELATIVE COST EFFECTIVENESS

(Eugene Moore) The relative clinical effectiveness evaluation for the OAB drugs concluded that Enablex, Vesicare, Detrol LA, generic Ditropan XL, and the Oxytrol patch had higher persistence rates in the MHS than Detrol IR and generic Ditropan IR. Therefore, the cost effectiveness of the OAB agents was evaluated by cost minimization analysis, cost effectiveness analysis, and by budget impact analysis. Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

a) Results from the cost minimization analysis for the immediate release OAB agents, generic Ditropan IR, Detrol, and Sanctura IR revealed that generic Ditropan IR was the most cost effective immediate release OAB agent overall.

b) Results from the cost minimization analysis of extended release OAB agents, generic Ditropan XL, Detrol LA, Sanctura XR, Oxytrol patch, Enablex, and Vesicare revealed that

   i) Sanctura XR was the most cost effective extended release OAB agent overall; and

   ii) When the price for generic formulations of Ditropan XL drops by 21.3% from the current price, Ditropan XL will become the most cost-effective agent.

c) The results from a cost effectiveness analysis comparing immediate release vs. extended release agents revealed that patients are more persistent with therapy when taking extended release products than when taking immediate release products. This is done at a significantly higher incremental cost per day of persistence gained by taking extended release products. However, the incremental cost per day of persistence gained is ~ 18% lower than when compared to MHS costs in 2006 when the OAB drugs were previously reviewed for UF placement.

d) The budget impact analysis evaluated the potential impact of scenarios with selected OAB agents designated formulary or non-formulary on the UF. Results from the budget impact analysis revealed that the scenario that designated Detrol IR and Sanctura IR as non-formulary under the UF was more favorable to the MHS.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusion stated above.

OAB AGENTS – UNIFORM FORMULARY RECOMMENDATION

(Eugene Moore) In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Overactive Bladder Drugs, and other relevant factors, the P&T Committee, based upon its collective professional judgment voted (14 for, 0 opposed, 1 abstained, and 0 absent)to recommend that:

1) Generic Ditropan IR, generic Ditropan XL, Oxytrol patch, Detrol LA, Vesicare, Sanctura XR, and Enablex be classified as formulary on the UF.

2) Detrol IR and Sanctura IR be designated as non-formulary under the UF, based on cost effectiveness.

All OAB drugs recommended for inclusion on the UF were covered by Uniform Formulary Voluntary Agreement for Retail Refunds (UF VARR) submissions at or below the Federal Ceiling Price (FCP).

NF JUSTIFICATION:

The P&T Committee recommended that tolterodine immediate-release (Detrol) and trospium immediate-release (Sanctura) be classified as non formulary under the UF. The Committee's recommendation was based on the following:

1) Results of the clinical effectiveness evaluation did not support clinically significant advantages to Detrol IR or Sanctura IR in improving symptoms of OAB compared to the other agents.
2) These two drugs were not cost effective relative to the other OAB agents in this class.

OAB– IMPLEMENTATION PLAN

(Eugene Moore) The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent)an effective date of the first Wednesday one week after the minutes are signed following a 90-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following the approval by the Director, TMA.

COL Lounsbery will provide the Committee physician member perspective.

OAB AGENTS - COMMITTEE PHYSICIAN PERSPECTIVE

(COL Lounsbery): *(BAP discussion comes next)*

NEWLY APPROVED DRUGS

(Angela Allerman) – There are 2 newly approved drugs that fall into classes previously reviewed for the Uniform Formulary. The first of these new drugs is Pristiq, which is found on page 8, Table 4 of your handout.

DESVENLAFAXINE (PRISTIQ) – RELATIVE CLINICAL EFFECTIVENESS

(Angela Allerman) The clinical effectiveness evaluation was conducted by CDR Matt Carlberg, the Navy physician at the PEC.

Background - Desvenlafaxine (Pristiq) is a serotonin norepinephrine re-uptake inhibitor (SNRI) that is classified as part of the Antidepressant-1 (AD-1) drug class. The AD-1s were reviewed for Uniform Formulary (UF) placement in November 2005. Other SNRIs included on the UF are venlafaxine immediate release (Effexor, generics) and venlafaxine extended release (ER) (Effexor XR).

Pristiq is an extended release formulation of the major active metabolite of venlafaxine ER, Effexor XR. Pristiq is FDA-approved for the treatment of major depressive disorder in adults. Generic formulations of Effexor XR are expected in 2010.

Utilization – Utilization for the Antidepressant – 1 class is found on Figure 3 on page 9 of your handout. Generic Zoloft has the highest utilization in the MHS. For Pristiq, we updated the utilization from April 1st to September 7th. A total of 756 prescriptions were dispensed during the time; 705 in the Retail Network, 51 in the TMOP and none in the MTFs.

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded that Pristiq does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other AD-1 agents currently included on the UF.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusion stated above.

PRISTIQ – RELATIVE COST EFFECTIVENESS

(Eugene Moore) The cost effectiveness evaluation for Pristiq was evaluated by LTC Chris Conrad, the army pharmacist at the PEC. The P&T Committee evaluated the relative cost effectiveness Pristiq in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the AD-1 class. A cost minimization analysis (CMA) was employed to evaluate the cost effectiveness of Pristiq relative to the UF AD-1s: citalopram (generic Celexa), sertraline (generic Zoloft), venlafaxine IR (generic Effexor), and venlafaxine ER (Effexor XR), and the Non-formulary (NF) AD-1s bupropion ER (Wellbutrin XL), and duloxetine (Cymbalta). , particularly to the following medications: citalopram (Celexa, generics), sertraline (Zoloft, generics), venlafaxine, venlafaxine ER, bupropion ER (Wellbutrin XL), and duloxetine.

Results of the CMA showed that the average daily cost of Pristiq was significantly higher than its AD-1 class comparators.

Relative Cost Effectiveness Conclusion: - The P&T Committee concluded that Pristiq is not cost effective relative to the other AD-1s included on the UF.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusion stated above.

PRISTIQ– UNIFORM FORMULARY RECOMMENDATION

(Eugene Moore) Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (14 for, 0 opposed, 1 abstained, 0 absent) that desvenlafaxine Pristiq be designated as non-formulary on the UF.

NF JUSTIFICATION

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

1) The relative clinical effectiveness conclusion did not support clinically significant differences in the efficacy or safety profile of Pristiq compared to the other Serotonin Norepinephrine Re-uptake Inhibitor (SNRI) drugs on the UF, and
2) The relative cost effectiveness evaluation determined that generic Celexa, generic Zoloft, sertraline, generic Effexor IR, and Effexor XR remain the most cost effective Antidepressant I agents on the UF compared to Pristiq.

PRISTIQ – IMPLEMENTATION

(Eugene Moore) The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following approval by the Director, TMA.

PRISTIQ - COMMITTEE PHYSICIAN PERSPECTIVE

(COL Lounsbery)....*(BAP discussion comes next)*

NEWLY APPROVED DRUGS – NISOLDIPINE GEOMATRIX (SULAR GEOMATRIX) – RELATIVE CLINICAL EFFECTIVENESS

(Angela Allerman) The last item on the agenda today is the UF review for the new drug nisoldipine geomatrix, or Sular geomatrix, which is found on Table 5 on page 10 of your handout. Nisoldipine geomatrix (Sular geomatrix) is a dihydropyridine calcium channel blocker (DHP CCB) approved for treating hypertension. It is a follow-up to the original nisoldipine formulation, which is called nisoldipine coat core, or Sular coat core.

The CCBs were reviewed for UF placement at the August 2005 P&T Committee meeting. Other anti-hypertensive DHP CCBs included on the UF are amlodipine (generic Norvasc), felodipine (generic Plendil), nisoldipine coat core (generic Sular), and nifedipine ER (generic Adalat CC).

Sular geomatrix employs a different extended-release mechanism than the original Sular product, Sular coat core; both products are dosed once daily. Generic formulations of the original coat core product recently became commercially available. The geomatrix delivery system allows for a 15% lower dosage than the coat core product.

Utilization - Utilization is provided on page 11, Figure 4 of the handout. Generic Norvasc has the highest utilization of the DHP CCBs in the MHS. When we looked at updated utilization for Sular geomatrix from April 1st to September 7th, there were a total of 7,531 prescriptions dispensed in the entire Military Health System, including 5,014 in the Retail Network, 2,142 in the TMOP and 375 at the MTF. Some of the utilization for Sular geomatrix can be accounted for a shortage of the Sular coat core, prior to the availability of generic Sular coat core.

Relative Clinical Effectiveness Conclusion - The P&T Committee concluded that there is no evidence to suggest that there are clinically relevant differences in the efficacy, safety, and clinical outcomes of Sular geomatrix compared to generic Sular coat core, as both products contain the same active ingredient. Additionally, the Committee agreed that Sular geomatrix does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other DHP CCB agents currently included on the UF.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusion stated above.

SULAR GEOMATRIX – RELATIVE COST EFFECTIVENESS

(Eugene Moore) The cost effectiveness evaluation for Sular Geomatrix was evaluated by LTC Chris Conrad, the army pharmacist at the PEC. The DoD P&T Committee evaluated the relative cost effectiveness of Sular Geomatrix in relation to efficacy, safety, tolerability, and clinical outcomes of other DHP CCBs, particularly to generic Norvasc, generic Plendil, and generic Sular coat core.

A CMA was employed to determine the relative cost effectiveness of nisoldipine geomatrix relative to other UF DHP CCBs (generics to Sular coat core, Plendil and Norvasc). The results from the CMA revealed that the projected weighted average cost per day for therapy for Sular Geomatrix is significantly higher than other UF CCBs to which it was compared.

Relative Cost Effectiveness Conclusion: P&T Committee, based upon its collective professional judgment, voted that Sular Geomatrix is not cost effective relative to other UF DHP CCB agents.

COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusion stated above.

SULAR GEOMATRIX – UNIFORM FORMULARY RECOMMENDATION

(Angela Allerman) Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness of nisoldipine geomatrix, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend that nisoldipine geomatrix (Sular geomatrix) be designated as non-formulary on the UF.

SULAR GEOMATRIX – NF JUSTIFICATION

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

1) The relative clinical effectiveness conclusion did not support clinically significant differences in the efficacy or safety profile of Sular Geomatrix compared to the other DHP CCBs on the UF and

2) The relative cost effectiveness evaluation determined that generic Norvasc, generic Plendil and generic Sular coat core remain the most cost-effective DHP CCBs on the UF, compared to Sular Geomatrix.

SULAR GEOMATRIX– IMPLEMENTATION PLAN

(Angela Allerman) The P&T Committee voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend an effective date of the first Wednesday following a 60-day implementation period in TMOP and TRRx, and at MTFs no later than a 60-day implementation period. The implementation period will begin immediately following approval by the Director, TMA.

SULAR GEOMATRIX – COMMITTEE PHYSICIAN PERSPECTIVE

(COL Lounsbery)…*(BAP discussion is next)*