

Executive Summary

UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL COMMENTS

~~26 January~~ 2009

March

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

1. Inhaled Corticosteroids Drug Class: The P&T Committee recommended the following:

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS, and other relevant factors, the P&T Committee voted (8 for, 5 opposed, 2 abstained, and 0 absent) to recommend that:

- 1) Budesonide inhalation solution (Pulmicort Respules, generic), fluticasone HFA MDI (Flovent HFA), fluticasone DPI (Flovent Diskus), and mometasone DPI (Asmanex Twisthaler) be classified as formulary under the UF; and
- 2) Beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid M) and triamcinolone CFC MDI (Azmacort) be designated as non-formulary on the UF, based on cost-effectiveness.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 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.

Summary of Panel Vote/Comments:

- The Panel voted 8 Concur, 2 Non-Concur, 2 Absent regarding the recommendations for formulary and non-formulary agents.
- The two BAP members non-concurred with the P&T recommendations based on the "high level of disagreement among the experts" and because the choice was made based on cost effectiveness considerations that are not plain to the BAP members.
- The Panel voted 10 Concur, 0 Non-Concur, 2 Absent regarding the recommended implementation period of 120 days.

Director, TMA:

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

Ellen P. Embrey

2. Long-Acting Beta Agonists (LABAs) Drug Class: The P&T Committee recommended the following:

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS, and other relevant factors, the P&T Committee voted (14 for, 0 opposed, 2 abstained, 0 absent) to recommend:

- 1) Salmeterol (Serevent dry powder inhaler), formoterol (Foradil dry powder inhaler), and arformoterol nebulizer solution (Brovana) be classified as formulary under the UF.
- 2) Formoterol inhalation solution (Perforomist) be designated as non-formulary under the UF, based on cost effectiveness.

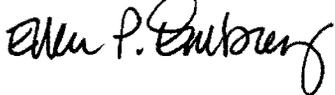
The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday following a 120-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) program and in the TRICARE Retail Network Pharmacy Program (TRRx), and at the MTFs no later than a 120-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

Summary of Panel Vote/Comments:

- The Panel voted 9 Concur, 1 Non-Concur, 2 Absent regarding the recommendations for formulary and non-formulary agents.
- The one non-concur vote was based on his preference for having more choices available to beneficiaries.
- The Panel voted 10 Concur, 0 Non-Concur, 2 Absent regarding the recommended implementation period of 120days.

Director, TMA:

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



3. Inhaled Corticosteroids (ICS) / Long-Acting Beta Agonists (LABAs) Drug Class: The P&T Committee recommended the following:

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

- 1) Fluticasone/salmeterol HFA (Advair HFA) and DPI (Advair Diskus) and budesonide/formoterol (Symbicort) inhaler be classified as formulary on the UF; and
- 2) That no ICS/LABA combination agents be designated as non-formulary under the UF, based on cost-effectiveness.

Summary of Panel Vote/Comments:

- The Panel voted 10 Concur, 0 Non-Concur, 2 Absent regarding the recommendations for formulary and non-formulary agents.

4. TRUE-TEST SELF-MONITORING BLOOD GLUCOSE SYSTEM (SMBGS) TEST STRIPS – RELATIVE CLINICAL EFFECTIVENESS : 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 (14 for, 0 opposed, 1 abstained, 0 absent) that the TRUEtest SMBGS test strip remain designated as formulary on the UF.

Summary of Panel Vote/Comments:

- The Panel voted 10 Concur, 0 Non-Concur, 2 Absent regarding the recommendations for formulary and non-formulary agents.

Uniform Formulary Beneficiary Advisory Panel (BAP)

Meeting Summary

March 26, 2009

Washington, D.C.

Panel Members Present:

- Deborah Fryar, National Military Family Association, representing The Military Coalition, Chairperson
- Morgan Brown, National Association of Uniformed Services, representing the National Military and Veterans Alliance
- Kathryn Buchta, Medical Professional, Health Net Federal Services
- John Class, Military Officers Association of America, representing The Military Coalition
- Barbara Cohoon, National Military Family 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.
- Marissa Schlaifer, Medical Professional, Academy of Managed Care Pharmacy
- Robert Washington, Fleet Reserve Association, representing The Military Coalition

The meeting was held at the Naval Heritage Center Theater, 701 Pennsylvania Ave., N.W., Washington, D.C. Lt Col Thomas Bacon, the Designated Federal Officer (DFO), called the proceedings to order at 8:15 A.M.

Lt Col Bacon said the meeting of the Panel has been convened to review and comment on the recommendations of the Department of Defense (DOD) Pharmacy and Therapeutic (P&T) Committee meeting held February 18, 2009 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:
 - Inhaled Corticosteroids (ICS)
 - Long-Acting Beta Agonists (LABAs)
 - Inhaled Corticosteroid / Long-Acting Beta Agonist Combinations
 - Designated Newly-Approved Drugs: TRUEtest Self-Monitored Blood Glucose Test Strip

- Wrap-up comments

Opening Remarks

Lt Col Bacon noted that Title 10 United States Code (U.S.C.) section 1074g requires the Secretary of Defense to establish a DOD Uniform Formulary (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 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 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 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 UF 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, Lt Col Bacon said the role of the BAP is to comment on the UF recommendations made by the P&T Committee at their last meeting. While the Department appreciates that the BAP may be interested in the drug classes selected for review, drugs recommended for the basic core formulary (BCF) or specific pricing data, these topics do not fall under the purview of the BAP.

The P&T Committee met for approximately 20 hours to consider the class review recommendations presented today. Since this meeting is considerably shorter, the Panel will not receive the same extensive information that is presented to the P&T Committee members. However, the BAP will receive an abbreviated version of each presentation and its discussion. The materials provided to the Panel are available on the TRICARE website.

Detailed minutes of this meeting are being prepared. The BAP minutes, the DOD P&T Committee meeting minutes and Dr. Casscells' decisions will be available on the TRICARE website in approximately four – six weeks.

Lt Col Bacon next provided the ground rules for conducting the meeting:

- All discussions take place in the open public forum. There is to be no committee discussion outside the room, during breaks or at lunch.
- Audience participation is limited to private citizens who signed up to address the Panel.
- Members of the Pharmacoeconomic Center (PEC) and the P&T Committee are available to answer questions related to the BAP's deliberations. Should a misstatement be made, these individuals may interrupt to ensure that the minutes accurately reflect relevant facts, regulations or policy.

Lt Col Bacon then introduced the individual members of the BAP, noting that members Ms. Kimberly Owens and Mr. Charles Partridge were unable to attend today's meeting and briefly reviewed housekeeping considerations pertaining to the meeting.

Private Citizen Comments

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

Chairperson's Opening Remarks

BAP Chair, Deborah Fryar, expressed the Panel's appreciation to the TRICARE support staff, the P&T Staff and others for the work done in preparation for today's meeting. The Chair also thanked LtCol Bacon for his efforts to work with the Panel to educate beneficiaries and noted with appreciation the updates to the BAP website that make it easier for beneficiaries to see what their pharmaceutical benefit is. She also thanked the individual Panel members for their dedication, commitment and time to the BAP process.

Presentation of Drug Class Reviews

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

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I'm LTC Stacia Spridgen, the Pharmacoeconomic Center (PEC) Director. Joining me today from the PEC Clinical Operations staff are Dr. Dave Meade, the Clinical

Operations Director and CDR Matt Carlberg, our Navy Physician Consultant. Also joining us today is Major Jeremy King, an Air Force Obstetrician who is a voting member of the DoD P&T Committee. Dr. King will provide the physician perspective and comment on the recommendations made by the P&T Committee.

The DoD 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 UF.

CDR Carlberg and Dr. Meade 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 UF 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 UF recommendation based upon its collective professional judgment when considering the analyses from both the relative clinical and relative cost-effectiveness evaluations of the inhaled corticosteroids (ICS), the Long-Acting Beta Agonists (LABAs) and the Inhaled Corticosteroid/Long-Acting Beta Agonist Combinations.
- 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 UF. 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.
- 5) The DoD P&T Committee's recommendation on a self-monitoring blood glucose system, a new test strip in that class, which was reviewed as a whole in August, 2008.

We've given you a handout which includes the UF recommendations for all the drugs discussed today; they are found in the tables on pages 2 and 3. 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.

CDR Carlberg will now present the inhaled corticosteroids, long-acting beta agonists, and inhaled corticosteroid/long-acting beta agonist combinations relative clinical effectiveness evaluation.

INHALED CORTICOSTEROIDS DRUG CLASS REVIEW

Clinical Effectiveness Review

CDR Matt Carlberg of the PEC began the presentation of the analysis and evaluation of agents in the inhaled corticosteroids (ICS) drug class.

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The inhaled corticosteroids, abbreviated “I-C-S”, long-acting beta agonists, abbreviated “LABA” and inhaled corticosteroid/long-acting beta agonist combinations, abbreviated “combos”, are three of four subclasses in the Pulmonary I drug class. The fourth subclass is the short-acting beta agonists (SABA), which were evaluated by the DoD P&T Committee in November, 2008. The inhaled corticosteroid clinical effectiveness review was conducted by CDR Carlberg. If you look at Table 1 on page 2 of your handout, you’ll see that the P&T Committee evaluated the relative clinical effectiveness of the seven ICS marketed in the U.S. beclomethasone (QVAR), budesonide (Pulmicort Flexhaler), budesonide nebulizer solution (Pulmicort Respules, generic), ciclesonide (Alvesco), flunisolide (Aerobid, Aerobid-M), fluticasone (Flovent), mometasone (Asmanex), and triamcinolone (Azmacort). Budesonide nebulizer solution is the only generic formulation available. The P&T Committee evaluated ICS efficacy for asthma and Chronic Obstructive Pulmonary Disease, even though use for COPD is “off label.”

ICS are available in different delivery devices. Budesonide (Pulmicort Respules, generic) is the only ICS for administration via nebulizer. There are three ICS available as dry powder inhalers (Pulmicort Flexhaler, Flovent Diskus, and Asmanex). Three ICS are available as a metered-dose inhaler with hydrofluoroalkane (HFA) propellant (QVAR, Alvesco, and Flovent HFA). Two ICS are available as metered-dose inhalers with chlorofluorocarbon (CFC) propellant (Aerobid, Aerobid M, and Azmacort). Metered-dose inhaler propellant is relevant because CFC ICS metered-dose inhalers have been proposed for removal from the market by the United States Food and Drug Administration and the United States Environmental Protection Agency on 31 December 2009 because CFC’s are “greenhouse gases.” A final decision regarding this proposed date is pending.

If you turn to Figure 1 found on page 4 of the handout, you’ll see the utilization for the ICS inhalers. Utilization for the ICS nebulizer solution is found in Figure 2, also on page 4. MHS expenditures for the ICS were approximately \$35M for ICS inhalers and approximately \$13M on ICS nebulizer solutions in FY 2008. In terms of numbers of prescriptions dispensed, Flovent HFA is the highest utilized ICS, followed by Azmacort. I remind you that Azmacort is a CFC inhaler and is proposed for removal from the market at the end of CY 2009.

Relative Clinical Effectiveness Conclusions - The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent), as part of the Pulmonary I overall relative clinical effectiveness conclusion, to accept the following regarding the clinical effectiveness of the ICS products:

- FDA-approved indications – The Committee recognized that the ICS are approved only for the maintenance treatment of asthma and that pediatric FDA-approved ranges differ between the products.
- Clinical Practice Guidelines – Evidence-based guidelines from the National Asthma Education and Preventive Program (NAEPP) consider the ICS the preferred treatment for the maintenance treatment of persistent asthma. Guidelines for the use of ICS in Chronic Obstructive Pulmonary Disease (COPD) generally recommend an ICS for severe or very severe disease.
- Overall clinical efficacy – The Committee concluded that there is fair-to-moderate evidence that ICS do not differ with regards to symptom control, need for rescue medication, and exacerbations in patients with asthma. There is insufficient evidence to conclude that there are clinically relevant differences regarding the efficacy of ICS in patients with COPD.
- Minor adverse events – common ICS adverse events such as change in voice and oral candidiasis do not show a clinically significant difference in properly controlled clinical trials.
- Systemic effects – For systemic effects of hypothalamic-pituitary adrenal-axis suppression, growth suppression in pediatric patients, cataract formation, fracture risk, and pneumonia risk in COPD, there is insufficient evidence to determine whether one ICS is more likely to cause these effects than another. When given in recommended doses, the ICS are not generally associated with clinically significant systemic adverse effects.
- Overall safety/tolerability – The Committee concluded there is insufficient evidence to conclude that there are clinically relevant differences between ICS for common or significant adverse events.
- Special populations – budesonide (Pulmicort Flexhaler, Pulmicort Respules, generic) is the only ICS with a pregnancy category B rating by the FDA (low evidence of risk to humans), which was based on three Swedish registries and one prospective study. To meet the needs of the majority of MHS beneficiaries, both HFA metered-dose inhalers and dry powder inhalers need to be readily available to MHS providers.

Cost Effectiveness Review

Dr. Dave Meade presented the results of the relative cost effectiveness review for this drug class.

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The ICS relative cost effectiveness evaluation for the ICS was conducted by Dr. Eugene Moore, a Clinical Pharmacist on the PEC Staff. In considering the relative cost-effectiveness of pharmaceutical agents in this 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).

ICS Relative Cost Effectiveness Conclusion:

The cost effectiveness of the ICS agents was evaluated by cost minimization analysis (CMA) and by budget impact analysis (BIA). Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded:

1. Results of the CMA revealed that beclomethasone DPI (QVAR) was the most cost-effective ICS based on acquisition cost; and
2. Results of the BIA revealed that the ICS formulary scenario that included budesonide inhalation solution, fluticasone HFA metered-dose inhaler (Flovent HFA), fluticasone dry powder inhaler (Flovent DPI), and mometasone dry powder inhaler (Asmanex Twisthaler) was the most cost-effective overall.

Committee Action, Recommendations and Justification

Dr. Meade also discussed the P&T Committee's action, recommendations and justification with the Panel.

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COMMITTEE ACTION: The P&T Committee voted (15 for, 0 opposed, 1 abstained, 0 absent) to accept the cost effectiveness conclusions for the inhaled corticosteroids.

ICS – UNIFORM FORMULARY RECOMMENDATION

(Dave Meade) In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS, and other relevant factors, the P&T Committee voted (8 for, 5 opposed, 2 abstained, and 0 absent) to recommend that:

- 1) Budesonide inhalation solution (Pulmicort Respules, generic), fluticasone HFA MDI (Flovent HFA), fluticasone DPI (Flovent Diskus), and mometasone DPI (Asmanex Twisthaler) be classified as formulary under the UF; and
- 2) Beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid M) and triamcinolone CFC MDI (Azmacort) be designated as non-formulary on the UF, based on cost-effectiveness.

NON-FORMULARY JUSTIFICATION:

The P&T Committee recommended that Aerobid, Aerobid M, Alvesco, Azmacort, Pulmicort Flexhaler, and QVAR 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 differences between the inhaled corticosteroids recommended for non-formulary status, compared to those recommended for formulary status. The ICS selected for inclusion on the UF have the following benefits: Flovent HFA shows existing high utilization throughout the MHS; Flovent Diskus is available in a dry powder inhaler, for those patients who have difficulty manipulating MDIs; and Asmanex Twisthaler is a dry powder inhaler formulation and a newer product. Additionally, Flovent HFA, Flovent Diskus and Asmanex Twisthaler are approved for use in children as young as 4 years of age.
2. The ICS using the CFC propellant, Aerobid, Aerobid M, and Azmacort are likely to be removed from the market by the end of 2009.
3. The ICS recommended for non-formulary placement were not cost effective relative to those drugs recommended for inclusion on the UF.

Implementation Plan

Dr. Meade presented the implementation plan.

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The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 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.

P&T Committee Physician's Perspective

The physician's perspective was provided by Major Jeremy King, a member of the P&T Committee. Dr. King noted that the PEC did a great job presenting the information about this drug class and said the Committee felt comfortable with the data showing that there was no clinically significant difference between the inhaled corticosteroids in terms of controlling asthma symptoms. Consequently, the decision came down to other factors. Two of these were which agent had the highest utilization within DoD (Flovent Diskus) and which agents were approved for children. Also, providers indicated through a survey that they needed to have both metered dose inhalers and other inhalers available on the UF as well as both dry powder and inhalation solutions to ensure patients can use the medications properly. The Pulmicort agent was put on formulary because it is the only ICS that comes as a nebulizer solution. He also noted that inhalers using CFC as a

propellant are likely to be taken off the market within the year so they were made non formulary. Dr. King noted that the addition of menthol in the Aerobid M product does not appear to have improved patient compliance; moreover, the Budesonide inhalation solution is the only product in the class with a Food and Drug Administration (FDA) pregnancy “Category B” rating (safe). Overall, the drugs placed on formulary give providers a wide variety of products that the Committee feels will meet the needs of DoD beneficiaries very well.

BAP Questions and Discussion

The Chair next opened the floor for the Panel to ask questions of the presenters and discuss the recommendations.

Dr. Schlaifer asked about the statement made that QVAR was determined to be the most cost effective agent even though it is recommended for non formulary placement. She said she understands that Flovent has a high level of utilization and can understand its formulary placement, but said it doesn’t seem sensible that QVAR didn’t show up. Dr. Meade explained that the CMA (cost minimization analysis) looks at each individual drug, whereas the BIA (budget impact analysis) looks at different scenarios in which other factors, such as utilization, come into play. The analysis was narrowed down to about 20 different scenarios, of which 10 were presented to the P&T Committee. The scenario the Committee chose does not include QVAR on the UF.

Dr. Schlaifer asked if the situation is such that if QVAR were to be placed on the formulary, Flovent would have to come off. Dr. Meade replied that is not necessarily the case: the model uses all different combinations and there are different prices for the different agents under consideration in each scenario, which also come into play. Mr. Hutchings noted that QVAR has been on the market considerably longer than Flovent and is likely to go generic long before Flovent and asked if that would be taken into consideration. The answer given was no. The reason why Flovent was placed on the formulary relates more to utilization than cost.

Ms. Fryar noted that the P&T Committee had an unusual split vote on this drug class: 8 for, 5 opposed, 2 abstained and 0 absent. She asked about the reasons for the split vote and why the number opposed was so high. Dr. King answered that many different scenarios were presented, leading to a lot of discussion about the differences. The discussion centered on: (1) the number of different agents to be available and what they would be, and (2) their cost effectiveness. The Committee focused on the trade-off between what agents were available and cost effectiveness. The scenario that received the majority vote was the one that favored more agents on formulary, which was actually not the most cost effective model.

Mr. Class asked for further explanation of why QVAR wasn’t included on the formulary considering its relative cost effectiveness. CDR Carlberg explained that its relative cost effectiveness is based on a static model that doesn’t take into account the other important factors; only acquisition price. He said the Committee’s discussion was over saving a

little bit more money at the expense of availability. Mr. Class said that since QVAR was found to be the most cost effective agent, it would seem reasonable to include it in the choices available. Dr. Meade replied that for QVAR to be favorably considered, it would have to take over quite a bit of the market; its utilization in MHS is quite low. This tends to outweigh its relative cost advantage.

Panel Vote on P&T Committee Formulary Recommendations for the Inhaled Corticosteroids Drug Class

The Chair read the P&T Committee's formulary recommendations for the ICS drug class.

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS, and other relevant factors, the P&T Committee voted (8 for, 5 opposed, 2 abstained, and 0 absent) to recommend that:

- 1) Budesonide inhalation solution (Pulmicort Respules, generic), fluticasone HFA MDI (Flovent HFA), fluticasone DPI (Flovent Diskus), and mometasone DPI (Asmanex Twisthaler) be classified as formulary under the UF; and
- 2) Beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid M) and triamcinolone CFC MDI (Azmacort) be designated as non-formulary on the UF, based on cost-effectiveness.

There was no further discussion of the recommendations.

The BAP vote on the ICS formulary recommendations was:

8 concur; 2 non-concur; 0 abstain; 2 absent.

Panel Comments

Mr. Class commented that the decision centers on cost effectiveness considerations and that without the benefit of being able to look at the different scenarios it is hard to know whether or not the best one was chosen.

Ms. Fryar said she would feel better about the recommendations if there hadn't been such a high level of disagreement among the experts and if more agents had been included on the formulary placement.

ICS Implementation Plan Discussion and Vote

The Chair read the implementation plan recommendations for the ICS drug class:

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 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.

The brief discussion of the implementation plan recommendations focused on the need for the full 120 day period to ensure as much time as possible to make replacement products available for beneficiaries whose agents are being taken off formulary.

The BAP vote on the ICS implementation plan recommendation was

10 concur; 0 non-concur; 0 abstain and 2 absent.

LONG-ACTING BETA AGONISTS (LABAs) DRUG CLASS REVIEW

Before beginning the presentation on the long-acting beta agonists (LABAs), the Chairperson read into the record a letter received by the Designated Federal Officer (DFO) regarding the results of this drug class review. The letter is reproduced in full below:

March 20, 2009

Lieutenant Colonel Thomas Bacon
Designated Federal Officer
Uniform Formulary Beneficiary Advisory Panel
Skyline 5, Suite 810
5111 Leesburg Pike
Falls Church, VA 22041-3206

Sent by e-mail to: baprequests@tma.osd.mil

Dear Lieutenant Colonel Bacon:

Thank you for the opportunity to respond to the DOD Pharmacy and Therapeutics Committee recommendation regarding long-acting beta₂ agonist (LABA) inhaled solutions, in particular the decision to exclude Perforomist[®] (formoterol fumarate) inhalation solution from the Tricare formulary.

We are disappointed in your decision as Perforomist has unique clinical attributes that make it an important nebulized LABA option for the management of patients with COPD, including:

1. Perforomist is the only nebulized form of formoterol fumarate, the active ingredient in Foradil[®], an inhaled dry-powder formulation; and Symbicort[®], an inhaled, fixed-dose, dry-powder formulation of formoterol and budesonide. Formoterol is a well-established molecule in the treatment of COPD, used with confidence for the last 9 years.
2. Perforomist is not associated with tachyphylaxis. In the 12-week pivotal clinical trial (Gross 2008), there was no evidence of tachyphylaxis to Perforomist seen over the course of the study. This attribute translates into sustainable efficacy.
3. Perforomist has a well-studied CV profile. COPD and cardiovascular disease are co-morbid conditions in many patients; therefore, CV safety is an important consideration. The CV profile of Perforomist was assessed in a 12-week cardiovascular substudy and in a 1-year safety study. The results of these studies showed no evidence of increased cardiovascular risk with Perforomist (Nelson 2008; Donohue 2008).
4. Quality of life is important to COPD patients. The St. George's Respiratory Questionnaire (SGRQ) is a validated instrument that measures quality of life in various respiratory diseases, including COPD. In the 12-week pivotal study, Perforomist improved the SGRQ total score by 4.91 points; a 4-point change is both clinically meaningful and statistically significant (Gross 2008).
5. Perforomist has a longer unrefrigerated shelf life than Brovana[®] (12 weeks for Perforomist and only 6 weeks for Brovana), providing more flexibility and potentially less product wastage.

We believe that these key points demonstrate clinically relevant attributes that warrant inclusion of Perforomist on the Tricare formulary. Many Tricare beneficiaries may benefit from Perforomist, and we would appreciate your reevaluation and reconsideration of Perforomist for the Tricare formulary. To ensure the cost effectiveness of Perforomist as a Tier-2 product on the Tricare formulary, we would provide a VARR Program rebate of % of the 2008 Perforomist annual non-Federal Average Manufacturer Price of \$ per box of 60 vials (i.e., a rebate of \$ per box), resulting in a net price of \$ per box of 60 vials.

We look forward to hearing from you, and would welcome the opportunity to discuss this matter further with you.

Sincerely yours,

Davida J. White Pettaway, M.D.
Medical Scientific Affairs

Clinical Effectiveness Review Presentation

CDR Carlberg then presented the clinical effectiveness review for the LABA drug class.

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The long-acting beta agonist clinical effectiveness review was conducted by Dr. Angela Allerman, a Clinical Pharmacist at the PEC, and Major Misty Carlson, the Army Physician consultant at the PEC. Information regarding the safety, effectiveness, and clinical outcomes of the LABAs was considered by the Committee.

If you turn back to Table 1 on page 2 of your handout, you'll see that the P&T Committee evaluated the relative clinical effectiveness of the four LABA marketed in the U.S. Two LABA are available as dry powder inhalers, formoterol (Foradil) and salmeterol (Serevent). The other two are available as inhalation solutions for nebulizer use - formoterol (Perforomist) and arformoterol (Brovana). There are no generic formulations available for the LABAs.

If you turn to Figure 3 on page 5 of the handout, you'll see the utilization for the LABA dry powder inhalers. MHS expenditures for the LABAs in FY 2008 in the entire MHS exceeded \$9.1M (\$1.6M in the MTFs, \$5.8M in the TRRx, and \$1.7M in the TMOP). Salmeterol DPI (Serevent Diskus) is the most frequently used LABA in the entire MHS with approximately 250,000 prescriptions dispensed monthly. However overall, there is a trend for decreasing LABA use in the MHS. Figure 4 on the same page, shows the utilization for the LABA nebulizer solutions.

Relative Clinical Effectiveness Conclusions - The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent), as part of the Pulmonary I overall relative clinical effectiveness conclusion, to accept the following regarding the clinical effectiveness of the LABA products:

- a) With regard to efficacy/clinical effectiveness between the LABA oral inhalers, salmeterol DPI (Serevent Diskus) and formoterol DPI (Foradil Aerolizer), the following conclusions were made:
 - FDA-approved indications — Salmeterol and formoterol have similar FDA-approved indications (asthma, COPD, and exercise-induced bronchospasm [EIB]), with the exception that their pediatric-approved ages for asthma differ.
 - Pharmacokinetics — Formoterol has a faster onset of action than salmeterol, but clinical efficacy is similar for changes in forced expiratory volume in one second (FEV₁) and peak expiratory flow (PEF).
 - Guidelines — Evidence-based guidelines from the NAEPP for asthma and the Global Initiative for Obstructive Lung Disease (GOLD) for COPD do not state a preference for one LABA over another.
 - Asthma — For treating asthma, both salmeterol and formoterol have been shown to reduce the occurrence of asthma symptoms and reduce the need for rescue medications, when compared to placebo. Head-to-head studies show

no difference between salmeterol and formoterol in relieving asthma symptoms, reduced use of rescue medications, or improvement in spirometry measures.

- COPD and EIB — There is insufficient evidence to determine if clinically relevant differences exist when treating COPD or EIB.
- b) With regard to efficacy/clinical effectiveness between the LABA-inhaled solutions, formoterol solution (Perforomist), and arformoterol solution (Brovana), the following conclusions were made:
- COPD — There is insufficient evidence to determine if clinically relevant differences exist when treating COPD.
 - Place in therapy — The LABA inhalation solutions are relatively new additions to the market. Recommendations regarding their most appropriate use in patients with COPD have not been established by national guidelines.
- c) With regard to safety between the LABA oral inhalers, salmeterol DPI (Serevent Diskus), and formoterol DPI (Foradil Aerolizer):
- In patients with asthma, a higher risk of death was associated with salmeterol and formoterol use. This is based on data from the Salmeterol Multicenter Asthma Research Trial, an FDA meta-analysis conducted in 2008, and 2 Cochrane reviews. The risk of death is highest in subpopulations of African American patients and children 4 to 11 years of age. Using a LABA with an ICS reduces the risk of death in asthma. The FDA Advisory subcommittee is recommending removal of the LABA indication for asthma. These recommendations are pending approval at the FDA.
 - In patients with COPD, 1 meta-analyses (Rodrigo 2008) and 1 pooled analysis have reported no increased risk of death with salmeterol or formoterol.
 - For other serious adverse events, there do not appear to be clinically relevant differences between salmeterol and formoterol, based on similar numbers needed to harm (188 vs. 179, respectively) from 2 Cochrane reviews.
- d) With regard to safety between the LABA-inhaled solutions, formoterol solution (Perforomist) and arformoterol solution (Brovana) for treating COPD, there is insufficient evidence to determine if clinically relevant differences exist in the adverse effect profile. The LABA-inhaled solutions are not approved for treating asthma.
- e) With regard to other factors between the LABAs, the following conclusions were made:
- Ease of use: The formoterol DPI (Foradil Aerolizer) is more difficult for patients to use than salmeterol DPI (Serevent Diskus).
 - Special Populations: For asthma, salmeterol is approved for a younger patient population (approved for children as young as 4 years old) compared to formoterol (approved for children as young as 5 years old).

- Storage conditions: Storage conditions are more favorable with formoterol inhalation solution (Perforomist), which is stable at room temperature for up to 12 weeks vs. 6 weeks with arformoterol inhalation solution (Brovana).
- Clinical Coverage: A survey of MTF providers showed that the majority of respondents require a LABA oral inhaler to treat their patients with COPD.
- Therapeutic Interchangeability: The Committee concluded there is a high degree of therapeutic interchangeability between the two LABA inhalation solutions and, with the exception of convenience/ease of use, there is a high degree of therapeutic interchangeability between the two LABA oral inhalers.

Use of LABAs without concomitant use of ICS in MHS: Results of a preliminary analysis reported by the Pharmacy Outcomes Research Team (PORT) evaluated the use of LABAs in DoD beneficiaries, and whether patients were also receiving an ICS prescription with a LABA. Although about 45% of patients (6,118/13,533) filling a prescription for a LABA were found not to have filled a prescription for an ICS, the patients' ages and other medications suggested that these patients most likely had a diagnosis of COPD. The Committee agreed that the great majority of DoD beneficiaries receiving LABAs without concomitant ICS are probably COPD patients, in whom "unopposed" use of LABAs has not been associated with safety concerns, and that the absolute number of asthma patients in this category is likely to be small.

Relative Cost Effectiveness Review

Next, Dr. Dave Meade provided the BAP with the results of the cost effectiveness review for LABAs.

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The relative cost-effectiveness evaluation for the LABA was conducted by Dr. Meade. In considering the relative cost-effectiveness of pharmaceutical agents in this 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).

LABA Relative Cost Effectiveness Conclusion:

The cost effectiveness of the LABA agents was evaluated by cost minimization analysis (CMA) and by budget impact analysis (BIA). Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent):

1. Results of the CMA of the LABA oral inhalers revealed that formoterol DPI (Foradil Aerolizer) was the most cost-effective LABA oral inhaler overall;
2. Results of the CMA of the LABA inhalation solutions revealed that arformoterol solution (Brovana) was the most cost-effective overall; and

3. The BIA evaluated the potential impact of scenarios with selected LABA agents designated formulary or non-formulary on the UF. Results from the BIA revealed that the scenario that designated formoterol inhalation solution (Perforomist) non-formulary under the UF was most favorable to the MHS.

Committee Action, Recommendations and Justification

Dr. Meade also presented the LABA Uniform Formulary recommendations and justification.

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LABA – UNIFORM FORMULARY RECOMMENDATION

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS, and other relevant factors, the P&T Committee voted (14 for, 0 opposed, 2 abstained, 0 absent) to recommend:

- 1) Salmeterol (Serevent dry powder inhaler), formoterol (Foradil dry powder inhaler), and arformoterol nebulizer solution (Brovana) be classified as formulary under the UF.
- 2) Formoterol inhalation solution (Perforomist) be designated as non-formulary under the UF, based on cost effectiveness.

LABA NON-FORMULARY JUSTIFICATION:

The P&T Committee recommended that formoterol nebulizer solution (Perforomist) be classified as non-formulary under the UF. The Committee's recommendation was based on the following:

- a) Perforomist has existing low utilization in the MHS, and the exact place in therapy for the LABA inhalation solutions has yet to be addressed in national guidelines for COPD.
- b) Perforomist was not cost-effective relative to the other LABA inhalation solution (Brovana).

LABA Implementation Plan

Dr. Meade continued with the implementation plan.

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The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 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.

P&T Committee Physician's Perspective

Dr. King then provided the physician's perspective on this drug class. He noted that only one LABA was recommended for non-formulary placement (Perforomist). He noted the drug has low utilization in the MHS and is not cost-effective compared to the other agents. Further, the exact place in therapy of LABA inhalation solution products is not clear at this time. However, the Committee agreed that LABAs are needed on the Uniform Formulary to treat asthma.

BAP Questions and Discussion

The Chair next opened the floor for BAP questions and discussion of the LABA drug class.

Ms. Buchta asked whether the cost analyses of Perforomist were done before or after the new pricing. CDR Carlberg answered that the agents in this class, including Perforomist, were not re-evaluated based on new prices, which were submitted after the P&T Committee meeting. In further discussion, the General Counsel indicated that once the P&T Committee makes its decision, re-evaluating only one agent based on new prices would not be allowed; the PEC and the P&T Committee would have to go back, re-open the entire drug class and start over. That approach would be the only legal alternative. Dr. Meade added that it might not make a significant difference anyway as the cost numbers used are very close to the new bid numbers, if not identical to them.

Ms. Cohoon asked about the need for a 120-day implementation period. CDR Carlberg said that at least 90 days is needed to make sure that beneficiaries who have to switch have ample time to be notified, and that whenever possible the MHS likes to give them six to twelve months.

Mr. Hutchings expressed the view that the entire class should not be sent back for re-review. In regard to the letter received, he said that the issues raised fall within the purview of the P&T Committee, not the BAP.

Mr. Class asked how many different formulations of inhalation solutions are on the market. CDR Carlberg said there are a lot, but only two are LABAs. Mr. Class said that he prefers beneficiaries to have as much choice as possible when receiving medications. It appears that there will be a much bigger choice available among the ICS-class inhalers than among the LABAs which, by themselves, don't offer much choice.

Panel Vote on P&T Committee Formulary Recommendations for the Long-Acting Beta Agonists (LABAs) Drug Class

The BAP Chair read the P&T Committee's formulary recommendation to be voted on.

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS, and other relevant factors, the P&T Committee voted (14 for, 0 opposed, 2 abstained, 0 absent) to recommend:

- 1) Salmeterol (Serevent dry powder inhaler), formoterol (Foradil dry powder inhaler), and arformoterol nebulizer solution (Brovana) be classified as formulary under the UF.
- 2) Formoterol inhalation solution (Perforomist) be designated as non-formulary under the UF, based on cost effectiveness.

Without further discussion, the Panel vote was taken with the following result:

9 concur; 1 non-concur; 0 abstain; 2 absent.

Panel Comment

Mr. Class stated for the record that his vote to non-concur had nothing to do with the letter but was based on his preference for having more choices available to beneficiaries.

Panel Vote on P&T Committee Implementation Plan Recommendations for the Long-Acting Beta Agonists (LABAs) Drug Class

The Chair next read the implementation plan recommendations.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 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.

There was no Panel discussion of this recommendation. The vote was:

10 concur; 0 non-concur; 0 abstain; 2 absent.

No comments were provided by the Panel.

INHALED CORTICOSTEROIDS (ICS) / LONG-ACTING BETA AGONISTS (LABAs) COMBINATION DRUG CLASS REVIEW

Relative Clinical Effectiveness Review

CDR Carlberg next presented the results of the P&T Committee's clinical effectiveness review for the ICS-LABA combination agents.

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The ICS/LABA Combo clinical effectiveness review was conducted by CDR Carlberg. If you look at Table 1 on page 2 of your handout, you'll see that the P&T Committee evaluated the relative clinical effectiveness of the three ICS/LABA Combos marketed in the U.S. Fluticasone/salmeterol (Advair) is available as both a dry powder inhaler and as an HFA metered-dose inhaler. Budesonide/formoterol (Symbicort) is available as an HFA metered-dose inhaler.

If you turn to Figure 5 found on page 6 of the handout, you'll see the utilization for the ICS/LABA Combo subclass. MHS expenditures for this class were approximately \$154M in FY 2008. In terms of number of prescriptions dispensed, Advair dry powder inhaler (Advair Diskus) is by far the highest utilized ICS/LABA. Advair HFA and Symbicort are both FDA-approved for asthma in ages 12 and up. Advair Diskus is approved for asthma in ages 4 and up. A single dose (250/50) of Advair Diskus is also approved for COPD.

To be completely fair, subsequent to the P&T Committee meeting and subsequent to the script being prepared, Symbicort did receive a COPD indication from the Food and Drug Administration.

Relative Clinical Effectiveness Conclusions- The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent), as part of the Pulmonary I overall relative clinical effectiveness conclusion, to accept the following regarding the clinical effectiveness of the ICS/LABA combination oral inhalers.

- Efficacy/clinical effectiveness – The Committee concluded that there was fair evidence that there is no significant difference in efficacy between fluticasone/salmeterol and budesonide/formoterol for the treatment of asthma. There is insufficient evidence to conclude that there are clinically relevant differences between fluticasone/salmeterol and budesonide/formoterol for the treatment of asthma.
- Safety/tolerability – From comparative trials of ICS/LABA – ICS/LABA are generally well tolerated. The most common adverse events are nasopharyngitis, headache, upper respiratory infection, oral candidiasis, and dysphonia. Adverse events for ICS/LABA are similar to those of a matching dose of ICS.

Clinical coverage -- The Committee concluded that to meet the needs of the majority of MHS beneficiaries, both metered-dose inhaler and dry powder inhaler forms of ICS/LABA need to be readily available to MHS providers.

Relative Cost Effectiveness Review

Dr. Meade presented the BAP with the results of the relative cost effectiveness review for the ICS-LABA combination agents.

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The relative cost-effectiveness evaluation for the ICS/LABA Combos was conducted by Dr. Eugene Moore. In considering the relative cost-effectiveness of pharmaceutical agents in this 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).

ICS/LABA Combo Relative Cost Effectiveness Conclusion: - The cost effectiveness of the ICS/LABA agents was evaluated by cost minimization analysis (CMA) and by budget impact analysis (BIA). Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent):

- a. Results of the CMA of the ICS/LABA combination oral inhalers revealed that budesonide/formoterol (Symbicort) was the most cost-effective combination inhaler agent overall; and
- b. The BIA evaluated the potential impact of scenarios with selected ICS/LABA combination agents designated formulary or non-formulary on the UF. Results from the BIA revealed that the scenario that designated budesonide/formoterol (Symbicort) inhaler non-formulary (with an automated prior authorization) under the UF was most favorable to the MHS.

Committee Action, Recommendations and Justification

Dr. Meade presented the P&T Committee's recommendations and reasons.

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

- 1) Fluticasone/salmeterol HFA (Advair HFA) and DPI (Advair Diskus) and budesonide/formoterol (Symbicort) inhaler be classified as formulary on the UF; and

- 2) That no ICS/LABA combination agents be designated as non-formulary under the UF, based on cost-effectiveness.

NF JUSTIFICATION and IMPLEMENTATION PLAN:

Do not apply as all ICS/LABA combos currently available on the U.S. market are UF.

P&T Committee Physician's Perspective

In providing the physician's perspective on the P&T Committee's actions, Dr. King noted that with only two agents in the drug class, the recommendations were straight forward and non-controversial.

BAP Questions and Discussion

Mr. Hutchings asked why Symbicort was left on formulary when the cost analysis showed that making it non-formulary with an automated PA was most cost effective. Dr. Meade replied that there was a lot of discussion of that point, but in the end the Committee decided that they wanted to have Symbicort available. Different scenarios were presented and this was the one that was voted for. CDR Carlberg clarified that one of the dissenting votes came from the Department of Veterans Affairs' representative, who always abstains because the individual handles the VA's national contracts and needs to avoid any appearance of conflict of interest.

Panel Vote on P&T Committee Formulary Recommendations for the Inhaled Corticosteroid (ICS) / Long-Acting Beta Agonists (LABAs) Combination Drug Class

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

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the ICS/LABA combination products, and other relevant factors, the P&T Committee voted (12 for, 2 opposed, 1 abstained, 0 absent) to recommend that:

- 3) Fluticasone/salmeterol HFA (Advair HFA) and DPI (Advair Diskus) and budesonide/formoterol (Symbicort) inhaler be classified as formulary on the UF; and
- 4) That no ICS/LABA combination agents be designated as non-formulary under the UF, based on cost-effectiveness.

Without further discussion, the BAP voted:

10 concur; 0 non-concur; 0 abstain; 2 absent.

NEWLY APPROVED DEVICES IN A CLASS PREVIOUSLY REVIEWED

The Panel next considered recommendations regarding newly-approved devices in previously-reviewed drug classes. CDR Carlberg made the presentation.

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There is one newly approved device that falls into classes previously reviewed for the UF. The information on TRUEtest self-monitoring blood glucose test strips can be found on Table 2 on page 3 of your handout.

TRUEtest SELF-MONITORING BLOOD GLUCOSE SYSTEM (SMBGS) TEST STRIPS – RELATIVE CLINICAL EFFECTIVENESS

Clinical Effectiveness Review

This clinical effectiveness evaluation was conducted by Dr. Angela Allerman. The self-monitoring blood glucose system test strips were evaluated by the DoD P&T Committee at the August 2008 meeting. If you turn to Table 2, on page 3 of your handout, you'll see that the SMBGS test strips designated as formulary on the UF include Accu-chek Aviva, Precision Xtra, Freestyle Lite, and Ascensia Contour. The TRUEtest test strip was approved by the FDA in late August 2008 and, therefore, was not included in the original UF decision. The TRUEtest test strip clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1).

The TRUEtest SMBGS test strip meets the requirements for accuracy by the FDA and the International Standards Organization, does not require coding, is compatible with 2 SMBGS meters (TRUEresult and TRUE2go meters), requires a 0.5 microliter blood sample size, is approved for both fingertip and forearm testing, and provides results in 4 to 10 seconds. The TRUEtest SMBGS test strip employs glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) as the reagent. Other SMBGS test strips with GDH-PQQ have been rarely associated with falsely high blood glucose readings and potential patient harm when used concurrently with products containing maltose (e.g., dialysis patients receiving icodextrin dialysate solutions). The TRUEtest package label contains warnings for this interaction.

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent): that 1) the TRUEtest SMBGS test strip is similar to other SMBGS test strips included on the UF, in terms of meeting the minimum technical requirements; 2) there is a high degree of therapeutic interchangeability between TRUEtest and the other SMBGS test strips included on the UF; and 3) in terms of safety, TRUEtest is similar to other SMBGS test strips included on the UF that also use the GDH-PQQ reagent.

Relative Cost Effectiveness Review

Dr. Meade presented the relative cost-effectiveness review.

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The TRUEtest relative cost effectiveness evaluation was conducted by me. The P&T Committee evaluated the relative cost-effectiveness of TRUEtest SMBGS test strips in relation to efficacy, safety, tolerability, and clinical outcomes of the other test strips in the SMBGS 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).

A cost minimization analysis (CMA) was employed to evaluate the cost-effectiveness of TRUEtest blood glucose strips. The cost-effectiveness of TRUEtest was evaluated relative to the following agents: Accu-chek Aviva, Contour, Freestyle Lite, OneTouch Ultra, Precision Xtra, and TrueTrack. The results of the CMA showed that the projected weighted average daily cost of TRUEtest was significantly lower than the weighted average daily cost of all the other SMBGS test strips.

TRUEtest Relative Cost Effectiveness Conclusion: The P&T Committee concluded (14 for, 0 opposed, 1 abstained, 0 absent) that the TRUEtest SMBGS test strip for the TRUEresult and TRUE2go meters is cost effective relative to the other SMBGS test strips included on the UF when future market conditions were considered.

Uniform Formulary Recommendation

Dr. Meade presented the Committee's recommendation.

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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 the TRUEtest SMBGS test strip remain designated as formulary on the UF.

P&T Committee Physician's Perspective

Dr. King informed the Panel that this recommendation also was not controversial. The new test strips are faster; can be used on two different meters and are economical. It is advantageous for beneficiaries to have them on formulary.

BAP Questions and Discussion

Mr. Hutchings asked if the new strips would increase the price of the strips already available. The answer was they would not.

Ms. Fryar asked whether the PEC has received any feedback from beneficiaries as to how they were affected by the blood glucose monitoring test strips that were made non-formulary back in August. The PEC Director said she has seen one letter so far; it was not in favor of the action taken. A variety of test strips are available, so beneficiaries have a choice.

Panel Vote on P&T Committee Formulary Recommendations for the TRUEtest Self-Monitoring Blood Glucose System Test Strips

Ms. Fryar read the Committee's recommendation regarding this product.

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 the TRUEtest SMBGS test strip remain designated as formulary on the UF.

Without further discussion, the Panel voted:

10 concur; 0 non-concur; 0 abstain; 2 absent.

Closing Comments

In closing, the Chair thanked the people in the audience for attending the proceedings and thanked the PEC and the P&T Committee for their work

LtCol Bacon indicated he would consider moving the meeting to later in the day in the future.

He also said that a lot of the information on clinical outcomes, research results and the P&T process (including the BAP) is being published now and suggested that it might be of interest to Panel members as well as to beneficiaries. The January-February issue of the Journal of Managed Care Pharmacy (JMCP) has an evaluation of the outcome of when Nexium was reviewed and this month's issue has a benchmark article on the formulary process and how it functions. TMA will make it a point to keep the Panel updated on other articles.

The meeting was adjourned at 9:45.

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.

- AAAAI — American Academy of Allergy, Asthma and Immunology
- AE — Adverse event
- APR — Automated Profile Review
- BAP — Uniform Formulary Beneficiary Advisory Panel (the “Panel” referred to above)
- BCF — Basic Core Formulary
- BIA — Budget Impact Analysis
- BPA — Blanket Purchase Agreement
- CEA — Cost-effectiveness analysis
- CFC — Chlorofluorocarbon
- C.F.R — Code of Federal Regulations
- CMA — Cost-Minimization Analysis
- COPD — Chronic obstructive pulmonary disease
- CR — Controlled Release (a drug formulation)
- DEA — U.S. Drug Enforcement Administration
- DFO — Designated Federal Officer
- DHP — Dihydropyridine
- DOD — Department of Defense
- DPI — Dry powder inhaler
- ECF — Extended Core Formulary
- EIB — Exercise-induced bronchospasm
- 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
- GOLD — Global Initiative for Obstructive Lung Disease
- HFA — Hydrofluoroalkane
- HMO — Health Maintenance Organization
- ICS — Inhaled Corticosteroids (a drug class)
- IR — Immediate Release (a drug formulation)
- IV — Intravenous
- LABA — Long Acting Beta Agonists (a drug class)
- MDI — Metered dose inhalers

- MHS — Military Health System
- MN — Medical Necessity
- MTF — Military Treatment Facility
- NAEPP — National Asthma Education and Preventive Program
- NIH — National Institutes of Health
- NNH — Number Needed to Harm
- NNT — Number Needed to Treat
- OTC — Over the counter
- PA — Prior Authorization
- PAR — Perennial allergic rhinitis
- P&T Committee — DOD Pharmacy and Therapeutics Committee
- PDTS — Pharmacy Data Transaction Service
- PEC — DOD Pharmacoeconomic Center
- PEF — Peak Expiratory Flow
- PORT — Pharmacy Outcomes Research Team
- POS — Point of Service
- RCTs — Randomized Control Trials
- SABA — Short-Acting Beta Agonists (a drug class)
- SAR — Seasonal allergic rhinitis
- SMBGs — Self-Monitoring Blood Glucose Test Strips
- TMA — TRICARE Management Activity
- TMOP — TRICARE Mail Order Pharmacy
- 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
- VMR — Vasomotor rhinitis