

**DOD PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS  
INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY  
PANEL**

**I. Uniform Formulary Review Process**

Under 10 U.S.C. § 1074g, as implemented by 32 C.F.R. 199.21, the DoD P&T Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, TMA, on formulary status, pre-authorizations, and the effective date for a drug's change from formulary to non-formulary status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

**II. INHALED CORTICOSTEROIDS**

*P&T Comments*

**A. INHALED CORTICOSTEROIDS – Relative Clinical Effectiveness**

The P&T Committee evaluated the clinical effectiveness of the inhaled corticosteroids (ICS) as part of the Pulmonary I drug class. The ICS are available in several dosage formulations, including pressurized metered-dose inhalers (MDIs) and dry powder inhalers (DPIs). The MDIs use either chlorofluorocarbon (CFC) or hydrofluoroalkane (HFA) as the propellant. The ICS available as oral inhalers include beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid-M [menthol added to improve taste]), fluticasone HFA MDI (Flovent HFA), fluticasone DPI (Flovent Diskus), mometasone DPI (Asmanex Twisthaler), and triamcinolone CFC MDI (Azmacort). Budesonide (Pulmicort Respules) is also available as an inhalation solution. None of the oral ICS inhalers are available as generic formulations. One authorized generic formulation of budesonide inhalation solution became available in December 2008.

The Military Health System (MHS) spent over \$35M on oral ICS inhalers and over \$13M on ICS inhalation solutions in FY 2008. In FY 2008, for the oral ICS inhalers, expenditures in the Military Treatment Facilities (MTFs) were \$16.6M, expenditures in the TRICARE Retail Network (TRRx) were \$15.2M, and expenditures in the TRICARE Mail Order Pharmacy (TMOP) were \$3.5M. Expenditures for the inhalation solutions in FY 2008 are as follow: MTF \$2.4M, TRRx \$10.0M, and TMOP \$0.8M. In terms of numbers of prescriptions dispensed, fluticasone (Flovent) is the highest utilized ICS in the MHS, followed by triamcinolone (Azmacort).

The clinical review included consideration of pertinent information from a variety of sources determined by the P&T Committee to be relevant and reliable, including but not limited to sources of information listed in 32 CFR 199.21(e)(1).

*Relative Clinical Effectiveness Conclusion*

- a) With regard to efficacy/clinical effectiveness of the ICS, the following conclusions were made:

- FDA-approved indications — The Committee recognized that the ICS products are approved only for the maintenance treatment of asthma, and that FDA-approved age ranges for pediatric patients differ between the products.
  - Clinical Practice Guidelines — Evidence-based guidelines from the National Asthma Education and Preventive Program (NAEPP) consider the ICS as the preferred drug class 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. The Guidelines do not state a preference for one ICS over another.
  - Pharmacodynamic/pharmacokinetic properties — The Committee concluded that despite differences in topical potency, receptor binding affinity, pulmonary bioavailability, and systemic bioavailability, the overall clinical response does not appear to vary significantly between the ICS, when equipotent doses are compared.
  - Overall clinical efficacy for asthma — The Committee concluded that for asthma, 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.
  - Overall clinical efficacy for COPD — The Committee concluded that for COPD, there is insufficient evidence to conclude there are clinically relevant differences regarding the efficacy of ICS in patients with COPD.
- b) With regards to safety and tolerability, the following conclusions were made:
- Minor adverse events — There do not appear to be clinically relevant differences in the incidence and severity of common adverse events associated with the ICS, such as dysphonia and oral candidiasis.
  - Pharmacodynamic/pharmacokinetic properties — Differences in binding affinity, lipophilicity, pulmonary bioavailability, and systemic bioavailability between the ICS products have not correlated to clinically relevant differences in safety.
  - Systemic adverse effects — For systemic adverse effects of hypothalamic-pituitary-adrenal (HPA) axis suppression, growth suppression, 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. Providers and patients must assess the risks and benefits if higher than recommended doses are required.
  - Overall safety/tolerability — The Committee concluded there is insufficient evidence to determine whether there are clinically relevant differences between ICS in terms of minor adverse events or systemic adverse events
- c) With regards to differences in other factors, the following conclusions were made:

- **Special Populations – Pregnancy** — Budesonide is the only ICS with a pregnancy category B rating (low evidence of risk) from the FDA; the other ICS are rated pregnancy category C. The pregnancy category B rating for budesonide was granted based on information from 3 Swedish registries and 1 prospective study. However, national guidelines for asthma from the NAEPP state there is no data to indicate the other ICS preparations are unsafe during pregnancy, and that untreated asthma in pregnancy poses a risk to the fetus, including intrauterine growth retardation, premature delivery, and low birth weight.
- **Special Populations – Children** — Budesonide inhalation solution (Pulmicort Respules) is approved for treating asthma in children ranging between the ages of 1 and 8 years. Fluticasone (Flovent Diskus and Flovent HFA) and mometasone (Asmanex) are approved for treating asthma in children 4 years of age and older.
- **Clinical Coverage** — Responses from a survey of MTF providers revealed that to meet the needs of the majority of MHS beneficiaries, both HFA metered-dose inhalers and dry powder inhalers are required for inclusion on the UF.
- **Therapeutic Interchangeability** — There is a high degree of therapeutic interchangeability between the ICS products.

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

## **B. INHALED CORTICOSTEROIDS – Relative Cost Effectiveness**

In considering the relative cost-effectiveness of pharmaceutical agents in the ICS as part of the Pulmonary I 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). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost-effectiveness of the ICS.

### *Relative Cost Effectiveness Conclusion:*

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

- a) Results of the CMA revealed that beclomethasone DPI (QVAR) was the most cost-effective ICS based on acquisition cost; and
- b) 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:** The P&T Committee voted to accept the cost effectiveness conclusion stated above.

**C. INHALED CORTICOSTEROIDS – Uniform Formulary Recommendation**

In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the ICS products and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (8 for, 5 opposed, 2 abstained, 0 absent) to recommend:

- 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.

**D. INHALED CORTICOSTEROIDS – Implementation Plan**

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), and in the MTFs, no later than a 120-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

**III. INHALED CORTICOSTEROIDS**

*BAP Comments*

**A. INHALED CORTICOSTEROIDS - Uniform Formulary Recommendation:** In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Inhaled Corticosteroids, and other relevant factors, the P&T Committee voted to recommend that 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 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.

*BAP Comment:*  Concur  Non-concur

Additional Comments and Dissentions:

**B. INHALED CORTICOSTEROIDS – Implementation Plan:** 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), and in the MTFs, no later than a 120-day implementation period;. The implementation period will begin immediately following the approval by the Director, TMA.

*BAP Comment:*

Concur

Non-concur

Additional Comments and Dissentions:

#### IV. LONG-ACTING BETA AGONISTS (LABAs)

##### *P&T Comments*

##### **A. LABAs– Relative Clinical Effectiveness**

The P&T Committee evaluated the clinical effectiveness of the long-acting beta agonists (LABAs), as part of the Pulmonary I drug class. The LABAs include 2 DPIs, salmeterol (Serevent Diskus) and formoterol (Foradil Aerolizer), and 2 inhalation solutions, formoterol solution (Perforomist) and arformoterol solution (Brovana). There are no generic formulations available for the LABAs.

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.

*Relative Clinical Effectiveness Conclusion:* The P&T Committee concluded that:

- 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 (FEV<sub>1</sub>) 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 discussed in 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.
- f) **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.
- g) **Use of LABAs without concomitant use of ICS in MHS:** Results of a preliminary analysis reported by the Pharmacy Outcomes Research Team (PORT) indicated that of the 13,533 DoD beneficiaries who filled at least 1 prescription for a LABA during a 6-month study period (June – November 2008) at any DoD point of service, 6,118 (45%) had not filled a prescription for an ICS or an ICS/LABA combination during the 180 days prior to or the 60 days following the date of their first LABA prescription during the study period. The pronounced skew in this group toward older ages (mean: 69 years) and the fact that about 30% had filled an anticholinergic prescription during the same time period suggested a predominantly COPD population. 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.

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

## **B. LABAs – Relative Cost Effectiveness**

In considering the relative cost-effectiveness of pharmaceutical agents in the LABAs as part of the Pulmonary I 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). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost-effectiveness of the LABAs.

*Relative Cost Effectiveness Conclusion:* Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following

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

- c) 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:** The P&T Committee voted to accept the cost effectiveness conclusion stated above.

**C. LABAs – Uniform Formulary Recommendation**

In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the LABA products and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (14 for, 0 opposed, 2 abstained, 0 absent) to recommend that:

- a. Salmeterol DPI (Serevent Diskus), formoterol DPI (Foradil Aerolizer) and arformoterol inhalation solution (Brovana) be classified as formulary under the UF;
- b. Formoterol inhalation solution (Perforomist) be designated as non-formulary on the UF, based on cost-effectiveness.

**D. LABAs – Implementation Plan -** 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 TMOP and 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.

**V. LONG-ACTING BETA AGONISTS (SABAs)**

*BAP Comments*

**A. LABAs – Uniform Formulary Recommendation**

Taking into consideration of the conclusions from the relative clinical effectiveness conclusions and cost effectiveness determinations of the Long-Acting Beta Agonists and other relevant factors, the P&T Committee, based on its professional judgment, voted to recommend that salmeterol DPI (Serevent Diskus), formoterol DPI (Foradil Aerolizer) and arformoterol inhalation solution (Brovana) be classified as formulary under the UF, and that formoterol inhalation solution (Perforomist) be designated as non-formulary on the UF, based on cost-effectiveness.

<p><i>BAP Comment:</i></p>   	<p style="text-align: center;"> <input type="checkbox"/> Concur                      <input type="checkbox"/> Non-concur          Additional Comments and Dissentions:       </p>
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## B. LABAs – Implementation Plan

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 TMOP and 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.

*BAP Comment:*

Concur

Non-concur

Additional Comments and Dissentions:

## VI. INHALED CORTICOSTEROIDS / LONG-ACTING BETA AGONISTS COMBINATIONS (ICS/LABA COMOS)

### *P&T Comments*

#### A. ICS / LABA COMBOS– Relative Clinical Effectiveness

The P&T Committee evaluated the clinical effectiveness of the ICS/LABA combinations, as part of the Pulmonary I drug class. There are 2 ICS/LABA combinations available. Fluticasone/salmeterol (Advair Diskus) is available as both a dry powder inhaler and as an HFA metered-dose inhaler (Advair HFA). Budesonide/formoterol (Symbicort) is available as an HFA metered-dose inhaler.

MHS expenditures for the ICS/LABA combinations exceeded \$153M in FY 2008 (MTF \$55.2M, TRRx \$75.1M, TMOP \$23.4M). In terms of number of prescriptions dispensed, fluticasone/salmeterol DPI (Advair Diskus) is by far the highest utilized ICS/LABA across all 3 points of service.

*Relative Clinical Effectiveness Conclusion:* The P&T Committee concluded that:

- a) With regard to efficacy/clinical effectiveness between the ICS/LABA combinations, the following conclusions were made:
  - FDA-approved Indications — The Committee recognized that the ICS/LABA combinations are all approved for the long-term treatment of asthma, and that pediatric age ranges differ between the products. Additionally, fluticasone/salmeterol DPI (Advair Diskus) dry powder inhaler is FDA-approved to reduce air flow obstruction and reduce exacerbations in COPD. These FDA indications for COPD apply only to the fluticasone 250 mcg /salmeterol 50 mcg Advair Diskus dosage strength. Note: Following the meeting on 27 Feb 2009, the FDA approved formoterol/budesonide DPI (Symbicort) for treating COPD.

- Efficacy/clinical effectiveness for asthma — The Committee concluded that there was fair evidence to suggest that there are no clinically relevant differences in efficacy between fluticasone/salmeterol and budesonide/formoterol for the treatment of asthma. This is based on the conclusions of 2 systematic reviews (Cochrane and the state of Oregon Drug Effectiveness Review Project) and head-to-head trials showing similar improvements in PEF, mean reduction of asthma exacerbations, and increases in the percentage of symptom-free days.
  - Efficacy/clinical effectiveness for COPD — The Committee concluded that there was insufficient evidence to determine whether there are clinically relevant differences in efficacy between fluticasone/salmeterol and budesonide/formoterol for the treatment of COPD.
- b) With regard to safety/tolerability:
- Product labeling — The Committee recognized that the safety information contained in the product labeling for the ICS/LABA combinations closely reflects the product labels for the individual ICS and LABA components.
  - Minor adverse events — Comparative trials of the ICS/LABA combinations show that the products are generally well-tolerated. The most common adverse events are nasopharyngitis, headache, upper respiratory infection, oral candidiasis, and dysphonia. Adverse events for ICS/LABA combination are similar to those reported with an equipotent dose of the individual ICS component.
- c) With regard to other factors between the ICS/LABA combination oral inhalers:
- Clinical Coverage – The Committee concluded that, to meet the needs of the majority of MHS beneficiaries, MHS providers require availability of both a metered-dose inhaler and dry powder inhaler formulation of the ICS/LABA combinations.
  - Therapeutic Interchangeability — The Committee concluded that there is a high degree of therapeutic interchangeability between fluticasone/salmeterol (Advair) and budesonide/formoterol (Symbicort).
  - DoD Persistence Data —
    - The PORT reported preliminary results of an analysis of persistence on treatment among DoD beneficiaries who are new users of ICS/LABA combinations (Advair or Symbicort). The study sample consisted of 3,857 patients randomly sampled from the population of DoD beneficiaries. Persistence was measured as percentage of days covered (PDC) over 1 year. Based on ICD-9 diagnosis codes from medical claims and prescription fills for anticholinergics (indicative of COPD), 72% of the study sample had a diagnosis of asthma and 12% had a diagnosis of COPD or had received an anticholinergic prescription, with 8% of patients falling into both groups. Of the remaining 24% (n=920), about two-thirds had diagnoses for acute respiratory illness and/or

allergic rhinitis, while about one-third did not have a claim coded for any study diagnosis.

- Persistence was low compared to those found for other chronic medications, with a mean PDC over 1 year of 28.3% (SD 25.2%). These findings were influenced by patients who received only an initial ICS/LABA prescription (47%), with no other fills during the 365-day follow-up period. Notably, the percentage of patients receiving only 1 ICS/LABA prescription was greatest (69%) among the 920 patients without an asthma or COPD diagnosis, compared to about 40% among the 2,957 patients who did not have asthma or COPD diagnosis. These results suggest that a considerable proportion of ICS/LABA use may be for acute rather than chronic conditions. The Committee suggested that MTFs may wish to review appropriateness of ICS/LABA combination use at their facilities, particularly with regard to acute vs. chronic use.

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

#### **B. ICS/ LABA COMBOs – Relative Cost Effectiveness**

In considering the relative cost-effectiveness of pharmaceutical agents in the ICS/LABA combination oral inhalers as part of the Pulmonary I 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). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost-effectiveness of the ICS/LABA combinations.

*Relative Cost Effectiveness Conclusion:* Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following

- 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;
- 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:** The P&T Committee voted to accept the cost effectiveness conclusion stated above.

#### **C. ICS / LABA COMBOs – Uniform Formulary Recommendation**

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, based upon its collective professional judgment, voted (12 for, 2 opposed, 1 abstained, 0 absent) to recommend that:

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

**D. ICS/LABA COMBOs – Implementation Plan** –Since no drugs were designated non-formulary, the implementation period is not applicable.

**VII. INHALED CORTICOSTEROIDS / LONG-ACTING BETA AGONIST COMBINATIONS (ICS/ LABA COMBOs)**

*BAP Comments*

**A. ICS / LABA COMBOs – Uniform Formulary Recommendation**

Taking into consideration of the conclusions from the relative clinical effectiveness conclusions and cost effectiveness determinations of the Inhaled Corticosteroid /Long-Acting Beta Agonist Combinations, and other relevant factors, the P&T Committee, based on its professional judgment, voted to recommend that Fluticasone/salmeterol HFA (Advair HFA) and DPI (Advair Diskus) and budesonide/formoterol (Symbicort) inhaler be classified as formulary on the UF, and that no ICS/LABA combination agents be designated as non-formulary under the UF, based on cost-effectiveness

<p><i>BAP Comment:</i></p>   	<p style="text-align: center;"> <input type="checkbox"/> Concur                      <input type="checkbox"/> Non-concur         </p> <p style="text-align: center;">Additional Comments and Dissentions:</p>
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**VIII. NEWLY APPROVED AGENTS – TRUEtest Self-Monitored Blood Glucose Test Strip**

*P&T Comments*

**A. TRUEtest strip – Relative Clinical Effectiveness** –The self-monitored blood glucose system (SMBGS) test strips were evaluated for Uniform Formulary (UF) placement at the August 2008 DoD P&T Committee meeting. The other 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 Standard for 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.

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

*Relative Clinical Effectiveness Conclusion* - The P&T Committee concluded the following 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.

- B. TRUEtest strip – Relative Cost Effectiveness** –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.

*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.

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

- C. TRUEtest strip – Uniform Formulary Recommendation** - Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended that (14 for, 0 opposed, 1 abstained, 0 absent) that the TRUEtest SMBGS test strip remain designated as formulary on the UF.

**IX. NEWLY APPROVED AGENTS – TRUEtest Self-Monitored Blood Glucose Test Strip**

***BAP Comments***

**TRUEtest strip – Uniform Formulary Recommendation -** The P&T Committee, based upon its collective professional judgment, recommended that the TRUEtest SMBGS test strip remain designated as formulary on the UF.

<i>BAP Comment:</i>	<input type="checkbox"/> Concur	<input type="checkbox"/> Non-concur
Additional Comments and Dissentions:		