

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. NASAL ALLERGY DRUGS

P&T Comments

A. Nasal Allergy Drugs – Relative Clinical Effectiveness

The P&T Committee evaluated the relative clinical effectiveness of the Nasal Allergy Drugs. The class is comprised of three subclasses as listed below. The nasal corticosteroids were previously reviewed for UF placement in November 2005 and August 2007.

- *Nasal corticosteroids*: beclomethasone (Beconase AQ), budesonide (Rhinocort AQ), ciclesonide (Omnaris), flunisolide (Nasarel, generics), fluticasone furoate (Veramyst), fluticasone propionate (Flonase, generics), mometasone furoate (Nasonex), and triamcinolone (Nasacort AQ)
- *Nasal Antihistamines*: azelastine (Astelin) and olopatadine (Patanase)
- *Nasal Anticholinergics*: ipratropium (Atrovent, generics)

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).

MHS expenditures for the Nasal Allergy Drug class exceeded \$63M in FY 2008 (Military Treatment Facility [MTF]: \$18.6M, TRICARE Retail Network [TRRx] \$37.5M, TRICARE Mail Order Pharmacy [TMOP] \$7M). In terms of numbers of prescriptions dispensed, generic fluticasone propionate (Flonase) is the highest utilized nasal allergy drug in the MTFs, followed by mometasone furoate (Nasonex), and azelastine (Astelin). This utilization pattern is also seen in the TRRx.

Relative Clinical Effectiveness Conclusion

Nasal corticosteroids

- a) With regards to efficacy/clinical effectiveness of the nasal corticosteroids, the following conclusions were made:

- FDA-approved indications – The Committee recognized that there were minor differences among the drugs with regard to FDA-approved uses for seasonal allergic rhinitis (SAR), perennial allergic rhinitis (PAR), prophylaxis of allergic rhinitis (AR) symptoms, nonallergic rhinitis, and nasal polyps. Additionally, the pediatric FDA-approved age ranges differ between the products.
 - Clinical Practice Guidelines – Evidence-based guidelines from the American Academy of Allergy, Asthma and Immunology (AAAAI) consider the nasal corticosteroids as the most effective drug class at reducing allergic rhinitis symptoms of sneezing, rhinorrhea, nasal congestion, and itching.
 - Pharmacodynamic/pharmacokinetic properties – The AAAAI guidelines concluded that despite differences in topical potency, lipid solubility, receptor binding affinity, and systemic bioavailability, the overall clinical response does not appear to vary significantly between drugs.
 - Efficacy for SAR/PAR – The Committee concluded there was no new data to change the previous conclusion from the 2005 meeting that there was no evidence of clinically relevant differences between beclomethasone (Beconase AQ), budesonide (Rhinocort AQ), flunisolide (Nasarel, generics), fluticasone propionate (Flonase, generics), mometasone (Nasonex), and triamcinolone (Nasacort) at relieving AR symptoms.
 - Efficacy of newer agents – Fluticasone furoate (Veramyst) was non-inferior to fluticasone propionate (Flonase, generics) at relieving symptoms of SAR; there was no new data to change this conclusion. The newest nasal corticosteroid, ciclesonide (Omnaris) does not have published data comparing efficacy to other nasal corticosteroids. Placebo-controlled trials with ciclesonide report statistically significant improvements in patients with SAR and PAR.
 - Relief of ocular symptoms - None of the nasal corticosteroids are FDA-approved for use in reducing ocular symptoms of itching, tearing or erythema. However, all of the agents, with the exception of ciclesonide (Omnaris), have shown efficacy at reducing ocular symptoms in placebo-controlled trials.
 - Nasal polyps – Data from clinical trials conducted with beclomethasone, budesonide, and fluticasone propionate report reductions in the size of nasal polyps. Both mometasone furoate (Nasonex) and beclomethasone (Beconase AQ) are FDA-approved for nasal polyps.
- b) With regards to regards to safety and tolerability, the following conclusions were made:
- Local effects - Nasal irritation, epistaxis, and rhinorrhea are the most common local adverse effects and are equally likely to occur with any of the nasal corticosteroids.
 - Pharmacodynamic/pharmacokinetic properties – Minor differences in binding affinity, lipophilicity, and bioavailability between the products have not

correlated to clinically relevant differences in safety. Pharmacokinetic studies report that the newer agents would be expected to pose fewer risks than the older agents (flunisolide [Nasarel], beclomethasone [Beconase AQ], budesonide [Rhinocort AQ], and triamcinolone [Nasacort AQ]).

- Systemic effects- For systemic effects of hypothalamic pituitary adrenal-axis suppression, growth suppression, and cataract formation, there is insufficient evidence to determine whether one nasal corticosteroid is more likely to cause these effects than another. When given in recommended doses, the nasal corticosteroids are not generally associated with clinically significant systemic adverse effects. Providers and patients must assess the risks to benefits, if higher than recommended doses are required.
 - Tolerability and patient preferences - Patient preferences may play a role in differentiating between the nasal corticosteroids. However, the available clinical data is poor, and no nasal corticosteroid has proven superior to the others in patient preference trials. More well-designed head-to-head trials are needed to support superiority of a nasal corticosteroid based on tolerability and compliance.
- c) With regards to differences in other factors, the following conclusions were made:
- Special populations – Budesonide (Rhinocort AQ) is the only nasal corticosteroid with a pregnancy category B rating by the FDA (low evidence of risk to humans), which was based on a retrospective review of data from three Swedish registries and one prospective study. All the nasal corticosteroids have a class labeling that these drugs should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
 - Provider survey – A survey of MTF providers found that the majority of prescribers (49%) preferred fluticasone propionate (Flonase, generics) as their first choice of nasal corticosteroid, followed by no preference (17%), and mometasone (15%). Providers showed no preference for differences in formulations between the products (e.g., hypotonic formulation, ergonomic design, prodrug active ingredient, scent-free product, or preservative-free product).

Nasal antihistamines

- a) With regards to efficacy/clinical effectiveness of the nasal antihistamines, the following conclusions were made:
- FDA-approved indications – The Committee recognized that there were minor differences between olopatadine (Patanase) and azelastine (Astelin) with regard to FDA-approved uses for seasonal allergy rhinitis (SAR) and nonallergic rhinitis (e.g., vasomotor rhinitis [VMR]), and pediatric approval.
 - Clinical Practice Guidelines – AAAAI guidelines state that nasal antihistamines are generally less effective than nasal corticosteroids for treating allergic rhinitis, but may be considered for use as first-line treatment

for allergic rhinitis and nonallergic rhinitis. Nasal antihistamines are associated with a clinically significant effect on nasal congestion.

- Efficacy for seasonal allergic rhinitis – Both nasal antihistamines are superior to placebo in relieving symptoms of SAR. Determining whether there are relevant clinical differences in efficacy between olopatadine (Patanase) and azelastine (Astelin) is difficult because different rating scores were used in the individual placebo-controlled trials.
 - Efficacy for vasomotor rhinitis (VMR): Only azelastine (Astelin) is FDA-approved for treating the symptoms of VMR, which consist of postnasal drip, sneezing, rhinorrhea, and nasal congestion. FDA-approval was based on the results of two placebo-controlled studies in 200 patients that used a rating scale not previously seen in the literature.
 - Head to head study- The one head-to-head trial comparing the use of olopatadine (Patanase) with azelastine (Astelin) was conducted in an allergan exposure unit, making applicability to the clinical setting difficult.
- b) With regards to safety and tolerability of the nasal antihistamines, the following conclusions were made:
- Local adverse effects: package insert data- For safety data, package insert data report a higher incidence of bitter taste and somnolence with azelastine (Astelin), while olopatadine (Patanase) has a higher incidence of epistaxis.
 - Local adverse effects: AAAAI guidelines – the AAAAI guidelines recognize that the two nasal antihistamines can cause sedation and can inhibit skin test reactions, due to systemic absorption.
 - Patient preferences and tolerability – There is insufficient evidence to determine whether clinically relevant differences exist between the nasal antihistamines with respect to patient preferences and tolerability. The available clinical data is sparse, and is limited to manufacturer-sponsored studies that are not yet available in peer-reviewed publications.
- c) With regards to other factors,
- Provider survey - A survey of MTF providers found that 37% of responders preferred a nasal corticosteroid over a nasal antihistamine for managing AR and nonallergic rhinitis.
 - Onset and duration of action – The Committee recognized that the onset of action to relieve allergic rhinitis symptoms was slightly faster with olopatadine (Patanase) compared to the package insert data for azelastine (Astelin) ;0.5 - 1 hour vs. 2-3 hours. However, the onset of action with both nasal antihistamines is faster than that reported overall with nasal corticosteroids (2-3 days).

Nasal anticholinergic agents

- a) With regards to efficacy/clinical effectiveness, safety, tolerability and other factors of the ipratropium nasal spray (Atrovent, generics), the following conclusions were made:
- FDA-approved indications – Ipratropium is solely indicated for the relief of SAR in adults and children 12 years of age and older.
 - Clinical Practice Guidelines – AAAAI guidelines state that nasal anticholinergics may effectively reduce rhinorrhea, but have no effect on other nasal symptoms. Although adverse effects are minimal, dryness of the nasal membranes may occur.
 - Efficacy - Further head-to-head trials are needed to prove the superiority of a nasal anticholinergic over a nasal antihistamine or nasal corticosteroid in the treatment of rhinorrhea.

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

B. NASAL ALLERGY DRUGS – Relative Cost Effectiveness

In considering the relative cost-effectiveness of pharmaceutical agents in the Nasal Allergy Drug 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 NAD agents.

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 from the CMA of nasal corticosteroid agents revealed that flunisolide (Nasarel, generics) was the most cost effective nasal corticosteroid agent overall.
- b) Results from the CMA of nasal antihistamines agents revealed that azelastine (Astelin) was the most cost effective nasal antihistamine agent overall.

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

C. NASAL ALLERGY DRUGS – Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Nasal Allergy Drugs, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended that:

- 1) Fluticasone propionate (Flonase, generics), flunisolide (Nasarel generics), mometasone (Nasonex), azelastine (Astelin), and ipratropium nasal spray (Atrovent, generics) be classified as formulary on the UF.
- 2) Beclomethasone dipropionate (Beconase AQ), budesonide (Rhinocort Aqua), ciclesonide (Omnaris), fluticasone furoate (Veramyst), olopatadine HCl (Patanase), and triamcinolone acetonide (Nasacort AQ) be designated as nonformulary under the UF, based on cost effectiveness.

D. NASAL ALLERGY DRUGS – Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Network Pharmacy Program (TRRx), and in the MTFs, no later than a 60-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

III. NASAL ALLERGY DRUGS

BAP Comments

A. NASAL ALLERGY DRUGS - Uniform Formulary Recommendation: In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Nasal Allergy Drugs, and other relevant factors, the P&T Committee voted to recommend that:

- 1) Fluticasone propionate (Flonase, generics), flunisolide (Nasarel generics), mometasone (Nasonex), azelastine (Astelin), and ipratropium nasal spray (Atrovent, generics) be classified as formulary on the UF.
- 2) Beclomethasone dipropionate (Beconase AQ), budesonide (Rhinocort Aqua), ciclesonide (Omnaris), fluticasone furoate (Veramyst), olopatadine HCl (Patanase), and triamcinolone acetonide (Nasacort AQ) be designated as nonformulary under the UF, based on cost effectiveness.

BAP Comment: Concur Non-concur

Additional Comments and Dissentions:

B. NASAL ALLERGY DRUGS – Implementation Plan: The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Network Pharmacy Program (TRRx), and in the MTFs, no later than a 60-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. SHORT-ACTING BETA AGONISTS (SABAs)

P&T Comments

A. SABAs– Relative Clinical Effectiveness

The P&T Committee evaluated the clinical effectiveness of the inhaled Short-Acting Beta Agonists (SABAs). There are four SABA products marketed in the US that are formulated as pressurized metered dose inhalers (MDIs) or solutions for inhalation: albuterol (a racemic mixture), levalbuterol (the (R)-enantiomer form of albuterol), metaproterenol, and pirbuterol. The SABA inhaled solutions include albuterol (Accuneb, generics; various concentrations), levalbuterol (Xopenex), and metaproterenol (Alupent, generics).

As of 31 December 2008, hydrofluoroalkane (HFA) will replace chlorofluorocarbon (CFC) as the propellant in albuterol MDIs. The SABA MDI formulations include albuterol HFA (Ventolin HFA, Proventil HFA, ProAir), levalbuterol HFA (Xopenex), and pirbuterol (Maxair). Generic formulations of albuterol MDI and metaproterenol CFC (Alupent) using the CFC propellant are no longer manufactured, but supplies have not yet been exhausted. The three albuterol HFA products are not considered therapeutically interchangeable by the FDA.

In the past fiscal year, over \$43M was spent on the SABAs at all three points of service in the Military Health System (MHS), with \$30M spent in TRICARE Pharmacy Retail Network, \$10M in the Military Treatment Facilities, and \$3M in the TRICARE Mail Order Pharmacy. In terms of numbers of prescriptions dispensed in the MTFs, Proventil HFA is the highest utilized SABA, followed by Xopenex HFA, Ventolin HFA, and Proair HFA. In the TRRx, the top three drugs in terms of numbers of prescriptions dispensed are generic albuterol CFC MDI (but has declining usage due to dwindling stock), ProAir HFA MDI, and Xopenex HFA MDI.

Information regarding the safety, effectiveness, and clinical outcomes of the SABAs was considered by the Committee. The clinical effectiveness review for the SABAs was

limited to the outpatient setting; emergency department (ED) use was evaluated only when pertinent.

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

- a) In terms of efficacy/clinical effectiveness, there is little evidence to suggest there are clinically significant differences between agents for their FDA approved indications. Other conclusions regarding efficacy include the following:
 - Clinical Practice Guidelines – Evidence based guidelines from the VA/DoD Clinical Practice Group, Global Initiative for Asthma, National Heart, Lung and Blood Institute/National Asthma Education & Prevention Program, and Global Initiative for Chronic Obstructive Lung Disease do not list a preference for one SABA over another for treating asthma, exercise-induced bronchospasm (EIB) or chronic obstructive pulmonary disease (COPD).
 - Asthma
 - *MDI and inhalation solution administration – placebo-controlled studies:* For asthma, all the SABA agents were more efficacious than placebo at improving the change in forced expiratory volume in one second (FEV1) $\geq 12\%$ from baseline, whether administered via MDI or inhalational solution.
 - *MDI administration – albuterol vs. levalbuterol:* There are no studies in adults or children assessing efficacy of albuterol vs. levalbuterol (Xopenex) when administered by metered-dose inhaler in the outpatient setting.
 - *Inhalation administration – albuterol vs. levalbuterol in adults:* For adults with asthma, there is little evidence to suggest there are clinically relevant differences between albuterol and levalbuterol (Xopenex) when administered via inhaled solutions (e.g., nebulized route) in either the outpatient or emergency department (ED) settings in terms of number of puffs of rescue medication used daily or hospitalization admission rates from the ED.
 - *Inhalation administration – albuterol vs. levalbuterol in children:* There are conflicting and inconclusive results as to whether there are efficacy differences between albuterol and levalbuterol (Xopenex) inhalation solution when administered in the outpatient or ED settings to children with asthma. Some studies reported no clinically significant differences in outcomes such as changes in asthma symptom score, symptom-free days, rescue medication use, and hospitalization rates between albuterol and levalbuterol. However, levalbuterol (Xopenex) treatment resulted in statistically significant results in terms of more asthma-controlled days, higher quality of life scores, and lower hospitalization admission rates from the ED compared to albuterol. Interpretation of the results of these studies is complicated by the low patient enrollment, varying definitions of criteria for hospitalization, and enrollment of patients as old as 18-21 years.

- EIB – Placebo controlled trials with albuterol administered via MDI 15 to 30 minutes before exercise reported statistically significant results in terms of preventing exercise-related symptoms compared to placebo. Although levalbuterol MDI (Xopenex) is not currently approved by the FDA for EIB, the results of placebo-controlled phase III trials do not suggest that the effect of levalbuterol at preventing EIB symptoms would differ from albuterol.
 - COPD - There is insufficient evidence to compare the SABAs when used in COPD.
 - CFC vs. HFA efficacy - HFA products were as effective as CFC products when evaluated in head-to-head studies. Placebo-controlled trials assessing efficacy of HFA albuterol with CFC albuterol have reported similar effects on percentage change in FEV1.
- b) With regards to safety/tolerability, the following conclusions were made:
- *Discontinuation rates due to adverse events (AEs)* - SABAs are associated with similar systemic adverse effects. A systematic review found no clinically relevant differences in discontinuation rates due to changes in heart rate, blood pressure, palpitations, nervousness, anxiety, tremor, hyperglycemia or hypokalemia between albuterol and levalbuterol inhalation solution.
 - *Rare but serious AEs* – There do not appear to be clinically relevant differences between the SABAs in terms of serious adverse effects (e.g., paradoxical bronchospasm, cardiac effects).
 - *Inhalation solution administration – albuterol vs. levalbuterol* - In the outpatient setting, in both adults and children, the incidence of the withdrawal rates due to AEs and overall AE rates were similar between albuterol and levalbuterol (Xopenex) inhaled solutions. However, in children there is insufficient evidence from the outpatient studies to determine whether there are clinically relevant differences in the incidence of tachycardia, as conflicting results were reported. One study reported a lower incidence of tachycardia with albuterol compared to levalbuterol, while another reported that both drugs resulted in a change of heart rate of 4 beats per minute.
 - *MDI administration – albuterol vs. levalbuterol* - There is insufficient data with the SABA MDI formulations to assess safety differences between albuterol and levalbuterol (Xopenex).
 - *Drug-Drug interactions*- Drug-drug interactions between the SABAs are well-known and considered a class effect.
 - *FDA Adverse Event Reporting System (AERS)* – FDA AERS data shows higher signals than expected with device malfunction/failure for Proair HFA MDI and Proventil HFA MDI. However, this is observational data only and these safety signals have not been validated.
- c) With regards to differences between the SABAs in terms of other factors, the following conclusions were made:

- Special populations – The Committee recognized that the pediatric FDA-approved age ranges differ between the products. All four SABAs are labeled as category C drugs for pregnancy and breast feeding, and infant risk cannot be ruled out.
- CFC Phase out – By 31 December 2008, all albuterol CFC metered-dose inhalers will no longer be available. Metaproterenol CFC MDIs (Alupent) will also cease manufacturing by the end of 2008. It is likely that pirbuterol CFC MDIs (Maxair) will also be removed from the market.
- HFA formulations - There are only minor differences between the HFA formulations of albuterol and levalbuterol, including presence of a dose counter (Ventolin HFA is the only product with a dose counter), requirements for priming, storage conditions, and excipients (Ventolin HFA is the only SABA that does not contain alcohol). However, per FDA ruling, the HFA albuterol agents are not interchangeable.
- Delivery devices - There are no clinically relevant difference among the SABAs in terms of alternative delivery devices (MDI with a spacer/holding chamber, nebulizer, dry powder inhalers) compared with a standard MDI in stable asthma or COPD.
- Provider Survey – A survey of MTF providers found that albuterol HFA MDI was preferred over levalbuterol HFA MDI (Xopenex) in the outpatient setting for relief of bronchospasm.

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

B. SABAs – Relative Cost Effectiveness

In considering the relative cost-effectiveness of pharmaceutical agents in the SABA drug 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 SABA agents.

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 from the CMA of SABA MDIs revealed that Ventolin HFA was the most cost effective SABA MDI agent overall.
- b) Results from the CMA of SABA inhalant solutions revealed that albuterol inhalation solution (generic; 2.5 mg/3mL concentration) was the most cost effective agent overall.
- c) The potential impact of scenarios with selected SABA agents designated formulary or nonformulary on the UF was evaluated with the BIA. Generic albuterol CFC inhaler and metaproterenol inhaler (Alupent) were not included in the BIA as they are no longer being manufactured. BIA results designated

pirbuterol (Maxair) CFC MDI and metaproterenol inhalant solution (Alupent, generic) nonformulary on the UF as the most favorable scenario for the MHS.

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

C. SABAs – Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the SABA agents, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended that:

- a. Albuterol HFA inhaler (Ventolin HFA, Proventil HFA, Proair HFA), levalbuterol inhaler (Xopenex HFA), albuterol inhalation solution (Accuneb, generics), and levalbuterol inhalant solution (Xopenex inhalation solution) be classified as formulary on the UF; and
- b. Pirbuterol CFC inhaler (Maxair) and metaproterenol inhalation solution (Alupent, generics) be designated as nonformulary on the UF, based on cost effectiveness.

D. SABAs – Implementation Plan - The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed following a 60-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 60-day implementation period.. The implementation period will begin immediately following the approval by the Director, TMA.

V. SHORT-ACTING BETA AGONISTS (SABAs)

BAP Comments

A. SABAs – Uniform Formulary Recommendation

Taking into consideration of the conclusions from the relative clinical effectiveness conclusions and cost effectiveness determinations of the Short-Acting Beta Agonists and other relevant factors, the P&T Committee, based on its professional judgment, voted to recommend that albuterol HFA inhaler (Ventolin HFA, Proventil HFA, Proair HFA), levalbuterol inhaler (Xopenex HFA), albuterol inhalation solution (Accuneb, generics), and levalbuterol inhalant solution (Xopenex inhalation solution) be classified as formulary on the UF, and that pirbuterol CFC inhaler (Maxair) and metaproterenol inhalation solution (Alupent, generics) be designated as nonformulary on the UF, based on cost effectiveness

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

B. SABAs – Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed following a 60-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 60-day implementation period. The implementation period will begin immediately following the approval by the Director, TMA.

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