# DEPARTMENT OF DEFENSE
# PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
# November 2008

## 1) CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on 18 November 2008 and at 0730 on 19 November 2008 at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

## 2) ATTENDANCE

The attendance roster is found in Appendix A.

## 3) REVIEW MINUTES OF LAST TWO MEETINGS

**A. Updates to the minutes** — Updates to the June 2008 DoD P&T Committee meeting minutes for the reviewed drug classes' implementation dates were discussed. Implementation dates from the June 2008 meeting for the designated non-formulary drugs delayed to 26 November 2008.

**B. Approval of August minutes** — S. Ward Casscells, III, MD, approved the minutes of the August 2008 DoD P&T Committee meeting on 24 October 2008.

**C. Interim October meeting** — An interim teleconference meeting was held on 27 October 2008 to re-analyze the cost effectiveness of the triptan drug class for Uniform Formulary (UF) placement. The recommendations from the interim meeting were reviewed by CDR James Ellzy. The Committee agreed to maintain the original medical necessity (MN) criteria and implementation date (90 days; 26 November 2008). The minutes are under review by TMA.

## 4) REVIEW OF RECENTLY FDA APPROVED AGENTS

### A. Re-review of Antidepressant-1 (AD-1) - Desvenlafaxine (Pristiq)

The committee re-reviewed the cost-effectiveness and Uniform Formulary (UF) status of desvenlafaxine (Pristiq) that was originally conducted at the August 2008 meeting. Manufacturers were offered the opportunity to re-submit Uniform Formulary Voluntary Agreement for Retail Refunds (UF VARR) submissions that exceeded the Federal Ceiling Price. A revised UF VARR was submitted for desvenlafaxine. The August 2008 DoD P&T Committee meeting minutes were originally signed by the Director, TMA on 24 October 2008.

*Relative Clinical Effectiveness* — The committee agree that there was no reason to repeat the review since there was no significant new information in the intervening three months. The relative clinical effectiveness of desvenlafaxine (Pristiq) was reviewed at the August 2008 meeting. Desvenlafaxine (Pristiq) is a Serotonin Norepinephrine Reuptake Inhibitor (SNRI) that is included in the Antidepressant-1 (AD-1) drug class. The AD-1 drug class was originally reviewed for UF placement in November 2005. Desvenlafaxine is an extended release (ER) formulation of the major active metabolite of venlafaxine ER (Effexor XR), and is approved solely for treating major depressive disorder in adults. Generic formulations of venlafaxine ER are

expected in 2010.

*Relative Clinical Effectiveness Conclusion* — At the November 2008 meeting the committee agreed to accept the conclusion from the August 2008 meeting. August 2008 P&T Committee meeting members concluded (15 for, 0 opposed, 0 abstained, 0 absent) that desvenlafaxine does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other AD-1 agents currently included on the UF. A review of the literature from August 2008 to the present found no new data to alter the previous clinical conclusion.

*Cost Effectiveness* — A cost minimization analysis (CMA) was used to evaluate the cost effectiveness of desvenlafaxine relative to the UF AD-1s: citalopram (Celexa, generics), sertraline (Zoloft, generics), venlafaxine immediate release (Effexor, generics), venlafaxine ER (Effexor XR), and the nonformulary (NF) AD-1s bupropion ER (Wellbutrin XL, generics), and duloxetine (Cymbalta). The analysis included pricing to reflect the offered UF VARR. Results of the CMA showed that the projected weighted average daily cost of desvenlafaxine was significantly higher than the current market drug mix of AD-1 class comparators, when future market conditions were considered.

*Relative Cost Effectiveness Conclusion* — The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) that desvenlafaxine (Pristiq) is not cost effective relative to the other AD-1s included on the UF when future market conditions were considered.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 2 opposed, 1 abstained, 0 absent) that desvenlafaxine (Pristiq) remain designated as nonformulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the cost determination when future market conditions were considered. Citalopram, sertraline, venlafaxine, and venlafaxine ER (Effexor XR) remain the most cost effective AD-1 agents on the UF compared to desvenlafaxine.

   *Director, TMA, Decision*: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

2) ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —At the November 2008 meeting the Committee agreed to maintain the original MN criteria from the August 2008 meeting. Based on the clinical evaluation of desvenlafaxine and the conditions for establishing MN of a nonformulary medication provided for in the UF rule, the P&T Committee recommended in June 2008 (June vote:14 for, 0 opposed, 1 abstained, 0 absent) MN criteria for desvenlafaxine (Pristiq). (See Appendix B for full MN criteria.)

*Director, TMA, Decision*: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** —At the November 2008 meeting the committee agreed not to change the original 60-day implementation period from the August 2008 meeting (August vote: of 14 for, 0 opposed, 1 abstained, 0 absent). The implementation date will be effective 07 January 2009. TMA will send a letter to beneficiaries affected by this UF decision.

*Director, TMA, Decision*: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

## 5) DRUG CLASS REVIEW — SHORT-ACTING BETA AGONISTS (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 (TRRx), $10M in the Military Treatment Facilities (MTFs), and $3M in the TRICARE Mail Order Pharmacy (TMOP). 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 review included, but was not limited to, the requirements stated in the UF Rule, 32 CFR 199.21(e)(1). The P&T Committee was advised that there is a statutory presumption that pharmaceutical agents in a therapeutic

class are clinically effective and should be included on the UF, unless the P&T Committee finds by a majority vote that a pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over the pharmaceutical agents included on the UF in that therapeutic class. 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 voted (16 for, 0 opposed, 0 abstained, 0 absent) to accept the following clinical effectiveness conclusion:

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 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 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 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 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 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.
- *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 (16 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusions stated above.

*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/3mLconcentration) 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. Albuterol CFC

inhaler and metaproterenol inhaler were not included in the BIA as they are no longer being manufactured. BIA results designated pirbuterol (Maxair) CFC MDI and metaproterenol inhalant solution (generic) nonformulary on the UF as the most favorable scenario for the MHS.

***COMMITTEE ACTION:*** The P&T Committee voted (16 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusions stated above.

*A.* ***COMMITTEE ACTION: UF 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, voted (14 for, 1 opposed, 1 abstained, and 0 absent) to recommend that:

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

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

*B.* ***COMMITTEE ACTION: MN CRITERIA*** — Based on the clinical evaluation for pirbuterol inhaler (Maxair)and metaproterenol inhalation solution (Alupent, generics), and the conditions for establishing medical necessity for a nonformulary medication provided for in the UF rule, the P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for pirbuterol inhaler (Maxair) and metaproterenol inhalation solution (Alupent, generics). Albuterol CFC inhaler and metaproterenol CFC inhaler (Alupent) will not be included on the MN criteria as they will not be available after 31 Dec 08. (See Appendix B for full MN criteria).

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

*C.* ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** — The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday one week following a 60-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin the first Wednesday one week following approval by the Director, TMA.

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

***D. COMMITTEE ACTION: BCF RECOMMENDATION*** — The P&T Committee considered the BCF status of the SABA agents. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (15 for, 0 opposed, 1 abstained, and 0 absent) to recommend that albuterol inhalant solution (generics, excludes Accuneb and the 0.5% [2.5 mg/0.5ml] unit dose vial) and the Ventolin HFA brand of albuterol HFA MDI be designated as BCF immediately on signing of the November 2008 P&T Committee minutes by the Director, TMA.

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

***E. COMMITTEE ACTION: QUANTITY LIMITS*** - The P&T Committee updated the quantity limits (QLs) for the SABAs. The P&T Committee voted (15 for, 0 opposed, 1 abstained, and 0 absent) to recommend the QLs outlined in Appendix E.

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

## 6) DRUG CLASS REVIEW — NASAL ALLERGY DRUGS (NADs)

*Relative Clinical Effectiveness* — The P&T Committee evaluated the clinical effectiveness of the Nasal Allergy Drugs (NADs). 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)

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

MHS expenditures for the NAD class exceeded $63M in FY 2008 (MTF: $18.6M, TRRx $37.5M, 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* — The P&T Committee voted (16 for, 0 opposed, 0 abstained, 0 absent) to accept the following 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, budesonide, flunisolide, fluticasone propionate, mometasone, and triamcinolone 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, 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 and beclomethasone 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 AEs 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, beclomethasone, budesonide, and triamcinolone).
- 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 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 AR, but may be considered for use as first-line treatment for AR and nonallergic rhinitis. Nasal antihistamines are associated with a clinically significant effect on nasal congestion.
- Efficacy for SAR – Both nasal antihistamines are superior to placebo in relieving symptoms of SAR. Determining whether there are relevant clinical differences in efficacy between olopatadine and azelastine is difficult because different rating scores were used in the individual placebo-controlled trials.
- Efficacy for VMR: Only azelastine 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 with azelastine 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, while olopatadine 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 AR symptoms was slightly faster with olopatadine compared to the package insert data for azelastine (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 AEs 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 (16 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusions stated above.

*Relative Cost Effectiveness* – In considering the relative cost-effectiveness of pharmaceutical agents in the NAD 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). CMA and 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 (16 for, 0 opposed, 0 abstained, 0 absent) the following:

a) Results from the CMA of nasal corticosteroid agents revealed that flunisolide was the most cost effective nasal corticosteroid agent overall.

b) Results from the CMA of nasal antihistamines agents revealed that azelastine was the most cost effective nasal antihistamine agent overall.

***COMMITTEE ACTION:*** The P&T Committee voted (16 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusions stated above.

A. ***COMMITTEE ACTION: UF RECOMMENDATION*** — In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the NADs, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (14 for, 1 opposed, 1 abstained, and 0 absent) 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.

*Director, TMA, Decision*: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

***B. COMMITTEE ACTION: MN CRITERIA*** — Based on the clinical evaluation for Beclomethasone dipropionate (Beconase AQ), budesonide (Rhinocort Aqua), ciclesonide (Omnaris), fluticasone furoate (Veramyst), olopatadine HCl (Patanase), triamcinolone acetonide (Nasacort AQ), and the conditions for establishing medical necessity for a nonformulary medication provided for in the UF rule, the P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for beclomethasone dipropionate (Beconase AQ), budesonide (Rhinocort Aqua), ciclesonide (Omnaris), fluticasone furoate (Veramyst), olopatadine HCl (Patanase), and triamcinolone acetonide (Nasacort AQ). (See Appendix B for full MN criteria).

*Director, TMA, Decision*: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

***C. COMMITTEE ACTION: IMPLEMENTATION PERIOD*** — The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday one week following a 60-day implementation period in the TMOP and TRRx, and in the MTFs, no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin the first Wednesday one week following the approval by the Director, TMA.

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

*D. COMMITTEE ACTION: BCF RECOMMENDATION* — The P&T Committee considered the BCF status of the NADs. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (9 for, 5 opposed, 1 abstained, and 1 absent) to recommend that fluticasone propionate (Flonase, generics) and azelastine (Astelin) be designated as BCF immediately on signing of the November 2008 P&T Committee minutes by the Director, TMA.

*Director, TMA, Decision*: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

## 7) UTILIZATION MANAGEMENT — PRIOR AUTHORIZATIONS (PA)/ Quantity Limits (QL) / MEDICAL NECESSITY (MN)

### A. Serotonin subtype 3 receptor-blocking agents – QLs

*Palonosetron capsules (Aloxi)* – The serotonin subtype 3 receptor-blocking agent (5-HT3 antagonist) palonosetron was previously available only in an intravenous solution. The antiemetic is now approved as a 0.5 mg capsule for the prevention of chemotherapy induced nausea and vomiting (CINV) associated with initial and repeat courses of chemotherapy. It is administered as one capsule one hour prior to moderately emetogenic chemotherapy. There is no published data to support the chronic continuous use of palonosetron for prevention of nausea and vomiting. Palonosetron has the longest half-life of the 5-HT3 antagonists (37 - 48 hours), vs. 4-5 hours with ondansetron, 8 hours with oral granisetron, and 9-11 hours with dolasetron. Quantity limits apply to the other 5-HT3 receptor antagonists. The Committee recommended a QL of 1 capsule per fill in both the TRRx and TMOP, due to the long half-life and limited FDA-approved indication for palonosetron (solely for prevention of CINV). A new prescription would be required for each course of chemotherapy.

*Granisetron transdermal (Sancuso)* – Granisetron is now available in a new transdermal formulation, in addition to tablets (Kytril, generics) and an oral solution. The transdermal system is approved for the prevention of CINV for patients receiving moderately to highly emetogenic chemotherapy regimens. Granisetron is available as a 34.3 mg patch that delivers 3.1 mg per 24 hours for up to 7 days. It is applied as a single patch to the arm 24 hours prior to receiving chemotherapy, and removed 24 hours after completion of chemotherapy; it can be worn for up to 7 days, depending on the duration of chemotherapy. The Committee recommended a QL of 1 patch per fill in both the TRRx and TMOP, due to the long duration of action and limited FDA-approved indication for granisetron transdermal system (solely for prevention of CINV). A new prescription would be required for each course of chemotherapy.

***COMMITTEE ACTION:*** The Committee voted (15 for, 0 opposed, 1 abstained, 0 absent) to recommend quantity limits for palonosetron of 1 capsule per prescription fill in the TMOP and TRRx, and for granisetron transdermal system of 1 patch per prescription fill in the TMOP and TRRx.

*Director, TMA, Decision*: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

**B. Ciclesonide oral inhaler (Alvesco) – QL:** Ciclesonide is an oral inhaled corticosteroid approved for the treatment of asthma in patients 12 year of age and older. It is dosed twice daily. There are existing QLs for the other oral inhaled corticosteroids. The Committee recommended QLs for ciclesonide, consistent with the limits imposed on other inhaled corticosteroids in the class.

***COMMITTEE ACTION:*** The P&T Committee voted (15 for, 0 opposed, 1 abstained, 0 absent) to recommend QLs for ciclesonide oral inhaler of 2 inhalers per 30 days in the TRRx, and 6 inhalers per 90 days in the TMOP.

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

## 8) STATUS OF RAMIPRIL ON THE UF

On an ongoing basis, the DoD PEC monitors changes in the clinical information, current costs and utilization trends to determine whether the UF status of agents designated as non-formulary needs to be readdressed. The P&T Committee reevaluated the UF status of ramipril (Altace, generics) in light of recent price reductions in the generic formulations across all three points of service.

*Clinical Effectiveness Conclusion* — The angiotensin converting enzyme (ACE) inhibitors were evaluated for UF status at the August 2005 meeting. At that meeting, the Committee concluded, in general, that ramipril had similar clinical effectiveness relative to other ACE inhibitors in regards to efficacy for treating hypertension, safety, and tolerability. The P&T Committee recognized that there were differences in clinical outcomes for myocardial infarction, heart failure, diabetic nephropathy, and patients at high cardiovascular risk.

*Cost Effectiveness Conclusion* — The P&T Committee voted (16 for, 0 opposed, 0 abstained, 0 absent) that ramipril has similar cost effectiveness relative to the other UF ACE inhibitors.

***COMMITTEE ACTION: UF DECISION*** — Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional

judgment, voted (15 for, 0 opposed, 1 abstained, and 0 absent) that ramipril be immediately reclassified as generic on the UF. Ramipril was included on the "list of non-formulary drugs for re-evaluation of UF status" presented to the BAP in January 2008 and approved by the Director, TMA on 13 February 2008. As such, no further approval is needed.

## 9) BASIC CORE FORMULARY / EXTENDED CORE FORMULARIES (ECF) ISSUES

The Committee was briefed at the August 2008 meeting on the efforts to implement electronic prescribing in the MHS. As part of the ongoing plan to systematically review drugs represented on the BCF/ECF, the Committee periodically reviews recommendations for changes to the BCF/ECF. At this meeting, the BCF was reviewed, as greater specificity in the drug listings is required to assist with e-prescribing efforts. Several BCF deletions were recommended by the Committee, due to such factors as low MHS utilization, therapeutic duplication, change in prescribing patterns (e.g., newer therapies causing existing drugs to be outdated), availability of generic formulations, and VA/DoD joint contracts. Appendix F outlines those drugs recommended for deletion from the BCF.

***COMMITTEE ACTION:*** The P&T Committee voted (14 for, 1 opposed, 1 abstained, 0 absent) to recommend the BCF deletions as outlined in Appendix F.

*Director, TMA, Decision:* ☑ Approved ☐ Disapproved

Approved, but modified as follows:

## 10) ITEMS FOR INFORMATION

**A. Outcomes Research Reports —** The Pharmacy Outcomes Research Team (PORT) reported on the status of two large outcomes studies that focused on the effects of UF changes to DoD beneficiaries and are currently underway in conjunction with the MHS Scientific Advisory Panel (SAP).

1) *Hypertension/Diabetes* — The study focuses on hypertension management among DoD beneficiaries with diabetes. One arm is designed to assess the effect of the February 2006 formulary changes in the ACE inhibitor class (i.e., classification of moexipril, moexipril/hydrochlorothiazide (HCTZ), perindopril, quinapril, quinapril/HCTZ, and ramipril as Tier 3 [nonformulary] under the UF) on blood pressure control among DoD beneficiaries receiving care at MTFs. In late October 2008, medical record abstraction for this arm was approximately 81% complete. The study will also assess cardiovascular event and procedure rates among beneficiaries who were receiving Tier 3 (nonformulary) ACE inhibitors before February 2006 and were affected by changes in the formulary status of these agents in comparison to those who were receiving formulary ACE inhibitors. Results of the study will be reported to the DoD P&T Committee in FY09.

2) *Proton Pump Inhibitor (PPI)* — The study assesses the effect of the step therapy/prior authorization program instituted in the PPI class on 24 October 2007. The UF changes placed lansoprazole (Prevacid), omeprazole/sodium bicarbonate (Zegerid) pantoprazole (Protonix), and rabeprazole (Aciphex) in Tier 3 of the UF, with generic omeprazole and branded esomeprazole (Nexium) both available at a $3 copay in TRRx and TMOP. Beneficiaries presenting prescriptions at the retail and mail order points of service for nonformulary (Tier 3) PPIs who had not received a PPI prescription in the last 180 days (new users) were required to first try omeprazole or Nexium or meet MN criteria.

   The study will assess effects of the step therapy/prior authorization program on clinical outcomes (e.g., occurrence of serious gastrointestinal (GI) events) among TRICARE for Life (TFL) beneficiaries (age 65 and older) who were new users of omeprazole or Nexium (and would not have encountered a step therapy rejection) vs. those who were new users of PPIs subject to the step therapy/prior authorization program. The analysis plan for the study is currently under development; final results are expected in FY10.

**B. Joint Forces Pharmacy Seminar** – LTC Spridgen gave an abridged version of the PEC plenary presentation given at the 2008 Joint Forces Pharmacy Seminar. She highlighted the trends in MHS spending and utilization of the pharmacy benefit. Also identified were trends in MTF formulary management that resulted in significant cost avoidance at the individual points of service (MTF, TMOP, TRRX).

**C. National Defense Authorization Act (NDAA) Section 703 Inclusion of TRICARE Retail Pharmacy Program In Federal Procurement Of Pharmaceuticals Update** - CAPT Blanche updated the committee on the litigation and status of the final rule that will implement Section 703 of the 2008 NDAA. With regards to the current litigation, the judge had not rendered a decision. The final rule is at the Office of Management and Budget (OMB). Key members from the TMA Pharmacy Operations Department and Office of General Council have met with OMB personnel. The time table for approval and the impact on the DoD P&T process are not known.

## 11) UF DRUG CLASS OVERVIEWS

The drug class overviews for the Pulmonary I drug class (comprised of the long-acting beta agonists, inhaled corticosteroids, and combination long-acting beta agonists/inhaled corticosteroids), Antilipidemic-Is (statins, ezetimibe, niacin, and combination products) and Fluoroquinolones were presented to the P&T Committee. The Committee provided the PEC with expert opinion regarding those clinical outcomes considered most important to use in completing the clinical effectiveness review and developing appropriate cost effectiveness models. The clinical and economic analyses of this drug class will be completed at upcoming DoD P&T Committee meetings.

## 12) ADJOURNMENT

The second day of the meeting adjourned at 1100 hours on 19 November 2008. The next meeting will be 18-19 February 2009.

**Appendix A – Attendance**
**Appendix B – Table of Medical Necessity Criteria**
**Appendix C – Implementation Status of UF Recommendations/Decisions**
**Appendix D – Table of Abbreviations**
**Appendix E – Quantity Limit Criteria - SABAs**
**Appendix F – Basic Core Formulary Deletions**

**SUBMITTED BY:**

Col John Kugler, MC
DoD P&T Committee Chair

**DECISION ON RECOMMENDATIONS**

Director, TMA, decisions are as annotated above.

2 Feb-09

S. Ward Casscells, III, M.D.

## Appendix A – Attendance

| **Voting Members Present** | |
|---|---|
| COL John Kugler, MC | DoD P&T Committee Chair |
| LTC Stacia Spridgen, MSC | Director DoD Pharmacoeconomic Center (Recorder) |
| COL Ted Cieslak, MC | Army, Physician at Large |
| COL Peter Bulatao *for Col Isiah Harper, MSC* | Army, Pharmacy Officer, Alternate |
| CAPT Bill Blanche, MSC | Chief, Pharmaceutical Operations Directorate |
| CAPT Stephanie Simon, MSC | Navy, Pharmacy Officer |
| CAPT Vernon Lew | Coast Guard, Pharmacy Officer |
| Col Mark Butler, BSC | Consultant to the AF/SG |
| LTC Michael Wynn *for LTC Bruce Lovins* | Army, Family Practice Physician, Alternate |
| LTC Jack Lewi *for COL Doreen Lounsbery* | Army, Internal Medicine Physician, Alternate |
| CDR Walter Downs, MC *for LCDR Scott Akins* | Navy, Internal Medicine Physician, Alternate |
| CDR David Tanen, MC | Navy, Physician at Large |
| Lt Col Brian Crownover, MC | Air Force, Physician at Large |
| LCDR Ron Garcia | Navy, Internal Medicine Physician |
| Major Jeremy King, MC | Air Force, OB/GYN Physician |
| Mr. Joe Canzolino | Department of Veterans Affairs |
| **Voting Members Absent** | |
| LCDR Michelle Perrello, MC | Navy, Internal Medicine Physician |
| COL Isiah Harper, MS | Army, Pharmacy Officer |
| Major William Hannah, MC | Air Force, Internal Medicine Physician |
| LTC Bruce Lovins, MC | Army, Family Practice Physician |
| LCDR Scott Akins, MC | Navy, Pediatrics Physician Alternate |
| COL Doreen Lounsbery, MC | Army, Internal Medicine Physician |
| **Nonvoting Members Present** | |
| CDR James Ellzy | DoD P&T Vice Chairman |
| Lt Col Paul Hoerner | Deputy Director, DoD Patient Safety Center |
| Ms. Carol Cooper | Deputy General Counsel, TMA |
| **Nonvoting Members Absent** | |
| COL Kent Maneval, MS | Defense Medical Standardization Board |
| LCDR Thomas Jenkins | TMA Aurora |
| Maj Peter Trang | Defense Supply Center Philadelphia |

## Appendix A – Attendance – (continued)

| **Guests** | |
|---|---|
| LT Joe Bryant | Indian Health Service |
| Mr. Tom Emmendorfer | Department of Veterans Affairs PBM |
| Ms. Brenna Mann | University of Texas Pharmacy Student |
| **Others Present** | |
| CDR Matthew Carlberg | DoD Pharmacoeconomic Center |
| Lt Col James McCrary, MC | DoD Pharmacoeconomic Center |
| MAJ Misty Carlson, MC | DoD Pharmacoeconomic Center |
| Maj Joshua Devine, BSC | DoD Pharmacoeconomic Center |
| LCDR Joe Lawrence | DoD Pharmacoeconomic Center |
| Dr. Shana Trice | DoD Pharmacoeconomic Center |
| Dr. Eugene Moore | DoD Pharmacoeconomic Center |
| Dr. Angela Allerman | DoD Pharmacoeconomic Center |
| Dr. David Meade | DoD Pharmacoeconomic Center |
| Dr. Harsha Mistry | DoD Pharmacoeconomic Center |
| Dr. Jeremy Briggs | DoD Pharmacy Operations Center contractor |
| Dr. Stephen Yarger | DoD Pharmacy Outcomes Research Team contractor |
| Dr. Esmond Nwokeji | DoD Pharmacy Outcomes Research Team contractor |
| Ms. Deborah Garcia | DoD Pharmacy Outcomes Research Team contractor |

## Appendix B – Medical Necessity Criteria

| Drug / Drug Class | Medical Necessity Criteria |
|---|---|
| Olopatadine (Patanase)<br>Beclomethasone (Beconase AQ)<br>Budesonide (Rhinocort Aqua)<br>Ciclesonide (Omnaris)<br>Fluticasone furoate (Veramyst)<br>Triamcinolone (Nasacort AQ)<br><br>**Nasal Allergy Drugs** | • Use of formulary alternatives is contraindicated<br>• The patient has experienced significant adverse effects from formulary alternatives.<br>• Formulary agents have resulted or are likely to result in therapeutic failure. |
| Pirbuterol CFC* MDI (Maxair)<br>Metaproterenol inhalation solution<br><br>**Short-Acting Beta Agonists** | • Use of formulary alternatives is contraindicated<br>• The patient has experienced or is likely to experience significant adverse effects from formulary alternatives.<br>• The patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk. |
| Desvenlafaxine (Pristiq)<br><br>**(Antidepressant-1s)** | • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk. |

CFC: chlorofluorocarbon

MDI: metered dose inhaler

*: CFC-containing pressurized MDIs likely will cease marketing as of 31 Dec 2008

## Appendix C – Implementation Status of UF Class Review Recommendations / Decisions

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | **Decision Date** (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | **Effective Date for Non-Formulary Medications** (Implementation period) |
|---|---|---|---|---|---|---|
| **Nov 08** | Short-Acting Beta Agonists | ▪ albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured)<br>▪ metaproterenol (Alupent) CFC MDI (no longer marketed)<br>▪ metaproterenol inhalation solution<br>▪ pirbuterol (Maxair) MDI | BCF | ▪ Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI<br>▪ Albuterol inhalation solution;<br>Note – does not include the following:<br>Accuneb 0.021% [0.63 mg/mL]<br>Accuneb 0.042% [1.25 mg/3mL]<br>Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial] | pending approval | pending approval |
| **Nov 08** (update to include nasal antihistamines; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst) | Nasal Allergy Drugs | ▪ olopatadine (Patanase)<br>▪ ciclesonide (Omnaris)<br>▪ fluticasone furoate (Veramyst)<br>▪ beclomethasone (Beconase AQ)<br>▪ budesonide (Rhinocort Aqua)<br>▪ triamcinolone (Nasacort AQ) | BCF | ▪ Fluticasone propionate (generic Flonase)<br>▪ Azelastine (Astelin) | pending approval | pending approval |
| **Nov 08 & Aug 08** (update; reviewed Nov 05) | Antidepressants I | **Recommended for non-formulary status Aug 08; no change to non-formulary status in Nov 08**<br>▪ desvenlafaxine (Pristiq) | BCF | No changes to BCF recommended Aug 08 | Nov 08: pending approval; original signing date 24 Oct 08 | 26 Nov 08 (60 days) |
| **Aug 08** (update; reviewed Nov 05) | Antidepressants I | To remain NF<br>▪ paroxetine HCl CR (Paxil)<br>▪ fluoxetine 90 mg weekly admin. (Prozac Weekly)<br>▪ fluoxetine in special packaging for PMDD (Sarafem)<br>▪ escitalopram (Lexapro)<br>▪ duloxetine (Cymbalta)<br>▪ bupropion extended release (Wellbutrin XL) | BCF | Currently BCF<br>▪ citalopram<br>▪ fluoxetine (excluding weekly regimen & special packaging for PMDD)<br>▪ sertraline (Zoloft)<br>▪ trazodone<br>▪ bupropion sustained release | 19 Jan 06 | 19 Jul 06 (180 days) |
| **Nov 08** | ACE inhibitors – Renin Angiotensin Antihypertensives | Previously non-formulary, recommended for UF status Nov 08<br>▪ ramipril (Altace generic) | BCF | ▪ No changes recommended to BCF at Nov 08 meeting; ramipril removed from Non-formulary status and designated as Uniform Formulary immediately upon signing of the minutes | pending approval | N/A |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (Implementation period) |
|---|---|---|---|---|---|---|
| **Oct 08 (interim teleconference meeting) & Jun 08** | Triptans | ▪ almotriptan (Axert)<br>▪ frovatriptan (Frova)<br>▪ naratriptan (Amerge) | BCF | ▪ rizatriptan (Maxalt), immediate upon signing of the minutes<br>▪ sumatriptan oral and one injectable formulation, when multi-source generics are available | Nov 08 meeting pending approval: ; original signing date: 27 Aug 08 | 26 Nov 08 (90 days) |
| **Aug 08** | Self-Monitoring Blood Glucose Systems (SMBGS) test strips | ▪ One Touch Ultra 2 strips (for One Touch Ultra 2, Ultra Mini, and Ultra Smart meters)<br>▪ TrueTrack strips (for TrueTrack meter)<br>▪ Accu-chek Comfort Curve strips (for Accu-chek Advantage meter)<br>▪ Accu-chek Compact Plus drum (for Accu-check Compact Plus meter)<br>▪ Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check<br>▪ Plus all other store/private label brand strips not included on the UF (see BCF/ECF column) | BCF | **Basic Core Formulary SMBGS test strips**<br>▪ Precision Xtra strips (for Precision Xtra meter)<br><br>**Uniform Formulary SMBGS test strips**<br>▪ Accu-chek Aviva (for Accu-chek Aviva meter)<br>▪ Ascensia Contour (for Ascensia Contour meter)<br>▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters) | 24 Oct 08 | 17 Mar 09 (120 days) |
| **Aug 08 (re-review;** Feb 06 original review) | Overactive Bladder (OAB) Agents | ▪ tolterodine IR (Detrol)<br>▪ trospium IR (Sanctura) | BCF | ▪ tolterodine ER (Detrol LA)<br>▪ oxybutynin ER (Ditropan XL, generics)<br>(Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF) | 24 Oct 08 | 4 Feb 09 (90 days) |
| **Aug 08** (update; reviewed Aug 05; also updated Nov 07) | Calcium Channel Blockers | **Recommended for non-formulary status Aug 08**<br>▪ nisoldipine geomatrix (Sular geomatrix) | BCF | No changes to BCF recommended Aug 08 | 24 Oct 08 | 7 Jan 09 (60 days) |
| | | Previously non-formulary, recommended for UF status Nov 07<br>▪ amlodipine besylate (Norvasc generic) | | Recommended for addition to BCF Nov 07<br>▪ amlodipine besylate tablets | 13 Feb 08 | 13 Feb 08 |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (Implementation period) |
|---|---|---|---|---|---|---|
| | | To Remain Non-Formulary<br>▪ isradipine IR, ER (Dynacirc; Dynacirc CR)<br>▪ nicardipine IR (Cardene, generics)<br>▪ nicardipine SR (Cardene SR)<br>▪ verapamil ER (Verelan)<br>▪ verapamil ER HS dosing (Verelan PM, Covera HS)<br>▪ diltiazem ER for bedtime dosing (Cardizem LA) | | Currently BCF<br>▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting)<br>▪ nifedipine ER (Adalat CC, generics)<br>▪ verapamil SR<br>▪ diltiazem ER (Tiazac, generics) | 13 Oct 05 | 15 Mar 06<br>(150 days) |
| **Jun 08** | Osteoporosis Agents | ▪ calcitonin salmon nasal spray (Miacalcin) | BCF | ▪ alendronate (Fosamax)<br>▪ ibandronate (Boniva)<br>(Note: raloxifene (Evista) removed from BCF, but still UF) | 27 Aug 08 | 26 Nov 08<br>(90 days) |
| **Jun 08** (update; reviewed May 07) | Antilipidemic Agents II | No changes to NF recommended Jun 08 | BCF | **Recommended for addition to BCF Jun 08**<br>▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide)<br>(Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF) | 27 Aug 08 | Revised implementation da 26 Nov 08<br>original implementation da 29 Oct 08 (60 days) |
| | | To remain NF<br>▪ fenofibrate nanocrystallized (Tricor)<br>▪ fenofibrate micronized (Antara)<br>▪ omega-3 fatty acids (Omacor)<br>▪ colesevelam (Welchol) | | Currently BCF<br>▪ gemfibrozil | 24 July 07 | 21 Nov 07<br>(120 days) |
| **Jun 08** (update; reviewed Nov 07) | Adrenergic Blocking Agents | **Recommended for non-formulary status Jun 08**<br>▪ nebivolol (Bystolic) | BCF | No change to BCF recommended Jun 08 | 27 Aug 08 | Revised implementation da 26 Nov 08<br>original implementation da 29 Oct 08 (60 days) |
| | | (No ABAs selected for NF placement at Nov 07 meeting) | | Currently BCF<br>▪ atenolol tablets<br>▪ metoprolol tartrate IR tablets<br>▪ carvedilol IR tablets<br>▪ metoprolol succinate ER tablets | 13 Feb 08 | - |
| **Jun 08** (update; reviewed Aug 07 | Newer Antihistamines | **Recommended for non-formulary status Jun 08**<br>▪ levocetirizine (Xyzal) | BCF | No change to BCF recommended Jun 08 | 27 Aug 08 | Revised implementation da 26 Nov 08<br>original implementation da 29 Oct 08 (60 days) |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (Implementation period) |
|---|---|---|---|---|---|---|
| | | To remain NF<br>• desloratadine (Clarinex)<br>• desloratadine/pseudoephedrine (Clarinex D) | | • MTFs required to carry at least one single ingredient agent from the newer antihistamine class (loratadine, cetirizine, or fexofenadine) on their local formulary, including at least one dosage form suitable for pediatric use | 17 Oct 07 | 16 Jan 08<br>(90 days) |
| **Jun 08** (update; reviewed Aug 07) | Leukotriene Modifiers | **Recommended for non-formulary status Jun 08**<br>• Zileuton ER (Zyflo CR) | BCF | No changes to BCF rec Jun 08 | 27 Aug 08 | Revised implementation da<br>26 Nov 08<br>original implementation da<br>29 Oct 08 (60 days) |
| | | To remain NF<br>• zileuton (Zyflo) | | Currently BCF<br>• montelukast (Singulair) | 17 Oct 07 | 16 Jan 08<br>(90 days) |
| **Jun 08** (update)<br>Original reviews<br>• ACE inhibitors: Aug 05<br>• Miscellaneous antihypertensives, including ACE/CCB combos. Feb 06<br>• ARBs: May 07<br>• Renin inhibitors. Aug 07<br>• CCB/ARB combos Nov 07 update | Renin Angiotensin Antihypertensives | **Recommended for non-formulary status Jun 08**<br>• olmesartan/amlodipine (Azor) | BCF | No change to BCF recommended Jun 08 | 27 Aug 08 | Revised implementation da<br>26 Nov 08<br>original implementation da<br>29 Oct 08 (60 days) |
| | | To remain NF<br>• valsartan amlodipine (Exforge) | | No change to BCF recommended Nov 07 | 13 Feb 08 | 16 Apr 08<br>(60 days) |
| | | To remain NF<br>ACE inhibitors<br>• Moexipril +/- HCTZ (Univasc; Uniretic)<br>• perindopril (Aceon)<br>• ramipril (Altace)<br>ACE/CCB combos<br>• felodipine/enalapril (Lexxel) (D/C'd from market)<br>• verapamil/trandolapril (Tarka)<br>ARBs<br>• eprosartan +/- HCTZ (Teveten; Teveten HCT)<br>• irbesartan+/- HCTZ (Avapro, Avalide)<br>• olmesartan +/- HCTZ (Benicar; Benicar HCT)<br>• valsartan +/- (Diovan; Diovan HCT) | | Currently on the BCF<br>ACE inhibitors<br>• captopril<br>• lisinopril<br>• lisinopril / HCTZ<br>ACE/CCB combos<br>• amlodipine/benazepril (Lotrel, generics)<br>ARBs<br>• telmisartan (Micardis)<br>• telmisartan HCTZ (Micardis HCT) | ACE inhibitors<br>• 13 Oct 05<br>ACE/CCB combos<br>• 26 Apr 06<br>ARBs<br>• 24 July 07 | ACE inhibitors<br>• 15 Feb 06<br>ACE/CCB combos<br>• 26 Jul 06<br>ARBs<br>• 21 Nov 07 |
| **Nov 07** | Targeted Immunomodulatory Biologics | • etanercept (Enbrel)<br>• anakinra (Kineret) | ECF | • adalimumab (Humira) injection | 13 Feb 08 | 18 Jun 08<br>(120 days) |
| **Nov 07 re-review**<br>(Aug 05 original) | BPH Alpha Blockers | • tamsulosin (Flomax)<br>Automated PA requiring trial of alfuzosin (Uroxatral) applies to new users of tamsulosin (no use of uroselective alpha blockers in last 180 days) | BCF | • terazosin tablets or capsules<br>• alfuzosin tablets (Uroxatral) | 13 Feb 08 | 16 Apr 08<br>(60 days) |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (implementation period) |
|---|---|---|---|---|---|---|
| **Nov 07** (update, original review Nov 06) | ADHD / Narcolepsy Agents | **Recommended for non-formulary status Nov 07**<br>▪ lisdexamfetamine (Vyvanse) | BCF | No change to BCF recommended Nov 07 | 13 Feb 08 | 16 Apr 08 (60 days) |
| | | To remain NF<br>▪ dexmethylphenidate IR (Focalin)<br>▪ dexmethylphenidate SODAS (Focalin XR)<br>▪ methylphenidate transdermal system (Daytrana) | | Currently on the BCF<br>▪ methylphenidate OROS (Concerta)<br>▪ mixed amphetamine salts ER (Adderall XR)<br>▪ methylphenidate IR (Ritalin) | 17 Jan 07 | 18 Apr 07 |
| **Nov 07** (update, original review May 06) | Contraceptives | **Recommended for non-formulary status Nov 07**<br>▪ EE 20 mcg/levonorgestrel 0.09 mg in special packaging for continuous use (Lybrel) | BCF | No change to BCF recommended Nov 07 | 13 Feb 08 | 16 Apr 08 (60 days) |
| | | To remain NF<br>▪ EE 30 mcg / levonorgestrel 0.15 mg in special packaging for extended use (Seasonale)<br>▪ EE 25 mcg / norethindrone 0.4 mg (Ovcon 35)<br>▪ EE 50 mcg / norethindrone 1 mg (Ovcon 50)<br>▪ EE 20/30/35 mcg / noreth. 1 mg (Estrostep Fe) | | Currently on the BCF<br>▪ EE 20 mcg / 3 mg drospirenone (Yaz)<br>▪ EE 20 mcg / 0.1 mg levonorgestrel (Lutera, Sronyx, or equivalent)<br>▪ EE 30 mcg / 3 mg drospirenone (Yasmin)<br>▪ EE 30 mcg / 0.15 mg levonorgestrel (Nordette or equivalent / excludes Seasonale)<br>▪ EE 35 mcg / 1 mg norethindrone (Ortho-Novum 1/35 or equivalent)<br>▪ EE 35 mcg / 0.25 mg norgestimate (Ortho-Cyclen or equivalent)<br>▪ EE 25 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo)<br>▪ EE 35 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen or equivalent)<br>▪ 0.35 mg norethindrone (Nor-QD, Ortho Micronor, or equivalent) | 26 Jul 06 | 24 Jan 07 |
| | | ▪ EE 30/10 mcg / 0.15 mg levonorgestrel in special packaging for extended use (Seasonique)<br>▪ EE 20 mcg / 1 mg norethindrone (Loestrin 24 Fe) | | | 17 Jan 07 | 18 Mar 07 |
| **Aug 07** | Growth Stimulating Agents | ▪ somatropin (Genotropin, Genotropin Miniquick)<br>▪ somatropin (Humatrope)<br>▪ somatropin (Omnitrope)<br>▪ somatropin (Saizen) | ECF | ▪ somatropin (Norditropin) | 17 Oct 07 | 19 Dec 07 (60 days) |
| **May 07 re-review** (Feb 05 original) | PPIs | ▪ lansoprazole (Prevacid)<br>▪ omeprazole/sodium bicarbonate (Zegerid)<br>▪ pantoprazole (Protonix)<br>▪ rabeprazole (Aciphex)<br>Automated PA requiring trial of omeprazole OR esomeprazole (Nexium) applies to new users of non-formulary PPIs (no use of PPIs in last 180 days) | BCF | ▪ generic omeprazole 10 mg and 20 mg (excludes Prilosec 40 mg)<br>▪ esomeprazole (Nexium) | 24 July 07 | 24 Oct 07 (90 days) |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (Implementation period) |
|---|---|---|---|---|---|---|
| **May 07 re-review** (Feb 05 original) | ARBs | • eprosartan +/- HCTZ (Teveten; Teveten HCT)<br>• irbesartan +/-HCTZ (Avapro; Avalide)<br>• olmesartan +/- HCTZ (Benicar; Benicar HCT)<br>• valsartan +/- HCTZ (Diovan; Diovan HCT) | BCF | • telmisartan (Micardis)<br>• telmisartan HCTZ (Micardis HCT) | 24 July 07 | 21 Nov 07 (120 days) |
| **May 07** | 5-Alpha Reductase Inhibitors | • dutasteride (Avodart) | BCF | • finasteride | 24 July 07 | 24 Oct 07 (90 days) |
| **Feb 07** | Newer Sedative Hypnotics | • zolpidem ER (Ambien CR)<br>• zaleplon (Sonata)<br>• ramelteon (Rozerem)<br>Automated PA requiring trial of zolpidem IR applies to new users of eszopiclone (Lunesta), ramelteon (Rozerem), zaleplon (Sonata), or zolpidem ER (Ambien CR) (new users = no use of newer sedative hypnotics in last 180 days) | BCF | • zolpidem IR (Ambien) | 02 May 07 | 01 Aug 07 (90 days) |
| **Feb 07** | Monoamine Oxidase Inhibitors | • selegiline transdermal patch (Emsam) | ECF | • phenelzine (Nardil) | 02 May 07 | 01 Aug 07 (90 days) |
| **Feb 07** | Narcotic Analgesics | • tramadol ER (Ultram ER) | BCF | • morphine sulfate IR 15 mg, 30 mg<br>• morphine sulfate 12-hour ER (MS Contin or equivalent) 15, 30, 60 mg<br>• oxycodone/APAP 5/325 mg<br>• hydrocodone/APAP 5/500 mg<br>• codeine/APAP 30/300 mg<br>• codeine/APAP elixir 12/120 mg/5 mL<br>• tramadol IR | 02 May 07 | 01 Aug 07 (90 days) |
| **Feb 07** | Ophthalmic Glaucoma Agents | • travoprost (Travatan, Travatan Z)<br>• timolol maleate for once daily dosing (Istalol)<br>• timolol hemihydrate (Betimol)<br>• brinzolamide (Azopt) | BCF | • latanoprost (Xalatan)<br>• brimonidine (Alphagan P); excludes 0.1%<br>• timolol maleate<br>• timolol maleate gel-forming solution<br>• pilocarpine | 02 May 07 | 01 Aug 07 (90 days) |
| **Nov 06** | Older Sedative Hypnotics | - | BCF | • temazepam 15 and 30 mg | 17 Jan 07 | - |
| **Nov 06** (update; reviewed Nov 06) | Dermatologic Topical Antifungals* | **Recommended for non-formulary status Nov 06:**<br>0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion) | BCF | No change to BCF recommended Nov 06 | 14 Jul 05 | 17 Aug 05 (30 days) |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (Implementation period) |
|---|---|---|---|---|---|---|
| | | ▪ econazole<br>▪ ciclopirox<br>▪ oxiconazole (Oxistat)<br>▪ sertaconazole (Ertaczo)<br>▪ sulconazole (Exelderm) | | ▪ nystatin<br>▪ clotrimazole | 17 Jan 07 | 18 Mar 07<br>(60 days) |
| **Aug 06** | H2 Antagonists / GI protectants | - | BCF | ▪ ranitidine (Zantac) – excludes gelcaps and effervescent tablets | 23 Oct 06 | - |
| **Aug 06** | Antilipidemic Agents I | ▪ rosuvastatin (Crestor)<br>▪ atorvastatin / amlodipine (Caduet) | BCF | ▪ simvastatin (Zocor)<br>▪ pravastatin<br>▪ simvastatin / ezetimibe (Vytorin)<br>▪ niacin extended release (Niaspan) | 23 Oct 06 | 1 Feb 07<br>(90 days) |
| **May 06** | Antiemetics | ▪ dolasetron (Anzemet) | BCF | ▪ promethazine (oral and rectal) | 26 Jul 06 | 27 Sep 06<br>(60 days) |
| **Feb 06**<br>(re-classified Aug 07; and updated Jun 08; see above) | Misc Antihypertensive Agents (ACE/CCB combos now part of RAAs class) | (ACE/CCB combos now part of RAAs class)<br>▪ felodipine/enalapril (Lexxel)<br>▪ verapamil/trandolapril (Tarka) | BCF | (ACE/CCB combos now part of RAAs class)<br>▪ amlodipine/benazepril (Lotrel)<br>▪ hydralazine<br>▪ clonidine tablets | 26 Apr 06 | 26 Jul 06<br>(90 days) |
| **Feb 06** | GABA-analogs | ▪ pregabalin (Lyrica) | BCF | ▪ gabapentin | 26 Apr 06 | 28 Jun 06<br>(60 days) |
| **Nov 05** | Alzheimer's Drugs | ▪ tacrine (Cognex) | ECF | ▪ donepezil (Aricept) | 19 Jan 06 | 19 Apr 06<br>(90 days) |
| **Nov 05** | Macrolide/ Ketolide Antibiotics | ▪ azithromycin 2 gm (Zmax)<br>▪ telithromycin (Ketek) | BCF | ▪ azithromycin (Z-Pak)<br>▪ erythromycin salts and bases | 19 Jan 06 | 22 Mar 06<br>(60 days) |
| **May 05** | PDE5 Inhibitors | ▪ sildenafil (Viagra)<br>▪ tadalafil (Cialis) | ECF | ▪ vardenafil (Levitra) | 14 Jul 05 | 12 Oct 05<br>(90 days) |
| **May 05** | MS-DMDs | - | ECF | ▪ interferon beta-1a intramuscular injection (Avonex) | 14 Jul 05 | - |

| Meeting | Drug Class | Non-Formulary Medications | BCF/ ECF Class | BCF/ECF Medications | Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes) | Effective Date for Non-Formulary Medications (Implementation period) |
|---|---|---|---|---|---|---|

BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary
CFC = chlorofluorocarbon; ER = extended release; HFA = hydrofluoroalkane; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle;
AD-1s: Antidepressant-1 Drugs; ADHD = Attention Deficit Hyperactivity Disorder; ARBs = Angiotensin Receptor Blockers; ACE Inhibitors = Angiotensin Converting Enzyme Inhibitors; BPH = Benign Prostatic Hyperplasia; CCBs = Calcium Channel Blockers; EE = ethinyl estradiol; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HCTZ = hydrochlorothiazide; LIP-1 = Antihyperlipidemic-1 Drugs; LIP-2 = Antihyperlipidemic-2 Drugs; MDIs = metered dose inhalers; MOAIs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NADs = Nasal Allergy Drugs; OAB = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAs = Renin Angiotensin Antihypertensives Drugs; SABAs = Short-Acting Beta Agonists; SMBGS: Self-Monitoring Blood Glucose Systems; TIBs = Targeted Immunomodulatory Biologics; TZDs= Thiazolidinediones
*The Dermatologic Topical Antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])

## Appendix D – Table of Abbreviations

| | |
|---|---|
| 5-HT3 | Serotonin subtype 3 receptor-blocking agents (5-HT3 antagonists) |
| ACE I / RAAs | Angiotensin Converting Enzyme Inhibitor / Renin Angiotensin Antihypertensive drug class |
| AD-1 | Antidepressant-1 drug class |
| AE | adverse event |
| AERS | Adverse Event Reporting System |
| AAAAI | American Academy of Allergy, Asthma and Immunology |
| AR | allergic rhinitis |
| BAP | Beneficiary Advisory Panel |
| BCF | Basic Core Formulary |
| BIA | budget impact analysis |
| BID | twice daily |
| CEA | cost effectiveness analysis |
| CFC | chlorofluorocarbon |
| CFR | Code of Federal Regulations |
| CI | confidence interval |
| CINV | chemotherapy-induced nausea and vomiting |
| CMA | cost minimization analysis |
| COPD | chronic obstructive pulmonary disease |
| DoD | Department of Defense |
| ED | emergency department |
| EIB | exercise-induced bronchospasm |
| ER | Extended release |
| ESI | Express Scripts, Inc |
| FCP | Federal Ceiling Price |
| FDA | Food and Drug Administration |
| FEV1 | forced expiratory volume in one second |
| FSS | Federal Supply Schedule Price |
| FY | fiscal year |
| HA | Health Affairs |
| HCTZ | hydrochlorothiazide |
| HFA | hydrofluoroalkane |
| IR | immediate release |
| LIP-1 | Antilipidemic-1 drug class |
| MDI | metered dose inhaler (pressurized) |
| MHS | Military Health System |
| MN | medical necessity |
| MTF | military treatment facility |
| NAD | Nasal Allergy drug class |
| NDAA | National Defense Authorization Act |
| OMB | Office of Management and Budget |
| P&T | Pharmacy and Therapeutics |
| PA | prior authorization |
| PAR | Perennial allergic rhinitis |
| PEC | Pharmacoeconomic Center |
| PORT | Pharmaceutical Outcomes Research Team |
| PPI | Proton Pump Inhibitor |
| QD | once daily |
| QL | quantity limit |
| SABAs | Short-Acting Beta Agonist drug class |
| SAR | Seasonal allergic rhinitis |
| SNRI | Serotonin Norepinephrine Reuptake Inhibitor |

## Appendix D – Table of Abbreviations (continued)

| | |
|---|---|
| TFL | TRICARE for life beneficiary |
| TMA | TRICARE Management Activity |
| TMOP | TRICARE Mail Order Pharmacy |
| TRRx | TRICARE Retail Pharmacy Network |
| UF VARR | Uniform Formulary Voluntary Agreement for Retail Refunds |
| VMR | vasomotor rhinitis |

## Appendix E – Table of Short-Acting Beta Agonists Quantity Limits

| Drug | TMOP QL | TRRx QL |
|---|---|---|
| **Current Quantity Limits** | | |
| Albuterol (AccuNeb; generic) soln 0.63mg/3mL & 1.25 mg/3mL | 1650 mL per 90 days (550 unit-dose vials) | 600 mL per 30 days (200 unit-dose vials) |
| Albuterol (generic) soln 0.083% 2.5 mg/3 mL | 1650 mL per 90 days (550 unit-dose vials) | 600 mL per 30 days (200 unit-dose vials) |
| Albuterol (generic) soln 0.5% 2.5 mg/0.5 mL (20 mL) | 180 mL per 90 days (9 bottles) | 60 mL per 30 days (3 bottles) |
| Levalbuterol (Xopenex) soln 0.63 mg/3 mL & 1.25 mg/3 mL | 1080 mL per 90 days (360 unit-dose vials) | 360 mL per 30 days (120 unit-dose vials) |
| Albuterol CFC (generic) 90 mcg MDI | 102 gm per 90 days (17 gm MDI: 6 inhalers) | 34 gm per 30 days (17 gm MDI: 2 inhalers) |
| **Proposed Quantity Limits (in addition to current QLs)** | | |
| Levalbuterol (Xopenex) soln 0.31 mg/3 mL | 1080 mL per 90 days (360 unit-dose vials) | 360 mL per 30 days (120 unit-dose vials) |
| Levalbuterol HFA (Xopenex) 45 mcg MDI (8.4 gm MDI) | 50.4 gm per 90 days (8.4 gm MDI: 6 inhalers) | 16.8 gm per 30 days (8.4 gm MDI: 2 inhalers) |
| Levalbuterol HFA (Xopenex) 45 mcg MDI (15 gm MDI) | 90 gm per 90 days (15 gm MDI: 6 inhalers) | 30 gm per 30 days (15 gm MDI: 2 inhalers) |
| Albuterol HFA (Ventolin HFA) 90 mcg MDI | 108 gm per 90 days (18 gm MDI: 6 inhalers) | 36 gm per 30 days (18 gm MDI: 2 inhalers) |
| Albuterol HFA (Proventil HFA) 90 mcg MDI | 40.2 gm per 90 days (6.7 gm MDI: 6 inhalers) | 13.4 gm per 30 days (6.7 gm MDI: 2 inhalers) |
| Albuterol HFA (ProAir HFA) 90 mcg MDI | 51 gm per 90 days (8.5 gm MDI: 6 inhalers) | 17 gm per 30 days (8.5 gm MDI: 2 inhalers) |

CFC: chlorofluorocarbon
HFA: hydrofluoroalkane
MDI: metered dose inhaler
Soln: solution

## Appendix F – Basic Core Formulary Deletions

| Therapeutic Category | Generic Name | Dosage | Dosage Form |
|---|---|---|---|
| ALDOSTERONE ANTAGONISTS | SPIRONOLACTONE | 100MG | TABS |
| | SPIRONOLACTONE | 50MG | |
| ANTIARTHRITICS | NAPROXEN | 375MG | TABS |
| ANTICONVULSANTS | PHENYTOIN SODIUM | 30MG | CAPS |
| | CARBAMAZEPINE | 100MG | CP12 |
| | CARBAMAZEPINE | 200MG | |
| | CARBAMAZEPINE | 300MG | |
| | GABAPENTIN | 250MG/5ML | SOLN |
| | GABAPENTIN | 100MG | TABS |
| | GABAPENTIN | 400MG | |
| ANTIHISTAMINES | HYDROXYZINE PAMOATE | 100MG | CAPS |
| | HYDROXYZINE PAMOATE | 25MG | |
| | HYDROXYZINE PAMOATE | 50MG | |
| | PROMETHAZINE HCl | 12.5MG | TABS |
| | PROMETHAZINE HCl | 50MG | |
| ANTINAUSEANTS | PROMETHAZINE HCl | 50MG | SUPP |
| | METOCLOPRAMIDE HCl | 5MG | TABS |
| ANTIPARASITICS | METRONIDAZOLE | 375MG | CAPS |
| ANTIPARKINSON | AMANTADINE HCl | 100MG | TABS |
| | TRIHEXYPHENIDYL HCl | 5MG | |
| ANTI-ULCER PREPS/GASTROINTESTINAL PREPS | RANITIDINE HCl | 300MG | TABS |
| ATARACTICS-TRANQUILIZERS | BUSPIRONE HCl | 30MG | TABS |
| | BUSPIRONE HCl | 7.5MG | |
| BRONCHIAL DILATORS | ALBUTEROL SULFATE | 0.5% in unit dose (2.5 mg/0.5 mL) | NEBU |
| CEPHALOSPORINS | CEPHALEXIN MONOHYDRATE | 250MG | TABS |
| | CEPHALEXIN MONOHYDRATE | 500MG | |
| CNS STIMULANTS | METHYLPHENIDATE HCl | 20MG | TABS |
| DIURETICS | HYDROCHLOROTHIAZIDE; TRIAMTERENE | 25MG; 37.5MG | CAPS |
| | HYDROCHLOROTHIAZIDE; TRIAMTERENE | 25MG; 50MG | |
| | CHLORTHALIDONE | 100MG | TABS |
| | HYDROCHLOROTHIAZIDE | 12.5MG | |
| | CHLORTHALIDONE | 15MG | |
| | FUROSEMIDE | 80MG | |
| ELECTROLYTES & MISCELLANEOUS NUTRIENTS | POTASSIUM CHLORIDE | 8MEQ | CPCR |
| | POTASSIUM CHLORIDE | 20% | LIQD |
| | POTASSIUM CHLORIDE | 25MEQ | PACK |
| | POTASSIUM CHLORIDE | 10MEQ | TBCR |
| | POTASSIUM CHLORIDE | 8MEQ | |
| ERYTHROMYCINS | ERYTHROMYCIN | 250MG | CPEP |
| | ERYTHROMYCIN ETHYLSUCCINATE | 400MG/5ML | SUSP |
| | AZITHROMYCIN | 200MG/5ML | SUSR |
| | ERYTHROMYCIN ETHYLSUCCINATE | 400MG/5ML | |
| | ERYTHROMYCIN | 250MG | TABS |

| Therapeutic Category | Generic Name | Dosage | Dosage Form |
|---|---|---|---|
| ERYTHROMYCINS | ERYTHROMYCIN ETHYLSUCCINATE | 400MG | |
| | ERYTHROMYCIN<br>ERYTHROMYCIN STEARATE | 500MG | |
| | AZITHROMYCIN | 600MG | |
| | ERYTHROMYCIN | 333MG | TBEC |
| | ERYTHROMYCIN | 500MG | |
| ESTROGENS | ESTROGENS, CONJUGATED | 0.9MG | TABS |
| FUNGICIDES | NYSTATIN | 500000UNIT | TABS |
| GLUCOCORTICOIDS | FLUTICASONE PROPIONATE | 50MCG/BLIST | AEPB |
| | PREDNISONE | 5MG/ML | CONC |
| | BUDESONIDE | 180MCG/ACT | INHA |
| | BUDESONIDE | 90MCG/ACT | |
| | PREDNISONE | 2.5MG | TABS |
| | PREDNISONE | 50MG | |
| MUSCLE RELAXANTS | CYCLOBENZAPRINE HCl | 5MG | TABS |
| | METHOCARBAMOL | 750MG | TABS |
| NON-NARCOTIC ANALGESICS | ACETAMINOPHEN; BUTALBITAL; CAFFEINE | 325MG; 50MG; 40MG | CAPS |
| | SUMATRIPTAN SUCCINATE | 4MG/0.5ML | KIT |
| OPHTHALMIC PREPARATIONS | PILOCARPINE HCl | 3% | SOLN |
| | PILOCARPINE HCl | 6% | |
| OTHER ANTIBIOTICS | ERYTHROMYCIN | 2% | OINT |
| | CIPROFLOXACIN | 500MG/5ML | SUSR |
| OTHER CARDIOVASCULAR PREPS | VERAPAMIL HCl | 120MG | CP24 |
| | VERAPAMIL HCl | 180MG | |
| | VERAPAMIL HCl | 240MG | |
| | VERAPAMIL HCl | 360MG | |
| | AMIODARONE HCL | 100MG | TABS |
| | AMIODARONE HCL | 400MG | |
| OTHER HYPOTENSIVES | HYDRALAZINE HCl | 100MG | TABS |
| PENICILLINS | AMOXICILLIN; CLAVULANIC ACID | 200MG; 28.5MG | CHEW |
| | AMOXICILLIN; CLAVULANIC ACID | 400MG; 57MG | |
| | AMOXICILLIN | 875MG | TABS |
| PSYCHOSTIMULANTS-ANTIDEPRESSANTS | DOXEPIN HCl<br>IMIPRAMINE PAMOATE | 100MG | CAPS |
| | IMIPRAMINE PAMOATE | 125MG | |
| | DOXEPIN HCl<br>IMIPRAMINE PAMOATE | 150MG | |
| | LITHIUM CARBONATE | 600MG | |
| | NORTRIPTYLINE HCl | 75MG | |
| | AMITRIPTYLINE HCl | 100MG | TABS |
| | FLUOXETINE HCL | 10MG | |
| | AMITRIPTYLINE HCl | 150MG | |
| | FLUOXETINE HCL | 20MG | |
| | BUPROPION HCL | 200MG | TB12 |
| TB PREPARATIONS | RIFAMPIN | 150MG | CAPS |
| VASODILATORS CORONARY | NITROGLYCERIN | 0.3MG | SUBL |

| Therapeutic Category | Generic Name | Dosage | Dosage Form |
|---|---|---|---|
| VASODILATORS CORONARY | NITROGLYCERIN | 0.6MG | |
| | ISOSORBIDE DINITRATE | 2.5MG | |
| | ISOSORBIDE DINITRATE | 5MG | |
| XANTHINE DERIVATIVES | THEOPHYLLINE | 100MG | CP24 |
| | THEOPHYLLINE | 200MG | |
| | THEOPHYLLINE | 100MG | TB12 |
| | THEOPHYLLINE | 450MG | |
| | THEOPHYLLINE | 600MG | TB24 |