DEPARTMENT OF DEFENSE PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA), on formulary status, pre-authorizations, and the effective date for a drug's change from formulary to nonformulary (NF) status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. UF CLASS REVIEWS—SHORT-ACTING BETA AGONISTS (SABAs)

P&T Comments

A. SABAs—Relative Clinical Effectiveness and Conclusion

The SABAs administered via metered dose inhalers (MDIs) were evaluated by the P&T Committee. The drugs in the class include albuterol [ProAir hydrofluoroalkane (HFA), Proventil HFA, Ventolin HFA] and levalbuterol (Xoponex HFA). The nebulized products were not evaluated. No new clinical conclusions were made since the SABAs Drug Class was reviewed in November 2011. The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 1 absent) with the following conclusions:

- There are no studies in either adults or children assessing efficacy of albuterol versus levalbuterol when administered via MDIs for treating asthma.
- In exercise-induced bronchospasm (EIB), albuterol administered via MDI taken 15–30 minutes before exercise prevents symptoms significantly better than placebo. Although Xopenex HFA is not currently approved by the U.S. Food and Drug Administration (FDA) for EIB, phase III trials point to similar effect size as with albuterol.
- For chronic obstructive pulmonary disease, the SABAs are more efficacious than placebo. There is insufficient evidence to compare the efficacy of albuterol versus levalbuterol.
- Although there is a lack of comparative safety data between levalbuterol and albuterol MDIs, there is no evidence to suggest clinically relevant differences in safety between the drugs.
- Since the last UF review, ProAir HFA now includes a dose counter. Ventolin HFA also has a dose counter. Proventil HFA and Xopenex HFA do not have dose counters.

- Although the FDA states albuterol HFA products are separate entities and not substitutable, clinically there is a high degree of therapeutic interchangeability between ProAir HFA, Proventil HFA, Ventolin HFA, and Xoponex HFA.
- To meet the needs of Military Health System (MHS) patients, only one SABA is needed on the Basic Core Formulary (BCF).

B. SABAs—Relative Cost-Effectiveness Analysis and Conclusion

The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 3 absent) that among SABA HFA MDIs, ProAir HFA was the most cost-effective agent based on the weighted average cost per day of treatment across all three points of service (POS), followed by Xopenex HFA, Ventolin HFA, and Proventil HFA. Results from the cost minimization analysis (CMA) and budget impact analysis (BIA) showed that designating ProAir HFA as the sole UF agent in this class, with all other SABA HFA MDIs designated as NF, was the most cost-effective scenario for the MHS.

C. SABAs—UF Recommendation

The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 3 absent) that ProAir HFA remain designated formulary on the UF. The P&T Committee also recommended that Proventil HFA, Ventolin HFA, and Xopenex HFA be designated NF on the UF.

D. SABAs—UF Implementation Plan

The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 3 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

III. UF CLASS REVIEWS—SABAs

BAP Comments

A. SABAs—UF Recommendation

The P&T Committee recommended that ProAir HFA remain designated formulary on the UF. The P&T Committee also recommended that Proventil HFA, Ventolin HFA, and Xopenex HFA be designated NF on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. SABAs—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

IV. UF CLASS REVIEWS—BENIGN PROSTATIC HYPERPLASIA AGENTS

P&T Comments

A. 5-Alpha Reductase Inhibitors (5-ARIs) Subclass—Relative Clinical Effectiveness and Conclusion

The 5-ARIs include finasteride (Proscar, generics), dutasteride (Avodart), and the combination product dutasteride/tamsulosin (Jalyn), which contains an alpha-1 blocker (A1B). The 5-ARIs were previously reviewed for UF placement in May 2007. Jalyn was previously reviewed as a new drug in the A1B subclass in May 2011. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following for the 5-ARIs:

- The 5-ARIs finasteride and dutasteride (Avodart) improve lower urinary tract symptoms associated with benign prostatic hypertrophy (BPH), when compared to placebo. Because of the placebo effect in reducing symptoms, the magnitude of the effect due to treatment is small and may not be clinically significant.
- Finasteride and dutasteride (Avodart) appear interchangeable with regard to efficacy in treating lower urinary tract symptoms associated with BPH. Both agents result in similar decreases in prostate volume, increases in urinary flow rate, and improvement in symptoms. Similar reductions in risk of acute urinary retention and BPH-related surgery are seen with both agents.
- The 5-ARIs are most useful in men who have enlarged prostates, but show little efficacy in men with normal prostate volumes.
- Finasteride and dutasteride (Avodart) exhibit a high degree of therapeutic interchangeability. Either finasteride or dutasteride is expected to meet the needs of the majority of benign prostatic hyperplasia patients in the MHS who have BPH. Neither drug offers a unique benefit. It is unlikely that a patient who did not have an adequate response with one 5-ARI would have an improved response with the other.

- The combination product dutasteride/tamsulosin (Jalyn) confers no additional benefit when compared with using the individual components together. As the 5-ARIs are highly interchangeable, it likely makes little clinical difference which 5-ARI is used in combination with an A1B.

B. 5-ARIs Subclass—Relative Cost-Effectiveness Analysis and Conclusion

CMA and BIA were performed to evaluate the 5-ARI subclass. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that finasteride was the most cost-effective agent in this class. Dutasteride (Avodart) and dutasteride/ tamsulosin (Jalyn) were not cost-effective when compared with finasteride alone or in combination with generic uroselective A1Bs (tamsulosin or alfuzosin).

- BIA was performed to evaluate the potential impact of scenarios with selected 5ARIs designated formulary or nonformulary on the UF. BIA results showed the scenario with finasteride designated as formulary on the UF, and dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn) designated as nonformulary on the UF was the most cost-effective for the MHS.

C. 5-ARIs Subclass—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

- finasteride (Proscar, generic) remain designated with formulary status on the UF; and

- dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn) be designated NF.

This recommendation includes step therapy, which requires a trial of a finasteride prior to using dutasteride (Avodart) in all current and new patients, or dutasteride/tamsulosin (Jalyn) in new users.

D. 5-ARIs Subclass—Prior Authorization (PA) Criteria

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) PA criteria should apply to the nonformulary 5-ARIs. A trial of finasteride is required prior to using dutasteride (Avodart) in all current and new patients, or dutasteride/tamsulosin (Jalyn) in all new users. With the new requirement for use of finasteride prior to using Jalyn, the previous prior authorization criteria where a trial of alfuzosin or tamsulosin was required no longer apply.

- Automated PA criteria:
  - The patient has a previous step therapy (automated prior authorization) approval for dutasteride/tamsulosin (Jalyn),

    or

  - The patient has filled a prescription for finasteride at any MHS pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

    AND

- Manual PA criteria—If automated criteria are not met, Jalyn is approved (e.g., trial of finasteride is NOT required) if:

  - Use of finasteride is contraindicated and the patient requires therapy with both an A1B and a 5-ARI.
  - The patient has tried finasteride, was unable to tolerate it due to adverse effects, and requires therapy with both an A1B and a 5-ARI.
  - The patient is unable to take finasteride (due to a contraindication or adverse events), requires therapy with both an A1B and a 5-ARI, and requires a fixed-dose combination due to, for example, swallowing difficulties.

E. 5-ARIs Subclass—UF and PA Implementation Plan

The P&T Committee recommended (12 for, 0 opposed, abstained, 4 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

V. UF CLASS REVIEWS—BENIGN PROSTATIC HYPERPLASIA AGENTS

BAP Comments

A. 5-ARIs Subclass—UF Recommendation

The P&T Committee recommended the following:

- finasteride (Proscar, generic) remain designated with formulary status on the UF; and
- dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn) be designated NF.

This recommendation includes step therapy, which requires a trial of a finasteride prior to using dutasteride (Avodart) in all current and new patients, or dutasteride/tamsulosin (Jalyn) in new users.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

B. 5-ARIs Subclass—PA Criteria

The P&T Committee recommended PA criteria should apply to the nonformulary 5-ARIs. A trial of finasteride is required prior to using dutasteride (Avodart) in all current and new patients, or dutasteride/tamsulosin (Jalyn) in all new users. With the new requirement for use of finasteride prior to using Jalyn, the previous prior authorization criteria where a trial of alfuzosin or tamsulosin was required no longer apply.

- Automated PA criteria:
  - The patient has a previous step therapy (automated prior authorization) approval for dutasteride/tamsulosin (Jalyn),

    or

  - The patient has filled a prescription for finasteride at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

- Manual PA criteria—If automated criteria are not met, Jalyn is approved (e.g., trial of finasteride is NOT required) if:
  - Use of finasteride is contraindicated and the patient requires therapy with both an A1B and a 5-ARI.
  - The patient has tried finasteride, was unable to tolerate it due to adverse effects, and requires therapy with both an A1B and a 5-ARI.
  - The patient is unable to take finasteride (due to a contraindication or adverse events), requires therapy with both an A1B and a 5-ARI, and requires a fixed-dose combination due to, for example, swallowing difficulties.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. 5-ARIs Subclass—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VI. UF CLASS REVIEWS—ANTI-LIPIDEMIC-1s (LIP-1s)

P&T Comments

A. LIP-1s—Relative Clinical Effectiveness and Conclusion

New lipid treatment guidelines were released on November 12, 2013, one day prior to the November P&T Committee meeting. An interim meeting was held to determine the clinical and cost-effectiveness, and UF status of the LIP-1 drugs, based on the new guidelines (found at http://content.onlinejacc.org/article.aspx?articleID=1770217). MTFs and Managed Care Support Contractors were surveyed on their opinions of the new guidelines and potential changes in statin prescribing in the MHS.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 3 absent) the following clinical effectiveness conclusions:

- New lipid guidelines from the American College of Cardiology/American Heart Association (ACC/AHA) released on November 12, 2013, recommend statin therapy for patients in the following four risk categories:
    - With clinical atherosclerotic cardiovascular disease (ASCVD)
    - Low-density lipoprotein (LDL) cholesterol ≥190 mg/dL
    - Type 2 diabetic mellitus patients age 40–75 without ASCVD and with LDL between 70–189 mg/dL

    - Patients age 40–75 with 10-year cardiovascular (CV) risk ≥7.5% and LDL between 70–189 mg/dL but without history of ASCVD

- Based on the four risk groups, the number of patients eligible to receive statin therapy will likely increase.
- A new risk assessment scoring tool based on gender, race, age, total cholesterol, and LDL is now recommended.
- Other changes from the previous Adult Treatment Panel 3 guideline are that treatment targets based on LDL or high-density lipoprotein (HDL) are no longer recommended, dose titration based on LDL is not recommended, and there is no differentiation in statins in terms of primary and secondary prevention.
- Statins are categorized into three groups—
    - High intensity (LDL lowering ≥50%): atorvastatin 40 mg, 80 mg; rosuvastatin (Crestor) 20 mg, 40 mg
    - Moderate intensity (LDL lowering between 30% to <50%): atorvastatin 10 mg, 20 mg; rosuvastatin (Crestor) 5 mg, 10 mg; simvastatin 20 mg, 40 mg; pravastatin 40 mg, 80 mg; lovastatin 40 mg; fluvastatin ER (Lescol XL) 80 mg; fluvastatin 40 mg twice daily; pitavastatin (Livalo) 2 mg, 4 mg
    - Low intensity (LDL lowering <30%): simvastatin 10 mg; pravastatin 10 mg, 20 mg; lovastatin 20 mg; fluvastatin 20 mg, 40 mg; pitavastatin (Livalo) 1 mg
- Non-statin therapies (ezetimibe, niacin, fibrates, bile acid salts), whether alone or in addition to statins, do not provide acceptable ASCVD risk reduction benefits compared to their potential for adverse effects in the routine prevention of ASCVD.
- Non-statin therapies can be considered for patients who experience adverse events from statins, less than anticipated responses, those with statin tolerability issues, or those with drug interactions.
- Based on the current guidelines, and to meet the needs of DoD beneficiaries, at least one statin from each of the statin intensity groups (low, moderate, and high intensity) is required on the UF.

B. LIP-1s—Relative Cost-Effectiveness Analysis and Conclusion

Cost-effectiveness analysis (CEA) and BIA were performed for the LIP-1s. For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted. The CEA was based in part on evidence and efficacy outcomes published in the 2013 ACC/AHA lipid guidelines. The CEA assessed LIP-1s based on the efficacy (i.e., intensity) of statin therapy, according to the average expected LDL lowering from low-, moderate-, or high-intensity statins. The CEA evaluated the following:

- statin monotherapy agents: atorvastatin, fluvastatin, fluvastatin ER (Lescol XL), lovastatin, lovastatin ER (Altoprev), pitavastatin (Livalo), pravastatin, rosuvastatin (Crestor), simvastatin; and,

- fixed-dose combination therapy agents: amlodipine/atorvastatin, ezetimibe/atorvastatin (Liptruzet), ezetimibe/simvastatin (Vytorin), niacin/lovastatin (Advicor), and niacin/simvastatin (Simcor).

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 3 absent) the following:

- For low-intensity statins, generic simvastatin was the most cost-effective of this subgroup of drugs, based on the weighted average cost per day of treatment across all three POS, followed by lovastatin, pravastatin, fluvastatin, and pitavastatin (Livalo) (ranked in order from most to least cost-effectiveness)
- For moderate-intensity statins, generic simvastatin was the most cost-effective agent in this subgroup of drugs followed by generic atorvastatin 10 mg and 20 mg, lovastatin, pravastatin, rosuvastatin (Crestor) 5 mg and 10 mg, fluvastatin, pitavastatin (Livalo), amlodipine/atorvastatin, fluvastatin ER (Lescol XL), and lovastatin ER (Altoprev).
- For high-intensity statins, generic atorvastatin 40 mg and 80 mg was the most cost-effective of this subgroup of drugs, followed by rosuvastatin (Crestor) 20 mg and 40 mg.
- For branded fixed-dose combination agents, cost analysis results showed ezetimibe/simvastatin (Vytorin) to have the lowest average cost per day in this subgroup, followed by ezetimibe/atorvastatin (Liptruzet), niacin/lovastatin (Advicor), and niacin/simvastatin (Simcor).
- Among the formulary options examined, CEA and BIA results showed the most cost-effective scenario designated all generic statins UF and step-preferred, with rosuvastatin (Crestor) as the formulary non-preferred agent (all new users required to try generic statins with equivalent intensity), and all other branded statin agents with NF status and non-preferred.

C. LIP-1s—UF Recommendation

The P&T Committee recommended (12 for, 1 opposed, 0 abstained, 3 absent) the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:

- atorvastatin, atorvastatin/amlodipine, simvastatin, pravastatin, fluvastatin, and lovastatin be designated UF and step-preferred (e.g., “in front of the step”);
- rosuvastatin remain designated UF and non step-preferred (e.g., “behind the step”); and,

- atorvastatin/ezetimibe (Liptruzet), simvastatin/ezetimibe (Vytorin), pitavastatin (Livalo), fluvastatin ER (Lescol XL), lovastatin ER (Altoprev), lovastatin/niacin (Advicor), and simvastatin/niacin (Simcor) be designated NF and non step-preferred (e.g., "behind the step").
- This recommendation includes step therapy, which requires a trial of a generic statin at similar LDL-lowering intensity in new users of rosuvastatin (Crestor) 20 mg and 40 mg and the NF statins, and manual PA criteria for new users of rosuvastatin 5 mg and 10 mg.

Note that this recommendation does not affect the formulary status of ezetimibe (Zetia) or niacin ER (Niaspan). Ezetimibe remains UF and non step-preferred and Niaspan remains on the BCF.

MTF pharmacies are highly encouraged to switch patients currently receiving Vytorin to statin monotherapy at the appropriate LDL-lowering intensity.

MTFs are also encouraged to reserve new prescriptions for Crestor 20 mg or 40 mg for patients who are unable to tolerate atorvastatin 40 mg or 80 mg, and to consider a generic statin at the equivalent LDL-lowering intensity for new prescriptions, instead of Crestor 5 mg or 10 mg.

D. LIP-1s—PA Criteria

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) automated PA criteria (step therapy) and manual PA criteria for new users of rosuvastatin (Crestor) 20 mg and 40 mg, simvastatin/ezetimibe (Vytorin), atorvastatin/ezetimibe (Liptruzet), pitavastatin (Livalo), fluvastatin ER (Lescol XL), lovastatin ER (Altoprev), lovastatin/niacin (Advicor), and (simvastatin/niacin) Simcor, requiring a trial of a step-preferred statin with similar LDL-lowering intensity. The P&T Committee also recommended (11 for, 1 opposed, 1 abstained, 3 absent) manual PA criteria for new users of rosuvastatin (Crestor) 5 mg and 10 mg, requiring a trial of atorvastatin, simvastatin, and pravastatin. See full criteria listed below.

- **Rosuvastatin (Crestor) 20 mg, 40 mg—**All current users of Crestor are exempt from the PA criteria ("grandfathered"). New users of Crestor 20 mg, 40 mg must try a preferred statin at appropriate LDL lowering first.

  Automated PA criteria
  - The patient has filled a prescription for a preferred statin targeting similar LDL lowering >50% (generic atorvastatin 40 mg or 80 mg), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

  Manual PA criteria—If automated criteria are not met, Crestor 20 mg, 40 mg is approved in new users (e.g., trial of atorvastatin 40 mg, 80 mg is NOT required)

if:

- The patient requires a high-intensity statin (LDL lowering >50%) and has tried atorvastatin 40 mg or 80 mg and was unable to tolerate treatment due to adverse effects.
- The patient requires a high-intensity statin (LDL lowering >50%) and is on a concurrent drug metabolized by the cytochrome p450 3A4 pathway.

- **Rosuvastatin (Crestor) 5 mg, 10 mg—**All current users of Crestor are exempt from the PA criteria ("grandfathered"). New users of Crestor 5 mg, 10 mg must try a preferred statin at appropriate LDL lowering first.

  Manual PA criteria—For new users, Crestor 5 mg or 10 mg is approved (e.g., trial of a generic statin at appropriate LDL lowering is NOT required) if:

  - The patient is taking a concurrent drug that is metabolized by CYP3A4 and cannot take pravastatin. The provider must state why the patient cannot take pravastatin.
  - The patient requires moderate LDL lowering (LDL decrease by 30% to 50%), and has tried all 3 of the following drugs: atorvastatin ≥10 mg, simvastatin ≥20 mg, and pravastatin ≥40 mg and could not tolerate treatment due to adverse effects.

  Note that the previous requirements for step therapy are removed; all new users of Crestor 5 mg and 10 mg must have a manual ("hard copy") PA.

- **Atorvastatin/ezetimibe (Liptruzet), simvastatin/ezetimibe (Vytorin), fluvastatin ER, (Lescol XL), lovastatin ER (Altoprev), pitavastatin (Livalo), lovastatin/niacin (Advicor), simvastatin/niacin (Simcor)—**All new users of Liptruzet, Vytorin, Lescol XL, Livalo, Altoprev, Advicor, and Simcor must try a preferred statin at appropriate LDL lowering first.

  Automated PA criteria
  - The patient has received a prescription for a preferred agent (generic atorvastatin, simvastatin, pravastatin, fluvastatin, lovastatin, or pravastatin) targeting similar LDL reduction (LDL lowering <50%, LDL lowering between 30% to 50%, LDL lowering <30%) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

  Manual PA criteria—If automated criteria are not met, Liptruzet, Vytorin, Lescol XL, Livalo, Altoprev, Advicor, and Simcor is approved (e.g., trial of generic

statin is NOT required) if:

- For Vytorin: The patient requires a high-intensity statin and has tried atorvastatin ≥40 mg and was unable to tolerate treatment due to adverse effects.
- For Vytorin or Liptruzet: The patient requires high-intensity therapy and is receiving ezetimibe and atorvastatin or simvastatin separately, and has swallowing difficulties (needs a fixed-dose combination product).
- For Livalo, Lescol XL:
  - The patient has tried a preferred statin with similar LDL reduction (moderate or low intensity) and was unable to tolerate it due to adverse effects.
  - The patient is taking a drug that is metabolized by CYP3A4 .
- For Altoprev: The patient requires treatment with lovastatin 60 mg and cannot take another statin with similar LDL lowering.
- For Simcor, Advicor: The patient requires a drug that lowers LDL and raises HDL and cannot take two separate tablets (needs fixed-dose combination).

E. LIP-1s—UF and PA Implementation Plan

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service; and, 2) DHA send a letter to beneficiaries affected by the UF and PA decisions.

VII. UF CLASS REVIEWS—LIP-1s

BAP Comments

A. LIP-1s—UF Recommendation

The P&T Committee recommended the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:

- atorvastatin, atorvastatin/amlodipine, simvastatin, pravastatin, fluvastatin, and lovastatin be designated UF and step-preferred (e.g., “in front of the step”);
- rosuvastatin remain designated UF and non step-preferred (e.g., “behind the step”); and,
- atorvastatin/ezetimibe (Liptruzet), simvastatin/ezetimibe (Vytorin), pitavastatin (Livalo), fluvastatin ER (Lescol XL), lovastatin ER (Altoprev), lovastatin/niacin (Advicor), and simvastatin/niacin (Simcor) be designated NF and non step-preferred (e.g., “behind the step”).
- This recommendation includes step therapy, which requires a trial of a generic statin at similar LDL-lowering intensity in new users of rosuvastatin (Crestor) 20

mg and 40 mg and the NF statins, and manual PA criteria for new users of rosuvastatin 5 mg and 10 mg.

Note that this recommendation does not affect the formulary status of ezetimibe (Zetia) or niacin ER (Niaspan). Ezetimibe remains UF and non step-preferred and Niaspan remains on the BCF.

MTF pharmacies are highly encouraged to switch patients currently receiving Vytorin to statin monotherapy at the appropriate LDL-lowering intensity.

MTFs are also encouraged to reserve new prescriptions for Crestor 20 mg or 40 mg for patients who are unable to tolerate atorvastatin 40 mg or 80 mg, and to consider a generic statin at the equivalent LDL-lowering intensity for new prescriptions, instead of Crestor 5 mg or 10 mg.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. LIP-1s—PA Criteria

The P&T Committee recommended automated PA criteria (step therapy) and manual PA criteria for new users of rosuvastatin (Crestor) 20 mg and 40 mg, simvastatin/ezetimibe (Vytorin), atorvastatin/ezetimibe (Liptruzet), pitavastatin (Livalo), fluvastatin ER (Lescol XL), lovastatin ER (Altoprev), lovastatin/niacin (Advicor), and (simvastatin/niacin) Simcor, requiring a trial of a step-preferred statin with similar LDL-lowering intensity. The P&T Committee also recommended (11 for, 1 opposed, 1 abstained, 3 absent) manual PA criteria for new users of rosuvastatin (Crestor) 5 mg and 10 mg, requiring a trial of atorvastatin, simvastatin, and pravastatin. See full criteria listed below.

- **Rosuvastatin (Crestor) 20 mg, 40 mg—**All current users of Crestor are exempt from the PA criteria ("grandfathered"). New users of Crestor 20 mg, 40 mg must try a preferred statin at appropriate LDL lowering first.

  Automated PA criteria
  - The patient has filled a prescription for a preferred statin targeting similar LDL lowering >50% (generic atorvastatin 40 mg or 80 mg), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

  Manual PA criteria—If automated criteria are not met, Crestor 20 mg, 40 mg is approved in new users (e.g., trial of atorvastatin 40 mg, 80 mg is NOT required)

if:

- The patient requires a high-intensity statin (LDL lowering >50%) and has tried atorvastatin 40 mg or 80 mg and was unable to tolerate treatment due to adverse effects.
- The patient requires a high-intensity statin (LDL lowering >50%) and is on a concurrent drug metabolized by the cytochrome p450 3A4 pathway.

- **Rosuvastatin (Crestor) 5 mg, 10 mg—**All current users of Crestor are exempt from the PA criteria ("grandfathered"). New users of Crestor 5 mg, 10 mg must try a preferred statin at appropriate LDL lowering first.

  Manual PA criteria—For new users, Crestor 5 mg or 10 mg is approved (e.g., trial of a generic statin at appropriate LDL lowering is NOT required) if:

  - The patient is taking a concurrent drug that is metabolized by CYP3A4 and cannot take pravastatin. The provider must state why the patient cannot take pravastatin.
  - The patient requires moderate LDL lowering (LDL decrease by 30% to 50%), and has tried all 3 of the following drugs: atorvastatin ≥10 mg, simvastatin ≥20 mg, and pravastatin ≥40 mg and could not tolerate treatment due to adverse effects.

  Note that the previous requirements for step therapy are removed; all new users of Crestor 5 mg and 10 mg must have a manual ("hard copy") PA.

- **Atorvastatin/ezetimibe (Liptruzet), simvastatin/ezetimibe (Vytorin), fluvastatin ER, (Lescol XL), lovastatin ER (Altoprev), pitavastatin (Livalo), lovastatin/niacin (Advicor), simvastatin/niacin (Simcor)—**All new users of Liptruzet, Vytorin, Lescol XL, Livalo, Altoprev, Advicor, and Simcor must try a preferred statin at appropriate LDL lowering first.

  Automated PA criteria
  - The patient has received a prescription for a preferred agent (generic atorvastatin, simvastatin, pravastatin, fluvastatin, lovastatin, or pravastatin) targeting similar LDL reduction (LDL lowering <50%, LDL lowering between 30% to 50%, LDL lowering <30%) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

  Manual PA criteria—If automated criteria are not met, Liptruzet, Vytorin, Lescol XL, Livalo, Altoprev, Advicor, and Simcor is approved (e.g., trial of generic

statin is NOT required) if:

- For Vytorin: The patient requires a high-intensity statin and has tried atorvastatin ≥40 mg and was unable to tolerate treatment due to adverse effects.
- For Vytorin or Liptruzet: The patient requires high-intensity therapy and is receiving ezetimibe and atorvastatin or simvastatin separately, and has swallowing difficulties (needs a fixed-dose combination product).
- For Livalo, Lescol XL:
  - The patient has tried a preferred statin with similar LDL reduction (moderate or low intensity) and was unable to tolerate it due to adverse effects.
  - The patient is taking a drug that is metabolized by CYP3A4 .
- For Altoprev: The patient requires treatment with lovastatin 60 mg and cannot take another statin with similar LDL lowering.
- For Simcor, Advicor: The patient requires a drug that lowers LDL and raises HDL and cannot take two separate tablets (needs fixed-dose combination).

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. LIP-1s—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service; and, 2) DHA send a letter to beneficiaries affected by the UF and PA decisions.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

VIII. RECENTLY APPROVED U.S. FDA AGENTS—NON-INSULIN DIABETES DRUGS

P&T Comments

A. Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—Relative Clinical Effectiveness and Conclusion

Alogliptin (Nesina) is the fourth DPP-4 inhibitor to reach the market. Similar to the other DPP-4 inhibitors, it is combined with metformin (alogliptin/metformin; Kazano), but is the first DPP-4 inhibitor with a thiazolidinedione (TZD) combination [alogliptin/pioglitazone (Oseni)].

The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following with regard to the clinical efficacy and safety of the alogliptin-containing drugs:

- Alogliptin and the combinations with metformin and pioglitazone exhibit similar hemoglobin A1c (HbA1c) lowering effects compared to the other DPP-4 inhibitors. Dual therapy with alogliptin provided greater decreases in HbA1c from baseline in treatment naïve patients (HbA1c lowering of 1.22% to 1.71%) compared to patients previously treated with a DPP-4 inhibitor (HbA1c lowering of 0.39% to 0.6%). Triple therapy with alogliptin plus metformin and pioglitazone resulted in HbA1c changes from baseline ranging from 0.63% to 1.4%.
- Alogliptin, similar to the other DPP-4 inhibitors, is lipid- and weight-neutral and has minimal effects on blood pressure.
- The fixed-dose combinations of alogliptin with metformin or pioglitazone have the usual safety concerns (i.e., lactic acidosis, heart failure, fracture risk, edema, hepatic impairment, and bladder cancer).
- Alogliptin-containing products all require renal dosing.
- Although alogliptin is the only DPP-4 available in a fixed-dose combination with a TZD, it offers no additional clinical benefits, as alogliptin requires renal dosing and the multiple tablets strengths available may limit use.

B. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed. Based on the CMA results, the P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) that alogliptin (Nesina), alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni) are more costly than the current UF (linagliptin products), BCF (sitagliptin products), and NF (saxagliptin products) DPP-4-inhibitors.

C. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—UF Recommendation

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

- alogliptin (Nesina), aloglptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni) be designated NF and non-preferred.

- This recommendation includes step therapy, which requires a trial of a sitagliptin product (Januvia, Janumet, Janumet XR) (the preferred drugs) prior to using the other DPP4-inhibitors. Prior authorization for the DPP-4 inhibitors also requires a trial of metformin or sulfonylurea for new patients.

D. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—PA Criteria

Existing automated PA (step therapy) requires a trial of metformin or a sulfonylurea prior to use of a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 inhibitors subclass. New users must try a preferred sitagliptin product before trying linagliptin or saxagliptin-containing products. Juvisync has been voluntarily discontinued from the market as of October 2013, and will no longer be a preferred sitagliptin product on the UF.

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) PA criteria should apply to alogliptin (Nesina), alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni). See full criteria listed below.

- **Alogliptin (Nesina), alogliptin/metformin (Kazano), alogliptin/pioglitazone (Oseni)—**All new and current users of a DPP-4 inhibitor are required to try metformin or a sulfonylurea before receiving a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 inhibitors subclass. New users of alogliptin must try a sitagliptin product first.

  <u>Automated PA criteria</u>
  - The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

  - The patient has received a prescription for a preferred DPP-4 inhibitor (Januvia, Janumet, or Janumet XR) at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

Manual PA criteria—If automated criteria are not met, alogliptin, alogliptin/metformin, or alogliptin/pioglitazone is approved (e.g., trial of metformin or a sulfonylurea is NOT required) if:

- The patient has had an inadequate response to metformin or sulfonylurea.
- The patient has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or history of lactic acidosis [for alogliptin (Nesina) or alogliptin/pioglitazone (Oseni)].
- The patient has experienced the following adverse event while receiving a sulfonylurea: hypoglycemia requiring medical treatment.
- The patient has a contraindication to metformin or a sulfonylurea.

AND

In addition to the above criteria regarding metformin and sulfonylurea, the following PA criteria would apply specifically to alogliptin (Nesina), alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni):

- The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with alogliptin-containing products.
- The patient has had an inadequate response to a sitagliptin-containing product.
- The patient has a contraindication to sitagliptin.

E. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—UF and PA Implementation Plan

The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS); and, 2) the Defense Health Agency (DHA) send a letter to beneficiaries affected by the UF decision.

IX. RECENTLY APPROVED U.S. FDA AGENTS—NON-INSULIN DIABETES DRUGS

BAP Comments

A. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—UF Recommendation

The P&T Committee recommended the following:

- alogliptin (Nesina), aloglptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni) be designated NF and non-preferred.

- This recommendation includes step therapy, which requires a trial of a sitagliptin product (Januvia, Janumet, Janumet XR) (the preferred drugs) prior to using the other DPP4-inhibitors. Prior authorization for the DPP-4 inhibitors also requires a trial of metformin or sulfonylurea for new patients.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

B. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—PA Criteria

Existing automated PA (step therapy) requires a trial of metformin or a sulfonylurea prior to use of a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 inhibitors subclass. New users must try a preferred sitagliptin product before trying linagliptin or saxagliptin-containing products. Juvisync has been voluntarily discontinued from the market as of October 2013, and will no longer be a preferred sitagliptin product on the UF. The P&T Committee recommended PA criteria should apply to alogliptin (Nesina), alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni). See full criteria listed below.

- **Alogliptin (Nesina), alogliptin/metformin (Kazano), alogliptin/pioglitazone (Oseni)—**All new and current users of a DPP-4 inhibitor are required to try metformin or a sulfonylurea before receiving a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 inhibitors subclass. New users of alogliptin must try a sitagliptin product first.

  Automated PA criteria
  - The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

  - The patient has received a prescription for a preferred DPP-4 inhibitor (Januvia, Janumet, or Janumet XR) at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

    AND

Manual PA criteria—If automated criteria are not met, alogliptin, alogliptin/metformin, or alogliptin/pioglitazone is approved (e.g., trial of metformin or a sulfonylurea is NOT required) if:

- The patient has had an inadequate response to metformin or sulfonylurea.
- The patient has experienced any of the following adverse events while receiving metformin: impaired renal function that precludes treatment with metformin or history of lactic acidosis [for alogliptin (Nesina) or alogliptin/pioglitazone (Oseni)].
- The patient has experienced the following adverse event while receiving a sulfonylurea: hypoglycemia requiring medical treatment.
- The patient has a contraindication to metformin or a sulfonylurea.

AND

In addition to the above criteria regarding metformin and sulfonylurea, the following PA criteria would apply specifically to alogliptin (Nesina), alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni):

- The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with alogliptin-containing products.
- The patient has had an inadequate response to a sitagliptin-containing product.
- The patient has a contraindication to sitagliptin.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. DPP-4 Inhibitors: Alogliptin (Nesina), Alogliptin/Metformin (Kazano), and Alogliptin/Pioglitazone (Oseni)—UF and PA Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service (POS); and, 2) the Defense Health Agency (DHA) send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

X. RECENTLY APPROVED U.S. FDA AGENTS—OSTEOPOROSIS DRUGS

P&T Comments

A. Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)—Relative Clinical Effectiveness and Conclusion

Effervescent alendronate (Binosto) is a new effervescent formulation of alendronate (Fosamax, generics). The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) that although Binosto may be more convenient for patients by requiring less consumption of water and to those patients with swallowing difficulties, there is no data that Binosto is better tolerated or safer than other alendronate formulations. The high sodium content with Binosto is a disadvantage over other alendronate formulations. Binosto offers no clinically compelling advantages over current formulary bisphosphonate agents.

B. Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)—Relative Cost-Effectiveness Analysis and Conclusion

CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) effervescent alendronate (Binosto) is the least cost-effective oral bisphosphonate compared to current UF agents.

C. Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)—UF Recommendation

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) effervescent alendronate (Binosto) be designated NF.

D. Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)—UF Implementation Plan

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

XI. RECENTLY APPROVED U.S. FDA AGENTS—OSTEOPOROSIS DRUGS

BAP Comments

A. Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)—UF Recommendation

The P&T Committee recommended effervescent alendronate (Binosto) be designated NF.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

B. Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)—UF Implementation Plan

The P&T Committee recommended 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

XII. UTILIZATION MANAGEMENT

P&T Comments

A. Multiple Sclerosis (MS) Drugs: Dimethyl Fumarate (Tecfidera)—PA Criteria

Dimethyl fumarate is an oral disease modifying drug for MS that was FDA-approved in March 2013. The drug has not yet been reviewed for UF status. The package insert recommends measuring the complete blood count (CBC) within six months prior to initiation of therapy, due to the risk of lymphopenia. PA criteria apply to the other MS drugs.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) the following PA criteria for dimethyl fumarate (Tecfidera) for relapsing forms of MS, and CBC monitoring, consistent with the product labeling.

Coverage approved for patients with:

- Documented diagnosis of relapsing forms of MS.

- CBC within six months prior to imitation of therapy, due to risk of lymphopenia.
- Coverage NOT provided for concomitant use with other disease-modifying drugs of MS.

XIII. UTILIZATION MANAGEMENT

BAP Comments

A. MS Drugs: Dimethyl Fumarate (Tecfidera)—PA Criteria

The P&T Committee recommended the following PA criteria for dimethyl fumarate (Tecfidera) for relapsing forms of MS, and CBC monitoring, consistent with the product labeling.

Coverage approved for patients with:

- Documented diagnosis of relapsing forms of MS.
- CBC within six months prior to imitation of therapy, due to risk of lymphopenia.
- Coverage NOT provided for concomitant use with other disease-modifying drugs of MS.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XIV. UTILIZATION MANAGEMENT

P&T Comments

A. Targeted Immunomodulatory Biologics (TIBs): Certolizumab (Cimzia), Tocilizumab (Actemra), and Ustekinumab (Stelara)—PA Criteria

PA criteria currently apply to the TIBs. Tocilizumab was previously limited to injection by health care professionals, but is now available in pre-filled syringes labeled for patient self administration for treatment of rheumatoid arthritis. The FDA recently approved new indications for certolizumab for treatment of ankylosing spondylitis (AS) and psoriatic arthritis (PsA), and ustekinumab for treatment of PsA.

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) PA criteria for certolizumab for AS and PsA, tocilizumab for rheumatoid arthritis, and ustekinumab for PsA, consistent with the products' labeling. See for full criteria below.

- **Certolizumab (Cimzia)—**Coverage approved for patients ≥ 18 years with:
    - Active ankylosing spondylitis
    - Active psoriatic arthritis
    - Moderately to severely active Crohn's disease refractory to conventional therapy
    - Moderately to severely active rheumatoid arthritis
    - Coverage NOT provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia, or Rituxan
- **Tocilizumab (Actemra)—**Coverage approved for patients ≥ 18 years with:
    - Moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs
    - Not approved for use in systemic or polyarticular juvenile idiopathic arthritis
- **Ustekinumab (Stelara)—**Coverage approved for patients ≥ 18 years with:
    - Active psoriatic arthritis
    - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
    - Coverage NOT provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia, or Rituxan

XV. UTILIZATION MANAGEMENT

BAP Comments

A. Targeted Immunomodulatory Biologics (TIBs): Certolizumab (Cimzia), Tocilizumab (Actemra), and Ustekinumab (Stelara)—PA Criteria

PA criteria currently apply to the TIBs. Tocilizumab was previously limited to injection by health care professionals, but is now available in pre-filled syringes labeled for patient self administration for treatment of rheumatoid arthritis. The FDA recently approved new indications for certolizumab for treatment of ankylosing spondylitis (AS) and psoriatic arthritis (PsA), and ustekinumab for treatment of PsA.

The P&T Committee recommended PA criteria for certolizumab for AS and PsA, tocilizumab for rheumatoid arthritis, and ustekinumab for PsA, consistent with the products' labeling. See for full criteria below.

- **Certolizumab (Cimzia)—**Coverage approved for patients ≥ 18 years with:
    - Active ankylosing spondylitis
    - Active psoriatic arthritis
    - Moderately to severely active Crohn's disease refractory to conventional therapy
    - Moderately to severely active rheumatoid arthritis
    - Coverage NOT provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia, or Rituxan
- **Tocilizumab (Actemra)—**Coverage approved for patients ≥ 18 years with:
    - Moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs
    - Not approved for use in systemic or polyarticular juvenile idiopathic arthritis
- **Ustekinumab (Stelara)—**Coverage approved for patients ≥ 18 years with:
    - Active psoriatic arthritis
    - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
    - Coverage NOT provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia, or Rituxan

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

XVI. UTILIZATION MANAGEMENT

P&T Comments

A. Montelukast (Singulair)—PA Removal

PA criteria were recommended at the August 2011 meeting for montelukast (Singular), requiring automated PA criteria in patients with asthma, and requiring manual PA criteria for patients with seasonal allergic rhinitis or nasal polyps, based on professional treatment guidelines and cost. Generic montelukast tablets entered the market in August 2012 and, as of November 2013, there has been a significant decrease in the generic cost. The P&T

Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the PA requirements for montelukast be removed, effective upon signing of the minutes.

XVII. UTILIZATION MANAGEMENT

BAP Comments

A. Montelukast (Singulair)—PA Removal

The P&T Committee recommended that the PA requirements for montelukast be removed, effective upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissention

XVIII. FISCAL YEAR 2008 NATIONAL DEFENSE AUTHORIZATION ACT, SECTION 703

P&T Comments

The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not compliant with Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in MTFs. These NF drugs will remain available in the Mail Order POS without pre-authorization.

A. Section 703—UF Recommendation

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the products listed below (by manufacturer) be designated NF on the UF.

LUPIN PHAR	ANTARA
MISSION PH	BINOSTO LITHOSTAT THIOLA TINDAMAX UROCIT-K (10 MEQ) UROCIT-K (15 MEQ) UROCIT-K (5 MEQ)
ROMARK LAB	ALINIA

WESTWARD	ATIVAN
	ATIVAN INJECTION
	DOPRAM
	DURAMORPH
	GLYCOPYRROLATE
	INFUMORPH
	ROBAXIN
	ROBINUL

B. Section 703—Pre-Authorization Criteria

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) the following pre-authorization criteria for the drugs designated nonformulary (see XVIII, A, above): 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any point of service other than retail network pharmacies.

C. Section 703—Pre-Authorization Implementation Plan

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the drugs designated nonformulary (see XVIII, A, above) have 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by these decisions.

D. Section 703—Drugs Returned to Uniform Formulary

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the products listed below (by manufacturer) be designated with the drug's previous status on the UF because the manufacturer has become compliant with refund requirements.

ALLERGAN	ALOCRIL
	AVAGE
	AZELEX
	BETAGAN
	BLEPHAMIDE
	ELESTAT
	ELIMITE
	FML
	FML FORTE
	FML S.O.P.
	OCUFEN
	OCUFLOX
	POLY-PRED

	POLYTRIM
	PRED MILD
	PRED-G
BAXTER	TRANSDERM-SCOP
BEDFORD LABS	CAFCIT
	GLUCAGEN
BIOVITRUM	KINERET
DAVA	RHEUMATREX (REMAINS NF, NO PRE-AUTHORIZATION)
FRESENIUS MED	PHOSLO

E. Section 703—Removal of Pre-Authorization Criteria for Drugs Returned to UF and Implementation Plan

The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that pre-authorization criteria for the drugs listed in XVIII, D, above, be removed because the manufacturer has become compliant with refund requirements. The formulary designation change and removal of pre-authorization criteria shall become effective upon signing of the minutes.

XIX. UTILIZATION MANAGEMENT

BAP Comments

A. Section 703—UF Recommendation

The P&T Committee recommended that the products listed below (by manufacturer) be designated NF on the UF.

LUPIN PHAR	ANTARA
MISSION PH	BINOSTO
	LITHOSTAT
	THIOLA
	TINDAMAX
	UROCIT-K (10 MEQ)
	UROCIT-K (15 MEQ)
	UROCIT-K (5 MEQ)
ROMARK LAB	ALINIA
WESTWARD	ATIVAN
	ATIVAN INJECTION

DOPRAM
DURAMORPH
GLYCOPYRROLATE
INFUMORPH
ROBAXIN
ROBINUL

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

B. Section 703—PA Criteria

The P&T Committee recommended the following pre-authorization criteria for the drugs designated nonformulary (see XIX, A, above): 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any point of service other than retail network pharmacies.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

C. Section 703—PA Implementation Plan

The P&T Committee recommended that the drugs designated nonformulary (see XIX, A, above) have 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by these decisions.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

D. Section 703—Drugs Returned to Uniform Formulary

The P&T Committee recommended that the products listed below (by manufacturer) be designated with the drug's previous status on the UF because the manufacturer has become compliant with refund requirements.

ALLERGAN	ALOCRIL
	AVAGE
	AZELEX
	BETAGAN
	BLEPHAMIDE
	ELESTAT
	ELIMITE
	FML
	FML FORTE
	FML S.O.P.
	OCUFEN
	OCUFLOX
	POLY-PRED
	POLYTRIM
	PRED MILD
	PRED-G
BAXTER	TRANSDERM-SCOP
BEDFORD LABS	CAFCIT
	GLUCAGEN
BIOVITRUM	KINERET
DAVA	RHEUMATREX (REMAINS NF, NO PRE-AUTHORIZATION)
FRESENIUS MED	PHOSLO

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention

E. Section 703—Removal of Pre-Authorization Criteria for Drugs Returned to UF and Implementation Plan

The P&T Committee recommended that pre-authorization criteria for the drugs listed in XIX, D, above, be removed because the manufacturer has become compliant with refund requirements. The formulary designation change and removal of pre-authorization criteria shall become effective upon signing of the minutes.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissention