DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INTERIM MEETING

Addendum December 17, 2013

I. UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

A. Anti-Lipidemic-1s (LIP-1s)

Background—New lipid treatment guidelines were released on November 12, 2013, one day prior to the November Department of Defense (DoD) Pharmacy & Therapeutics (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). Military Treatment Facilities (MTFs) and Managed Care Support Contractors were surveyed on their opinions of the new guidelines and potential changes in statin prescribing in the Military Health System (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) 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 Uniform Formulary.

Relative Cost-Effectiveness—Cost-effectiveness analysis (CEA) and budget impact analysis (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), and 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 points of service, 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 nonformulary (NF) status and non-preferred.

1. ***COMMITTEE ACTION: 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) 20mg 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 Basic Core Formulary (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.

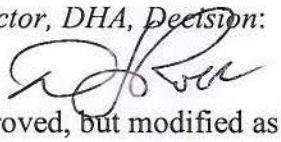
2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) maintaining simvastatin 10 mg, 20 mg, and 40 mg; atorvastatin; and, pravastatin on the BCF. Simvastatin 80 mg remains UF.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) MN criteria for atorvastatin/ezetimibe (Litptruzet), simvastatin/ezetimibe (Vytorin), pitavastatin (Livalo), fluvastatin ER (Lescol XL), lovastatin ER (Altoprev), lovastatin/niacin (Advicor), and simvastatin/niacin (Simcor). (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (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 Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—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; 2) DHA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

Director, DHA, Decision: ☒ Approved ☐ Disapproved



Approved, but modified as follows:

II. UTILIZATION MANAGEMENT

A. MONTELUKAST (SINGULAIR) PA—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.

1. ***COMMITTEE ACTION: MONTELUKAST (SINGULAIR) PA***—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.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

III. SECTION 716 NATIONAL DEFENSE AUTHORIZATION ACT FISCAL YEAR 2013 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM

A. Section 716 Revised Manual PA Criteria—After the November 2013 DoD P&T Committee meeting, the Interim Final Rule for the Section 716 Maintenance Medication Program was published in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2013-12-11/pdf/2013-29434.pdf.) The Rule is effective February 14, 2014. PA criteria were recommended at the November 2013 DoD P&T Committee meeting.

1. ***COMMITTEE ACTION: SECTION 716 MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) revising the manual PA criteria for maintenance medications for the following circumstances:

    a) Patient has barriers to receiving medications by mail (e.g., no permanent address, resides in rural setting).

    b) Patient is not on a stable dose of medication; the medication is currently being titrated.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

10 Feb 2014
Date

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Atorvastatin/ezetimibe (Liptruzet) • Simvastatin/ezetimibe (Vytorin) **Antilipidemic-1s**	• There is no alternative formulary agent: the patient requires high-intensity statin therapy (LDL lowering >50%) or moderate-intensity statin therapy (LDL lowering between 30%–50% for Vytorin 10/10 mg) and is receiving ezetimibe and atorvastatin or simvastatin therapy separately and has swallowing difficulties, requiring use of the fixed-dose combination.
• Fluvastatin ER (Lescol XL) • Pitavastatin (Livalo) **Antilipidemic-1s**	• Use of the formulary statins is contraindicated and the patient cannot take pravastatin. • The patient has experienced or likely to experience significant adverse effects from the formulary statins.
• Lovastatin ER (Altoprev) **Antilipidemic-1s**	• There is no alternative formulary agent; the patient requires treatment with lovastatin 60 mg.
• Lovastatin/niacin (Advicor) • Simvastatin/niacin (Simcor) **Antilipidemic-1s**	• There is no alternative formulary agent; the patient is receiving Niaspan and lovastatin or simvastatin separately, and has swallowing difficulties, requiring use of the fixed-dose combination.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Rosuvastatin (Crestor) 20 mg, 40 mg **Antilipidemic1-s (LIP-1s)**	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. <u>Automated PA criteria</u> • 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 <u>Manual PA criteria</u>—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 **Antilipidemic1-s (LIP-1s)**	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. <u>Manual PA criteria</u>—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) **Antilipidemic1-s (LIP-1s)**	All new users of Liptruzet, Vytorin, Lescol XL, Livalo, Altoprev, Advicor, and Simcor must try a preferred statin at appropriate LDL lowering first. <u>Automated PA criteria</u> • 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 <u>Manual PA criteria</u>—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

Drug / Drug Class	Prior Authorization Criteria
	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: o 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. o 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).

Appendix G—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Dec 2013 Interim Meeting	**Antilipdemic-1s**	UF Class review Previously reviewed	▪ atorvastatin ▪ pravastatin ▪ simvastatin 10, 20, & 40 mg	▪ atorvastatin/amlodipine ▪ fluvastatin ▪ lovastatin ▪ simvastatin 80 mg ▪ rosuvastatin (Crestor) – non-step preferred – see comments	▪ simvastatin/ezetimibe (Vytorin) ▪ atorvastatin/ezetimibe (Liptruzet) ▪ fluvastatin ER (Lescol XL) ▪ lovastatin ER (Altoprev) ▪ pitavastatin (Livalo) ▪ lovastatin/niacin (Advicor) ▪ simvastatin/niacin (Simcor)	Pending signing of the minutes / 60 days	PA applies – see comments and Appendix C	▪ Step therapy applies to new users of Crestor and the 7 nonformulary drugs ▪ Current Crestor users are grandfathered (exempt from PA process) ▪ See Appendix C for details

TRICARE Formulary Search tool: http://www.pec.ha.osd.mil/formulary_search.php

Appendix H—Table of Abbreviations

ACC/AHA	American College of Cardiology/American Heart Association
ASCVD	atherosclerotic cardiovascular disease
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	cost-effectiveness analysis
CV	cardiovascular
DoD	Department of Defense
ER	extended release
HDL	high-density lipoprotein cholesterol
LDL	low-density lipoprotein cholesterol
LIP-1s	Antilipidemic-1s Drug Class
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NF	nonformulary
P&T	Pharmacy & Therapeutics
PA	prior authorization
UF	Uniform Formulary

DECISION PAPER

DEPARMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

November 2013

I. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

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

Relative Clinical Effectiveness Conclusion—Alogliptin (Nesina) is the fourth DPP-4 inhibitor to reach the market. The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) that alogliptin exhibits similar lowering of hemoglobin A1c as the other DPP-4 inhibitors and has a similar safety profile. Although alogliptin is the only DPP-4 available in a fixed-dose combination with thiazolidinedione, it offers no additional clinical benefits, as alogliptin requires renal dosing, and the multiple tablets strengths available may limit use.

Relative Cost-Effectiveness Conclusion—A cost minimization analysis (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 Uniform Formulary (linagliptin products), Basic Core Formulary (sitagliptin products), and Nonformulary (saxagliptin products) DPP-4-inhibitors.

1. ***COMMITTEE ACTION: UNIFORM FORMULARY (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 nonformulary (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.

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for alogliptin (Nesina), alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (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 Appendix C for the full criteria.)

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Osteoporosis Drugs—Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)

Relative Clinical Effectiveness 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.

Relative Cost-Effectiveness 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.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) effervescent alendronate (Binosto) be designated NF.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for effervescent alendronate (Binosto). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***
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. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

II. UF DRUG CLASS REVIEWS

A. Short-Acting Beta Agonists (SABAs) Metered Dose Inhalers (MDIs)

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that in terms of clinical effectiveness, there is little evidence to suggest there are clinically relevant differences between the albuterol hydrofluoroalkane (HFA) products (ProAir HFA, Proventil HFA, Ventolin HFA) and levalbuterol (Xoponex HFA) for their FDA approved indications. No new clinical conclusions were found since the previous review in November 2011. ProAir HFA now includes a dose counter. In order to meet the needs of Military Health System (MHS) patients, only one SABA is needed on the Basic Core Formulary (BCF).

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

1. ***COMMITTEE ACTION: 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.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 3 absent) that ProAir HFA should be added to the BCF and Ventolin HFA should be removed from the BCF. The P&T Committee also recommended that local Military Treatment Facility (MTF) P&T Committees rapidly convert patients to ProAir HFA and provide patient education on proper inhaler technique.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 3 absent) MN criteria for Proventil HFA, Ventolin HFA, and Xopenex HFA. (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is May 14, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Benign Prostatic Hyperplasia Agents—5-Alpha Reductase Inhibitors (5-ARIs) Subclass

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following for the 5-ARIs:

- Finasteride and dutasteride (Avodart) appear interchangeable with regard to efficacy in treating lower urinary tract symptoms associated with benign prostatic hypertrophy (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.

- 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 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 alpha-1 blocker.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) that the most cost-effective scenario designated finasteride (Proscar, generic) with formulary status on the UF, with dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn) designated NF on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent,) the following:
    - finasteride (Proscar, generic) remain designated as formulary on the UF; and,
    - dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn) be designated NF on the UF.
    - 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.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T recommended (15 for, 0 opposed, 1 abstained, 0 absent) finasteride remain designated as the BCF 5-ARI product.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn). (See Appendix B for the full criteria.)

4. ***COMMITTEE ACTION: 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. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (12 for, 0 opposed, 0 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. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

III. UTILIZATION MANAGEMENT

A. PAs

1. **Multiple Sclerosis (MS) Drugs: Dimethyl Fumarate (Tecfidera)**—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.

    a) ***COMMITTEE ACTION: DIMETHYL FUMARATE (TECFIDERA) PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) PA criteria for dimethyl fumarate (Tecfidera) for relapsing forms of MS, and CBC monitoring, consistent with the product labeling. (See Appendix C for full criteria.)

2. **Targeted Immunomodulatory Biologics (TIBs): Certolizumab (Cimzia), Tocilizumab (Actemra), and Ustekinumab (Stelara)**—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.

a) ***COMMITTEE ACTION: CERTOLIZUMAB (CIMZIA), TOCILIZUMAB (ACTEMRA), AND USTEKINUMAB (STELARA) PA CRITERIA***—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 Appendix C for full criteria.)

B. Quantity Limits (QLs)

1. **TIB: Tocilizumab (Actemra)**—QLs currently apply to the TIBs. The P&T Committee evaluated QLs for tocilizumab for treatment of rheumatoid arthritis.

   a) ***COMMITTEE ACTION: TOCILIZUMAB (ACTEMRA) QLs***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) QLs for Actemra (162 mg/0.9 mL), limiting use to 4 pre-filled syringes per 28 days in the Retail Network, and 8 pre-filled syringes per 56 days via Mail Order, consistent with FDA-approved product labeling.

C. Copayment Change

1. **Niacin ER (Niaspan)**—The P&T Committee reviewed pricing for niacin ER (Niaspan). AB-rated generics are available for this product, but the branded product has significantly lower pricing.

   a) ***COMMITTEE ACTION: COPAYMENT CHANGE***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the Tier 1 copayment be assigned for Niaspan.

   b) ***COMMITTEE ACTION: COPAYMENT IMPLEMENTATION PERIOD***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the Tier 1 copayment change for Niaspan become effective upon signing of the minutes.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IV. FY2008 NATIONAL DEFENSE AUTHORIZATION ACT, SECTION 703

A. **Section 703**—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 FY2008 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.

1. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the products listed in Appendix D (listed by manufacturer) be designated nonformulary on the Uniform Formulary.

2. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) the following pre-authorization criteria for the drugs listed as nonformulary in Appendix D: 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.

3. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the drugs listed in Appendix D 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 the these decisions. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

4. ***COMMITTEE ACTION: DRUGS DESIGNATED FORMULARY***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the products listed in Appendix E (listed by manufacturer) be designated with the drug's previous status on the UF because the manufacturer has become compliant with refund requirements.

5. ***COMMITTEE ACTION: REMOVAL OF PRE-AUTHORIZATION CRITERIA*** The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that pre-authorization criteria for the drugs listed in Appendix E be removed because the manufacturer has become compliant with refund requirements.

6. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR UF DESIGNATION AND REMOVAL OF PRE-AUTHORIZATION CRITERIA***—The P&T Committee

recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the formulary designation change and removal of pre-authorization criteria for drugs listed in Appendix E become effective upon signing of the minutes.

REMOVAL OF PRE-AUTHORIZATION CRITERIA
Effective upon my signature, when a manufacturer becomes compliant with FY2008 National Defense Authorization Act, Section 703, the previously imposed pre-authorization criteria are removed.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. SECTION 716 NDAA FY2013 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM

The P&T Committee was briefed on pending legislation requiring TRICARE for Life beneficiaries (≥ 65 years) to obtain refills for maintenance medications for chronic conditions through the TRICARE mail order pharmacy or at MTFs. Beneficiaries would be able to opt out after one year, and waivers would be granted on an individual basis, if deemed appropriate. Waivers would allow refills from the retail pharmacy in certain circumstances, including when necessary due to personal needs or hardship, emergency, or other special circumstances. The pilot program would run through December 31, 2017.

A. Medication Drug List for the Pilot Program

Candidate drugs for the Maintenance Medication Program must meet the following requirements: the medication is prescribed for a chronic, long-term condition; it is clinically appropriate to dispense the medication from the Mail Order Pharmacy; the medication is generally available at MTF pharmacies for initial prescription fill and refills; the medication is available for refill through the Mail Order Pharmacy; and, it is cost effective to dispense from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: MAINTENANCE MEDICATION PROGRAM DRUG LIST***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) the list of covered maintenance medications for the Section 716 pilot program. (See Appendix F.)

B. Manual PA Criteria for Waivers

Manual PA criteria (waivers) allowing for refills at the Retail Network for other

circumstances were discussed by the P&T Committee.

1. ***COMMITTEE ACTION: SECTION 716 MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) PA criteria for maintenance medications for the following circumstances:
    a) Patient resides in a long-term care facility.
    b) Patient has other health insurance.
    c) Patient has barriers to receiving medications by mail (e.g., no permanent address, resides in rural setting).
    d) Patient is not on a stable dose of medication; the medication is currently being titrated.

Note: See Addendum from December 17, 2013, interim meeting.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, D.O., MPH
Lieutenant General, USAF, MC, CFS
Director

10 Feb 2014

Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

November 2013

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 13 and 14, 2013, at the Defense Health Agency (DHA) Pharmacoeconomic Branch, Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August Minutes**—Lt. Gen. Douglas J. Robb D.O.., MPH, Director, DHA , approved the minutes for the August 2013 DoD P&T Committee meeting on November 7, 2013.
2. **Correction to the August 2013 Minutes**—The August minutes were corrected to state the implementation period for the self-monitoring blood glucose test strips will be 180 days, instead of 120 days. The implementation date is May 7, 2014.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

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

Relative Clinical Effectiveness 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.

Relative Cost-Effectiveness Conclusion—A cost minimization analysis (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.

1. ***COMMITTEE ACTION: 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.
2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for alogliptin (Nesina),

alogliptin/metformin (Kazano), and alogliptin/pioglitazone (Oseni). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (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 Appendix C for the full criteria.)

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—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) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

B. Osteoporosis Drugs—Bisphosphonate Subclass: Alendronate Effervescent Tablet (Binosto)

Relative Clinical Effectiveness Conclusion—Effervescent alendronate (Binosto) is a new formulation of alendronate (Fosamax, generics). FDA approval was granted based on demonstrated bioequivalence to Fosamax 70 mg tablets. There are no clinical trials available with Binosto.

The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent):

- Effervescent alendronate (Binosto) may be more convenient for patients by requiring less consumption of water (4 ounces with Binosto versus 6–8 ounces with the other bisphosphonates) and to those patients with swallowing difficulties. It requires the same dosing and administration concerns as the other bisphosphonates.
- 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 drugs.

Relative Cost-Effectiveness 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.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) effervescent alendronate (Binosto) be designated NF.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 1 absent) MN criteria for effervescent alendronate (Binosto). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***
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. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

V. UF DRUG CLASS REVIEWS

A. Short-Acting Beta Agonists (SABAs)

Relative Clinical Effectiveness 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 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 BCF.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 3 absent) that among SABA HFA metered dose inhalers, ProAir HFA was the most cost-effective agent based on the weighted average cost per day of treatment across all three POS, followed by Xopenex HFA, Ventolin HFA, and Proventil HFA. Results from the 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.

1. ***COMMITTEE ACTION: 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.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***— The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 3 absent) that ProAir HFA should be added to the BCF and Ventolin HFA should be removed from the BCF. The P&T Committee also recommended that local Military Treatment Facility (MTF) P&T Committees rapidly convert patients to ProAir HFA and provide patient education on proper inhaler technique.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 3 absent) MN criteria for Proventil HFA, Ventolin HFA, and Xopenex HFA. (See Appendix B for full MN criteria.)

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is May 14, 2014.

B. Benign Prostatic Hyperplasia Agents—5-Alpha Reductase Inhibitors (5-ARIs) Subclass

Relative Clinical Effectiveness Analysis 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. 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.

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.

1. ***COMMITTEE ACTION: 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.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T recommended (15 for, 0 opposed, 1 abstained, 0 absent) that finasteride remain as the designated 5-ARI product on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for dutasteride (Avodart) and dutasteride/tamsulosin (Jalyn). (See Appendix B for the full criteria.)

4. ***COMMITTEE ACTION: 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. (See Appendix C for full PA criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—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. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

VI. UTILIZATION MANAGEMENT

A. PAs

1. **Multiple Sclerosis (MS) Drugs: Dimethyl Fumarate (Tecfidera)**—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.

    a) ***COMMITTEE ACTION: DIMETHYL FUMARATE (TECFIDERA) PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) PA criteria for dimethyl fumarate (Tecfidera) for relapsing forms of MS, and CBC monitoring, consistent with the product labeling. (See Appendix C for full criteria.)

2. **Targeted Immunomodulatory Biologics (TIBs): Certolizumab (Cimzia), Tocilizumab (Actemra), and Ustekinumab (Stelara)**—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.

    a) ***COMMITTEE ACTION: CERTOLIZUMAB (CIMZIA), TOCILIZUMAB (ACTEMRA), AND USTEKINUMAB (STELARA) PA CRITERIA***—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 Appendix C for full criteria.)

B. Quantity Limits (QLs)

1. **TIB: Tocilizumab (Actemra)**—QLs currently apply to the TIBs. The P&T Committee evaluated QLs for tocilizumab for treatment of rheumatoid arthritis.

    a) ***COMMITTEE ACTION: TOCILIZUMAB (ACTEMRA) QLs***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) QLs for Actemra (162 mg/0.9 mL), limiting use to 4 pre-filled syringes per 28 days in the Retail Network, and 8 pre-filled syringes per 56 days via Mail Order, consistent with FDA-approved product labeling.

C. Copayment Change

1. **Niacin ER (Niaspan)**—The P&T Committee reviewed pricing for niacin ER (Niaspan). AB-rated generics are available for this product, but the branded product has significantly lower pricing.

    a) ***COMMITTEE ACTION: COPAYMENT CHANGE***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the Tier 1 copayment be assigned for Niaspan.

    b) ***COMMITTEE ACTION: COPAYMENT IMPLEMENTATION PERIOD***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the Tier 1 copayment change for Niaspan become effective upon signing of the minutes.

VII. FY2008 NATIONAL DEFENSE AUTHORIZATION ACT (NDAA), SECTION 703

A. Section 703—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 FY2008 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.

1. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the products listed in Appendix D (listed by manufacturer) be designated nonformulary on the Uniform Formulary.

2. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) the following pre-authorization criteria for the drugs listed as nonformulary in Appendix D: 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.

3. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the drugs listed in Appendix D 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. Based on the P&T Committee's recommendation, the effective date is April 16, 2014.

4. ***COMMITTEE ACTION: DRUGS DESIGNATED FORMULARY***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the products listed in Appendix E (listed by manufacturer) be designated with the drug's previous status on the UF because the manufacturer has become compliant with refund requirements.

5. ***COMMITTEE ACTION: REMOVAL OF PRE-AUTHORIZATION CRITERIA*** The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that pre-authorization criteria for the drugs listed in Appendix E be removed because the manufacturer has become compliant with refund requirements.

6. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR UF DESIGNATION AND REMOVAL OF PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) that the formulary designation change and removal of pre-authorization criteria for drugs in Appendix E become effective upon signing of the minutes.

   REMOVAL OF PRE-AUTHORIZATION CRITERIA
   Effective upon signature of the Director, DHA, when a manufacturer becomes compliant with FY2008 National Defense Authorization Act, Section 703, the previously imposed pre-authorization criteria are removed.

VIII. SECTION 716 NDAA FY2013 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM

The P&T Committee was briefed on pending legislation requiring TRICARE for Life beneficiaries ($\geq$ 65 years) to obtain refills for maintenance medications for chronic conditions through the TRICARE mail order pharmacy or at MTFs. Beneficiaries would be able to opt out after one year, and waivers would be granted on an individual basis, if deemed appropriate. Waivers would allow refills from the retail pharmacy in certain circumstances, including when necessary due to personal needs or hardship, emergency, or other special circumstances. The pilot program would run through December 31, 2017.

A. Medication Drug List for the Pilot Program

Candidate drugs for the Maintenance Medication Program must meet the following requirements: the medication is prescribed for a chronic, long-term condition; it is clinically appropriate to dispense the medication from the Mail Order Pharmacy; the medication is generally available at MTF pharmacies for initial prescription fill and refills; the medication is

available for refill through the Mail Order Pharmacy; and, it is cost effective to dispense from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: MAINTENANCE MEDICATION PROGRAM DRUG LIST***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) the list of covered maintenance medications for the Section 716 pilot program. (See Appendix F.)

B. Manual PA Criteria for Waivers

Manual PA criteria (waivers) allowing for refills at the Retail Network for other circumstances were discussed by the P&T Committee.

1. ***COMMITTEE ACTION: SECTION 716 MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) PA criteria for maintenance medications for the following circumstances:
   a) Patient resides in a long-term care facility.
   b) Patient has other health insurance.
   c) Patient has barriers to receiving medications by mail (e.g., no permanent address, resides in rural setting).
   d) Patient is not on a stable dose of medication; the medication is currently being titrated.

Note: See Addendum from December 17, 2013, interim meeting.

IX. ITEMS FOR INFORMATION

A. Zolpidem and Gender Dosing—The FDA recommended new dosing guidelines for zolpidem and zolpidem extended release (ER) in January 2013, limiting dosing in females to 5 mg and 6.25 mg, respectively. The new dosing recommendations are based on data showing blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. In February 2013, the P&T Committee recommended monitoring zolpidem prescribing practices in the MHS. A review of zolpidem prescribing in women in the MHS shows that utilization of the lower doses of zolpidem and zolpidem ER in women has increased since January 2013, particularly at the MTFs. The P&T Committee recommended continued monitoring.

B. Acthar Gel PA Implementation Date—PA criteria and a 30-day PA implementation period for Acthar Gel were recommended at the August 2013 Committee meeting. The implementation date will be December 18, 2013.

C. **Points of Service Analysis Update**— The Pharmacy Outcomes Research Team (PORT) updated the P&T Committee on comparative drug costs across all three POS. Data from the third quarter in Fiscal Year (FY) 2013 showed drug costs for branded non-specialty maintenance medications (i.e., medications used for chronic conditions and not specialty medications) would have been lower overall if all prescriptions dispensed in the retail network during that quarter had instead been dispensed at MTFs or in mail order. Higher drug costs for brand medications at retail were primarily responsible for the cost differences. Costs for generically available non-specialty medications would have slightly increased. Fourth quarter results from FY12 are comparable; however, improved availability of generics for widely-used medications at MTFs (e.g., clopidogrel, atorvastatin) and in mail order have generated greater cost avoidance for the MHS in FY2013.

D. **Drug Utilization & Costs**—The PORT reported preliminary results of specialty drug utilization and costs across the MHS. This analysis used a broad list of specialty medications and was adjusted for retail refunds. Specialty medications accounted for about 19% of expenditures in FY2013, but fewer than 1% of total 30-day equivalent prescriptions. Prescriptions dispensed from the retail network accounted for about 66% of specialty medication spend, followed by MTFs (18%), and mail order (16%). Top specialty classes by total cost included oral oncologic agents, TIBs, and MS agents. The PORT also reported total FY2013 expenditures for the top 25 drugs and drug classes by cost, across both specialty and non-specialty agents.

E. **Specialty Care Medications**—The P&T Committee was briefed on potential options for utilization management for specialty medications. The list of specialty medications for inclusion in specialty care programs is in the process of being updated, and will be presented at a future meeting.

F. **Bulk Chemicals in Compounded Medications**—The P&T Committee was presented with an update on the status of bulk chemicals in compounded medications. Future updates will be provided when a final recommendation is available.

X. ADJOURNMENT

The meeting adjourned at 1145 hours on November 14, 2013. The next meeting will be in February 2014.

Appendix A—Attendance: November 2013 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Drugs Designated Nonformulary due to Section 703

Appendix E—Table of Drugs Returned to Uniform Formulary due to Section 703

Appendix F—Section 716 Maintenance Medication Program Drug List

Appendix G—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix H—Table of Abbreviations

Appendix A—Attendance: November 2013 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
LTC Robert Conrad, MS	Chief, DHA Pharmacoeconomic Branch (Recorder)
CDR Joseph Lawrence, MSC for Col George Jones, BSC	Deputy Chief, DHA Pharmacy Operations Division
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
Col Michael Wynn, MC	Army, Family Practice Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Rep
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
LTC Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Maj Temple Ratcliff, MC for Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Paul Hutter for Mr. David Hurt	Associate General Counsel, DHA
Capt Richard Caballero, via DCO	Defense Logistics Agency Troop Support
Guests	
Mr. Bill Davies via DCO	Defense Health Agency, Pharmacy Operations Division
CDR Matthew Baker via DCO	Indian Health Service

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	DHA Pharmacoeconomic Branch
LCDR Marisol Martinez, USPHS	DHA Pharmacoeconomic Branch
LCDR Joshua Devine, USPHS	DHA Pharmacoeconomic Branch
LCDR Linh Quach, MSC	DHA Pharmacoeconomic Branch
Maj David Folmar, BSC	DHA Pharmacoeconomic Branch
MAJ Misty Cowan, MC	DHA Pharmacoeconomic Branch
Dr. David Meade	DHA Pharmacoeconomic Branch
Dr. Angela Allerman	DHA Pharmacoeconomic Branch
Dr. Shana Trice	DHA Pharmacoeconomic Branch
Dr. Dean Valibhai	DHA Pharmacoeconomic Branch
Dr. Jeremy Briggs	DHA Pharmacoeconomic Branch
Dr. Brian Beck	DHA Pharmacoeconomic Branch
Dr. Amy Lugo	DHA Pharmacoeconomic Branch
LT Kendra Jenkins, USPHS, via DCO	DHA Pharmacy Operations Division
Ms. Deborah Garcia	DHA Pharmacoeconomic Branch contractor
Dr. Esmond Nwokeji	DoD Pharmacoeconomic Branch contractor
Mr. Kirk Stocker	DoD Pharmacoeconomic Branch contractor
Maj Ellen Roska, BSC	University of Texas PhD student
Andrew Delgado	University of Texas Health Science Center/University of Texas College of Pharmacy student
Roderick Sanchez	University of Incarnate Word, Feik School of Pharmacy student
Ankita Patel	University of Incarnate Word, Feik School of Pharmacy student
James Flink	University of Incarnate Word, Feik School of Pharmacy student

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Alogliptin (Nesina) • Alogliptin/metformin (Kazano) • Alogliptin/pioglitazone (Oseni) **Dipeptidyl-Peptidase-4 (DPP-4) Inhibitors**	• Use of sitagliptin- or linagliptin-containing products is contraindicated. • The patient has experienced significant adverse effects from sitagliptin- or linagliptin-containing products. • There is no alternative formulary agent: the patient requires a thiazolidinedione but cannot take the 2 drugs separately.
• Effervescent alendronate (Binosto) **Osteoporosis Drugs – Bisphosphonates**	• There is no alternative formulary agent: the patient cannot swallow tablets or cannot consume 8oz. of water and has no sodium restrictions.
• Proventil HFA • Ventolin HFA • Xoponex HFA **Short-Acting Beta Agonist Metered Dose Inhalers**	• The patient previously responded to a nonformulary agent and changing to a formulary agent would incur unacceptable risk.
• Dutasteride (Avodart) **BPH Drugs – 5-Alpha Reductase Inhibitors (5-ARI)**	• Use of finasteride is contraindicated (e.g., hypersensitivity). • The patient has experienced significant adverse effects from finasteride.
• Dutasteride/tamsulosin (Jalyn) **BPH Drugs – 5-Alpha Reductase Inhibitors (5-ARI)**	• Use of finasteride is contraindicated (e.g., hypersensitivity) and the patient requires therapy with both an alpha-1 receptor blocker (A1B) and 5-ARI. • The patient has experienced significant adverse effects from finasteride, and requires therapy with both an A1B and 5-ARI. • There is no alternative formulary agent: the patient is unable to take finasteride (due to contraindication or adverse effect), requires therapy with both an A1B and a 5-ARI, and requires a fixed-dose combination due to, for example, swallowing difficulties.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Alogliptin (Nesina) • Alogliptin/metformin (Kazano) • Alogliptin/pioglitazone (Oseni) **Dipeptidyl-Peptidase-4 (DPP-4) Inhibitors**	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.

Drug / Drug Class	Prior Authorization Criteria
• Dutasteride (Avodart) **BPH Drugs – 5-Alpha Reductase Inhibitors (5-ARIs)**	All new and current users of Avodart are required to try finasteride. Automated PA criteria • 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, Avodart is approved (e.g., trial of finasteride is NOT required) if: • Use of generic finasteride is contraindicated (e.g., due to hypersensitivity). • Patient has experienced or is likely to experience significant adverse effects from finasteride.
• Dutasteride/tamsulosin (Jalyn) **BPH Drugs – 5-Alpha Reductase Inhibitors (5-ARIs)**	All new users of Jalyn are required to try finasteride. 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 alpha-1 receptor blocker (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.

Drug / Drug Class	Prior Authorization Criteria
• Dimethyl fumarate (Tecfidera) **Multiple Sclerosis**	Coverage approved for patients with: • Documented diagnosis of relapsing forms of multiple sclerosis (MS). • Complete blood count drawn 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.
• Certolizumab (Cimzia) **Targeted Immunomodulatory Biologics (TIBs)**	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) **Targeted Immunomodulatory Biologics (TIBs)**	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) **Targeted Immunomodulatory Biologics (TIBs)**	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

Appendix D—Table of Drugs Designated Nonformulary due to Section 703

The drugs below are designated NF on the UF and pre-authorization is assigned.

Manufacturer	Drugs
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

Appendix E—Table of Drugs Returned to Uniform Formulary due to Section 703

The drugs below, except where noted, are returned to formulary status on the UF and pre-authorization is removed.

Manufacturer	Drugs
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

Appendix F—Section 716 Maintenance Medication Program Drug List

5-ALPHA-REDUCTASE INHIBITORS
JALYN
PROSCAR
ADRENALS
CORTEF
ALKALINIZING AGENTS
UROCIT-K
ALPHA-ADRENERGIC AGONISTS (EENT)
ALPHAGAN P
COMBIGAN
ALPHA-ADRENERGIC BLOCKING AGENT(SYMPATH)
FLOMAX
UROXATRAL
ALPHA-ADRENERGIC BLOCKING AGENTS
CARDURA
MINIPRESS
ALPHA-GLUCOSIDASE INHIBITORS
GLYSET
PRECOSE
AMINOGLYCOSIDES
TOBI
AMMONIA DETOXICANTS
KRISTALOSE
AMYLINOMIMETICS
SYMLIN
SYMLINPEN 120
SYMLINPEN 60
ANGIOTENSIN II RECEPTOR ANTAGONISTS
ATACAND
ATACAND HCT
AVALIDE
AVAPRO
BENICAR
BENICAR HCT
COZAAR
DIOVAN
DIOVAN HCT
EDARBI
EDARBYCLOR
DOPAMINE RECEPTOR AGONISTS
MIRAPEX
MIRAPEX ER
NEUPRO
REQUIP
REQUIP XL
EENT ANTI-INFLAMMATORY AGENTS, MISC.
RESTASIS
EENT DRUGS, MISCELLANEOUS
IOPIDINE
ESTROGEN AGONIST-ANTAGONISTS
EVISTA
ESTROGENS
ACTIVELLA
ALORA
ANGELIQ
CENESTIN
CLIMARA
CLIMARA PRO
COMBIPATCH
DIVIGEL
ELESTRIN
ENJUVIA
ESTRACE
ESTRADERM
ESTRASORB
ESTRING
ESTROGEL
FEMHRT
FEMRING
FEMTRACE
MENEST
MENOSTAR
MINIVELLE
PREFEST
PREMARIN
PREMPHASE
PREMPRO
VAGIFEM

ANGIOTENSIN II RECEPTOR ANTAGONISTS
HYZAAR
MICARDIS
MICARDIS HCT
TEVETEN
TEVETEN HCT
TWYNSTA
ANGIOTENSIN-CONVERTING ENZYME INHIBITORS
ACCUPRIL
ACCURETIC
ACEON
ALTACE
LOTENSIN
LOTENSIN HCT
MAVIK
PRINIVIL
TARKA
UNIRETIC
UNIVASC
VASERETIC
VASOTEC
ZESTORETIC
ZESTRIL
ANTIARRHYTHMIC AGENTS
CORDARONE
MULTAQ
NORPACE
NORPACE CR
RYTHMOL
RYTHMOL SR
TAMBOCOR
ANTICOAGULANTS
ARIXTRA
FRAGMIN
LOVENOX
PRADAXA
ANTIDEPRESSANTS
CELEXA
EFFEXOR XR
LEXAPRO
LUVOX CR
MARPLAN

ESTROGENS
VIVELLE-DOT
FIBRIC ACID DERIVATIVES
ANTARA
FENOGLIDE
FIBRICOR
LIPOFEN
LOFIBRA
LOPID
TRICOR
TRIGLIDE
TRILIPIX
HEMATOPOIETIC AGENTS
ARANESP
EPOGEN
LEUKINE
NEULASTA
NEUMEGA
NEUPOGEN
PROCRIT
HEMORRHEOLOGIC AGENTS
TRENTAL
HISTAMINE H2-ANTAGONISTS
AXID
PEPCID
ZANTAC
ZANTAC 25
HMG-COA REDUCTASE INHIBITORS
ADVICOR
ALTOPREV
CADUET
CRESTOR
LESCOL
LESCOL XL
LIPITOR
MEVACOR
PRAVACHOL
SIMCOR
ZOCOR
IMMUNOMODULATORY AGENTS
AVONEX
AVONEX ADMINISTRATION PACK

ANTIDEPRESSANTS
NARDIL
PARNATE
PAXIL
PEXEVA
PROZAC
VENLAFAXINE HCL ER
WELLBUTRIN
WELLBUTRIN SR
WELLBUTRIN XL
ZOLOFT
ANTIGOUT AGENTS
ULORIC
ZYLOPRIM
ANTI-INFLAMMATORY AGENTS (GI DRUGS)
APRISO
ASACOL HD
CANASA
DIPENTUM
LIALDA
LOTRONEX
PENTASA
DELZICOL
ANTILIPEMIC AGENTS, MISCELLANEOUS
LOVAZA
NIASPAN
ANTIMUSCARINICS
DETROL
DETROL LA
DITROPAN XL
SANCTURA
SANCTURA XR
VESICARE
ANTIMUSCARINICS/ANTISPASMODICS
ATROVENT HFA
CUVPOSA
SPIRIVA
ANTIMYCOBACTERIALS, MISCELLANEOUS
DAPSONE
ANTIRETROVIRALS
FUZEON
ANTITHYROID AGENTS
TAPAZOLE

IMMUNOMODULATORY AGENTS
AVONEX PEN
BETASERON
COPAXONE
REBIF
INCRETIN MIMETICS
BYDUREON
BYETTA
VICTOZA 2-PAK
VICTOZA 3-PAK
INSULINS
APIDRA
APIDRA SOLOSTAR
HUMALOG
HUMALOG MIX 50-50
HUMALOG MIX 75-25
HUMULIN 70-30
HUMULIN N
LANTUS
LANTUS SOLOSTAR
LEVEMIR
NOVOLIN 70-30
NOVOLIN N
NOVOLOG
NOVOLOG FLEXPEN
NOVOLOG MIX 70-30
NOVOLOG MIX 70-30 FLEXPEN
INTERFERONS
INTRON A
PEGASYS
PEGINTRON
PEGINTRON REDIPEN
LEUKOTRIENE MODIFIERS
ACCOLATE
SINGULAIR
LOOP DIURETICS
DEMADEX
EDECRIN
LASIX
MEGLITINIDES
PRANDIMET
PRANDIN
STARLIX

BETA-ADRENERGIC AGONISTS
- ARCAPTA NEOHALER
- BROVANA
- SEREVENT DISKUS
- VOSPIRE ER

BETA-ADRENERGIC BLOCKING AGENTS
- BETAPACE
- BETAPACE AF
- COREG
- COREG CR
- CORGARD
- CORZIDE
- DUTOPROL
- INDERAL LA
- INNOPRAN XL
- KERLONE
- LEVATOL
- LOPRESSOR
- LOPRESSOR HCT
- SECTRAL
- TENORETIC 100
- TENORETIC 50
- TENORMIN
- TOPROL XL
- TRANDATE
- ZEBETA
- ZIAC

BETA-ADRENERGIC BLOCKING AGENTS (EENT)
- BETAGAN
- BETOPTIC S
- OPTIPRANOLOL
- TIMOPTIC
- TIMOPTIC OCUDOSE
- TIMOPTIC-XE

BIGUANIDES
- GLUCOPHAGE
- GLUCOPHAGE XR
- RIOMET

BILE ACID SEQUESTRANTS
- COLESTID
- QUESTRAN

MINERALOCORTICOID (ALDOSTERONE) ANTAGNTS
- ALDACTAZIDE
- ALDACTONE
- INSPRA

MIOTICS
- ISOPTO CARBACHOL
- ISOPTO CARPINE
- PHOSPHOLINE IODIDE
- PILOPINE HS

MONOAMINE OXIDASE B INHIBITORS
- AZILECT
- ELDEPRYL
- ZELAPAR

MUCOLYTIC AGENTS
- PULMOZYME

MYDRIATICS
- CYCLOGYL
- CYCLOMYDRIL
- ISOPTO ATROPINE
- ISOPTO HOMATROPINE
- ISOPTO HYOSCINE
- MYDRIACYL

NITRATES AND NITRITES
- DILATRATE-SR
- IMDUR
- ISOCHRON
- ISORDIL
- ISORDIL TITRADOSE
- MINITRAN
- MONOKET
- NITRO-DUR

NONSTEROIDAL ANTI-INFLAMMATORY AGENTS
- ANAPROX
- ANAPROX DS
- ARTHROTEC 50
- ARTHROTEC 75
- BUTALBITAL-ASPIRIN-CAFFEINE
- CELEBREX
- CLINORIL
- DAYPRO
- EC-NAPROSYN

BILE ACID SEQUESTRANTS
- QUESTRAN LIGHT

BONE RESORPTION INHIBITORS
- ACTONEL
- BONIVA
- DIDRONEL
- FOSAMAX
- FOSAMAX PLUS D
- SKELID

CALCIUM-CHANNEL BLOCKING AGENTS, MISC.
- CALAN
- CALAN SR
- CARDIZEM
- CARDIZEM CD
- DILACOR XR
- ISOPTIN SR
- TIAZAC

CARBONIC ANHYDRASE INHIBITORS (EENT)
- COSOPT
- COSOPT PF
- DIAMOX SEQUELS
- NEPTAZANE
- TRUSOPT

CARDIAC DRUGS, MISCELLANEOUS
- RANEXA

CARDIOTONIC AGENTS
- LANOXIN

CATECHOL-O-METHYLTRANSFERASE (COMT) INHIBITORS
- COMTAN
- TASMAR

CENTRAL ALPHA-AGONISTS
- CATAPRES
- CATAPRES-TTS 1
- CATAPRES-TTS 2
- CATAPRES-TTS 3
- CLORPRES
- NEXICLON XR
- TENEX

NONSTEROIDAL ANTI-INFLAMMATORY AGENTS
- FELDENE
- MOBIC
- NALFON
- NAPROSYN
- VIMOVO
- VOLTAREN
- VOLTAREN-XR

NUCLEOSIDES AND NUCLEOTIDES
- COPEGUS
- REBETOL

OTHER MISCELLANEOUS THERAPEUTIC AGENTS
- CARNITOR
- POTABA

PARASYMPATHOMIMETIC (CHOLINERGIC AGENTS)
- ARICEPT
- ARICEPT ODT
- EVOXAC
- EXELON
- MESTINON
- RAZADYNE
- RAZADYNE ER

PARATHYROID
- FORTEO

PITUITARY
- DDAVP
- NORDITROPIN FLEXPRO
- NORDITROPIN NORDIFLEX
- NUTROPIN
- NUTROPIN AQ
- NUTROPIN AQ NUSPIN
- SAIZEN
- STIMATE
- TEV-TROPIN

PLATELET-AGGREGATION INHIBITORS
- BRILINTA
- EFFIENT
- PLAVIX
- PLETAL

CENTRAL NERVOUS SYSTEM AGENTS, MISC.
LODOSYN
ZANAFLEX
CHOLELITHOLYTIC AGENTS
ACTIGALL
URSO
URSO FORTE
CHOLESTEROL ABSORPTION INHIBITORS
VYTORIN
ZETIA
CORTICOSTEROIDS (RESPIRATORY TRACT)
ADVAIR DISKUS
ADVAIR HFA
ASMANEX
DULERA
FLOVENT DISKUS
FLOVENT HFA
PULMICORT
SYMBICORT
DIHYDROPYRIDINES
ADALAT CC
AZOR
EXFORGE
EXFORGE HCT
LOTREL
NORVASC
PROCARDIA
PROCARDIA XL
DIPEPTIDYL PEPTIDASE-4(DPP-4) INHIBITORS
JANUMET
JANUMET XR
JANUVIA
JENTADUETO
DIRECT VASODILATORS
BIDIL
PROGLYCEM
DIRECT-ACTING SKELETAL MUSCLE RELAXANTS
DANTRIUM
POTASSIUM-SPARING DIURETICS
DYAZIDE
DYRENIUM
MAXZIDE
MAXZIDE-25 MG
MIDAMOR
PROGESTINS
AYGESTIN
PROMETRIUM
PROVERA
PROSTAGLANDIN ANALOGS
LUMIGAN
XALATAN
PROSTAGLANDINS
CYTOTEC
PROTECTANTS
CARAFATE
PROTON-PUMP INHIBITORS
NEXIUM
PRILOSEC
PRILOSEC OTC
PROTONIX
ZEGERID OTC
RENIN INHIBITORS
AMTURNIDE
TEKTURNA
TEKTURNA HCT
VALTURNA
REPLACEMENT PREPARATIONS
EFFER-K
KLOR-CON
K-TAB
MICRO-K
RESPIRATORY SMOOTH MUSCLE RELAXANTS
DILEX-G 200
DILEX-G 400
ELIXOPHYLLIN
LUFYLLIN
LUFYLLIN-GG
THEO-24

DOPAMINE PRECURSORS PARCOPA SINEMET 10-100 SINEMET 25-100 SINEMET 25-250 SINEMET CR STALEVO 100 STALEVO 125 STALEVO 150 STALEVO 200 STALEVO 50 STALEVO 75	**SOMATOSTATIN AGONISTS** SANDOSTATIN SANDOSTATIN LAR **SULFONAMIDES (SYSTEMIC)** AZULFIDINE **SULFONYLUREAS** AMARYL DIABETA GLUCOTROL GLUCOTROL XL GLUCOVANCE GLYNASE METAGLIP
VITAMIN D HECTOROL ROCALTROL ZEMPLAR **VASODILATING AGENTS, MISCELLANEOUS** AGGRENOX PERSANTINE **VITAMIN B COMPLEX** NASCOBAL **PHOSPHODIESTERASE-5 INHIBITORS** VIAGRA	**THIAZIDE DIURETICS** DIURIL MICROZIDE **THIAZIDE-LIKE DIURETICS** THALITONE ZAROXOLYN **THIAZOLIDINEDIONES** ACTOPLUS MET ACTOPLUS MET XR ACTOS DUETACT
PLATELET-REDUCING AGENTS AGRYLIN	**THYROID AGENTS** ARMOUR THYROID CYTOMEL SYNTHROID THYROLAR-1 THYROLAR-1/2 THYROLAR-1/4 THYROLAR-2 THYROLAR-3 TIROSINT

Appendix G—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2013	**Short-Acting Beta Agonists** **Metered Dose Inhalers**	UF Class review Previously reviewed	▪ ProAir HFA	▪ None (ProAir HFA BCF)	▪ Proventil HFA ▪ Ventolin HFA ▪ levalbuterol (Xopenex HFA)	Pending signing of the minutes / 90 days	Quantity Limits apply see Formulary Search Tool	▪ None
May 2013	**Benign Prostatic Hypertrophy Drugs** **5-Alpha Reductase Inhibitor Subclass**	UF class review	▪ finasteride	▪ None (finasteride BCF)	▪ dutasteride (Avodart) ▪ dutasteride/tamsulosin (Jalyn)	Pending signing of the minutes / 60 days	Step therapy required – see comments	▪ Must try finasteride before Avodart in all new and current users; and, ▪ Must try finasteride before Jalyn in all new users. (See Appendix C)
Nov 2013	**Non-Insulin Diabetes Drugs** **DPP-4 Inhibitors Subclass** Previous reviews: Feb 2012, Aug 2012,and Aug 2013	New Drug in Already Reviewed Class alogliptin (Nesina) alogliptin/ metformin (Kazano) alogliptin/ pioglitazone (Oseni)	No change from previous review ▪ sitagliptin (Januvia) ▪ sitagliptin/metformin (Janumet) ▪ sitagliptin/ metformin ER (Janumet XR)	No change from previous review ▪ linagliptin (Tradjenta) ▪ linagliptin/metformin IR (Jentadueto) ▪ sitagliptin/simvastatin (Juvisync)	*Nov 2013* ▪ **alogliptin (Nesina)** ▪ **alogliptin/metformin (Kazano)** ▪ **alogliptin/pioglitazone (Oseni)** *Aug 2013* ▪ saxagliptin (Onglyza) ▪ saxagliptin/metformin ER (Kombiglyze XR)	Pending signing of minutes/ 60 days	Step therapy required – see comments	▪ Must try metformin and sulfonylurea first before any DPP-4 drug ▪ Must try sitagliptin-containing product first before Nesina, Kazano, Oseni, Tradjenta, Jentadueto, Onglyza, or Kombiglyze XR (See Appendix C)

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2013	**Osteoporosis Drugs** **Bisphosphonates Subclass** Previous review: June 2008, Nov 2011	New Drug in Already Reviewed Class	No change from previous review June 2008 ▪ alendronate ▪ alendronate with vitamin D ▪ ibandronate	No change from previous review June 2008 ▪ alendronate ▪ alendronate with vitamin D ▪ ibandronate ▪ risedronate IR (Actonel) ▪ risedronate IR with calcium (Actonel with Calcium)	*Nov 2013* ▪ **effervescent alendronate (Binosto)** Nov 2011 ▪ risedronate delayed release (Atelvia)	Pending signing of minutes/ 60 days	-	▪ None ▪ Section 703 drug-see Appendix E

TRICARE Formulary Search tool: http://www.pec.ha.osd.mil/formulary_search.php

Appendix H—Table of Abbreviations

5-ARIs	5-alpha reductase inhibitors
A1B	alpha-1 blocker
AS	ankylosing spondylitis
ASD(HA)	Assistant Secretary of Defense for Health Affairs
BCF	Basic Core Formulary
BIA	budget impact analysis
BPH	benign prostatic hypertrophy
CBC	complete blood count
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
DCO	Defense Connect Online
DHA	Defense Health Agency
DoD	Department of Defense
DPP-4	dipeptidyl peptidase-4 inhibitors
EIB	exercise-induced bronchospasm
ER	extended release
FDA	U.S. Food and Drug Administration
HbA1c	hemoglobin A1c- lowering
HFA	hydrofluoroalkane
MDIs	metered-dose inhalers
MHS	Military Health System
MN	medical necessity
MS	multiple sclerosis
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NF	nonformulary
P&T	Pharmacy and Therapeutics
PA	prior authorization
PORT	Pharmacy Outcomes Research Team
POS	points of service
PsA	psoriatic arthritis
QLs	quantity limits
SABAs	short-acting beta agonists
TIBs	targeted immunomodulatory biologics
TZD	thiazolidinedione
UF	Uniform Formulary

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

August 2013

Second Addendum

I. UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS—Self-Monitoring Blood Glucose System (SMBGS) Test Strips

The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips at the May 2013 P&T Committee meeting. The cost effectiveness, UF recommendation, Basic Core Formulary (BCF) recommendation, Prior Authorization (PA) criteria, Medical Necessity (MN) criteria, quantity limits (QLs), and implementation period were presented at the August 2013 P&T Committee meeting. An implementation period for the final decisions of 180 days, effective May 7, 2014, was approved by the Director, DHA, on November 7, 2013.

All steps necessary for implementation of the SMBGS test strips decisions were delayed 100 days, due to a GAO protest, which was dismissed on March 5, 2014. Due to the delay, the implementation period was extended to August 6, 2014, to allow for adequate time for DHA to send a letter to beneficiaries affected by the UF and PA decisions. Following dismissal of the GAO protest, a protest was filed in the Court of Federal Claims (CoFC). That protest has not yet been resolved and is not expected to be resolved until on or after August 20, 2014. Therefore, the effective date for implementation of the final SMBGS test strips decisions is postponed indefinitely, pending resolution of the CoFC protest. All steps necessary for implementation of the SMBG test strip decision remain on hold.

There is no change to the other decisions for the SMBGS test strips.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

31 Jul 2014
Date

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

August 2013

Addendum

I. UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS—Self-Monitoring Blood Glucose System (SMBGS) Test Strips

The Pharmacy and Therapeutics (P&T) Committee reviewed the clinical effectiveness of the SMBGS test strips at the May 2013 P&T Committee meeting. The cost effectiveness, Uniform Formulary (UF) recommendation, Basic Core Formulary (BCF) recommendation, Prior Authorization (PA) criteria, Medical Necessity (MN) criteria, quantity limits (QLs), and implementation period were presented at the August 2013 P&T Committee meeting. An implementation period for the final decisions of 180 days, effective May 7, 2014, was approved by the Director, DHA, on November 7, 2013.

All steps necessary for implementation of the SMBGS test strips decisions were delayed 100 days, due to a GAO protest, which was dismissed on March 5, 2014. Due to the delay, the implementation period is extended to August 6, 2014, to allow for adequate time for DHA to implement the decisions and to send a letter to beneficiaries affected by the UF and PA decisions. There is no change to the other decisions for the SMBGS test strips.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

29 Apr 2014
Date

DECISION PAPER

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

August 2013

I. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. Corticosteroid Immune Modulators (Topical Steroids)

Background and Relative Clinical Effectiveness Conclusion—The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee evaluated the Corticosteroid Immune Modulators (Topical Steroids) Drug Class. The drugs were categorized into high- (classes 1 and 2), medium- (classes 3, 4, and 5), and low-potency agents (classes 6 and 7). Appendix B lists all products in the Topical Steroids Drug Class and their respective potency classifications, formulations, and generic availability.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the following conclusions:

- There is very limited generalizable data for all of the topical steroids. Heterogeneity of the data precludes direct and indirect comparisons. A product formulated for hair (e.g., foam, shampoo) from each potency class is desirable for inclusion on the UF.
- Safety issues are considered class effects.
- A Coopman Class C product (e.g., desoximetasone, clocortolone) is less likely to cause an allergic response, compared with Coopman Classes A (hydrocortisone, hydrocortisone acetate) and D1 (clobetasol, betamethasone, diflurasone, fluticasone, mometasone, aclometasone) agents, and is required for inclusion on the UF.
- For the high-potency topical steroids, none of the products offer unique advantages in terms of efficacy or safety over other agents in the high-potency class.
- The medium-potency topical steroid Pediaderm TA combination product co-packages triamcinolone with an emollient vehicle. There are no compelling advantages to using the co-packaged product versus using triamcinolone and a comparable emollient sold separately.

- For the low-potency topical steroids, there is no evidence to support clinically meaningful differences in efficacy or safety among the agents.
  - The Pediaderm HC combination product co-packages hydrocortisone with an emollient vehicle. There are no compelling advantages to using the co-packaged product versus using hydrocortisone and a comparable emollient sold separately.
  - Desonate Gel, Verdeso Foam, and Capex Shampoo all remain uniquely branded, without clinical advantages over the other generic low-potency topical steroids

Relative Cost-Effectiveness Conclusion—A pharmacoeconomic analysis, including cost minimization analysis (CMA), was performed for the topical steroids within each potency class (high, medium, and low). CMA results showed that designating cost-effective agents from within each potency class as formulary on the UF yielded the most cost-effective results for the MHS.

The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 1 absent) that, for each topical steroid potency class, there were specific agents, strengths, and dosage forms determined to be cost-effective based on the weighted average cost per day of treatment across all three points of service (POS).

1. ***COMMITTEE ACTION: UNIFORM FORMULARY (UF) RECOMMENDATION***—The P&T Committee recommended (9 for, 3 opposed, 1 abstained, 1 absent) all topical steroid products be designated formulary on the UF, with the exception of the products listed below that are designated nonformulary (NF) (See Appendix H):
   - **Nonformulary High Potency products:** amcinonide 0.1% ointment (Cyclocort, generics); diflorasone 0.05% cream and ointment (Apexicon, generics); fluocinonide 0.1% cream (Vanos); halcinonide 0.1% cream and ointment (Halog);
   - **NF Medium Potency products:** amcinonide 0.1% cream and lotion (Cyclocort, generics); betamethasone valerate 0.12% foam (Luxiq, generics); clocortolone 0.1% cream (Cloderm); desonide 0.05% lotion (Desowen, generics); hydrocortisone probutate 0.1% cream (Pandel); hydrocortisone butyrate 0.1% cream and lotion (Locoid); triamcinolone with emollient #45, 0.1% cream kit (Pediaderm TA);
   - **NF Low Potency Products:** desonide 0.05% foam (Verdeso) and 0.05% gel (Desonate); fluocinolone 0.01% shampoo (Capex);

hydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC).

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) maintaining fluocinonide 0.05% cream and triamcinolone acetate 0.1% cream on the BCF. Additionally, the P&T Committee recommended adding fluocinonide 0.05% ointment, clobetasol 0.05% cream, clobetasol 0.05% ointment, and triamcinolone acetate 0.1% ointment to the BCF.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for all topical steroids that were designated as NF. (See Appendix D for full MN criteria.)

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (12 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) TMA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

Director, DHA, Decision:  ☒Approved ☐ Disapproved

Approved, but modified as follows:

B. Self-Monitoring Blood Glucose System (SMBGS) Test Strips

Background and Relative Clinical Effectiveness—The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips. Appendix C lists the products in the SMBGS Test Strips Drug Class. Candidates for inclusion on the UF met all minimum required technical standards and U.S. Federal Government contracting requirements.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following for the SMBGS test strips.

- *U.S. Federal Government contracting requirements*: SMBGS test strips eligible for inclusion on the UF must be available at all three POS and must be compliant with the Trade Agreements Act. Corresponding SMBGS glucometers must also

be compliant with the Trade Agreements Act. Manufacturers of SMBGS glucometers will be required to provide DoD beneficiaries with a no-cost glucometer.

- *Minimum technical requirements*: Candidate SMBGS test strips eligible for inclusion on the UF must meet minimum technical requirements in the areas of accuracy, sample size, alternate site testing, result time, memory capacity, ease of use, customer support, downloading capabilities, and data management capabilities. See pages 15-16 for detailed technical requirements. During the August 2013 meeting, newly proposed ISO standards were presented to the P&T Committee. However, the current 2003 ISO 15197 standard remains effective and there is no change regarding this minimum technical requirement.
- *SMBG strips meeting the final technical and U.S. Federal Government contracting requirements*: The SMBG test strips meeting the final technical and U.S. Federal Government contracting requirements are FreeStyle Lite (Abbott), FreeStyle InsuLinx (Abbott), Precision Xtra (Abbott); ACCU-CHEK Aviva Plus (Roche); CONTOUR NEXT (Bayer); TRUEtest (Nipro Diagnostics); Nova Max (Nova); Glucocard 01-Sensor (Arkray), Glucocard Vital (Akray); and Prodigy No Coding (Prodigy).
- *Overall relative clinical effectiveness conclusion:* The Committee concluded that any of the 10 final SMBGS test strip candidates were acceptable for inclusion on the UF. There are no clinically relevant differences between the 10 SMBGS test strips meeting the final technical and U.S. Federal Government contracting requirements set forth by the P&T Committee.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 2 absent) the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) were the most cost-effective SMBGS products, based on the weighted average cost per strip across all three POS, followed by (ranked in order from most cost effective to least cost effective) Arkray (GLUCOCARD 01-SENSOR, GLUCOCARD Vital), Bayer (CONTOUR NEXT), Nipro (TRUEtest), Roche (ACCU-CHEK Aviva Plus), Prodigy (Prodigy No Coding), and Nova (Nova Max) products.

Among the formulary options evaluated, CMA and budget impact analysis (BIA) results showed the most cost-effective scenario designated Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) as the UF step-preferred test strip "suite" with all other SMBGS test strips designated NF and non-preferred, where all current and new users are required to first try an Abbott test strip.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) the following:
    - Formulary and step-preferred on the UF:
        - Precision Xtra (Abbott)
        - FreeStyle Lite (Abbott)
        - FreeStyle InsuLinx (Abbott)
    - Nonformulary and non-step preferred on the UF:
        - ACCU-CHEK Aviva Plus (Roche)
        - GLUCOCARD 01-Sensor (Arkray)
        - GLUCOCARD Vital (Arkray)
        - CONTOUR NEXT (Bayer)
        - NovaMax (Nova)
        - TRUEtest (Nipro Diagnostics)
        - Prodigy No Coding (Prodigy)
        - One Touch Verio
        - One Touch Ultra
        - All other test strips listed in Appendix C (with the exception of FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra)
    - This recommendation includes step therapy, which requires a trial of one of the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra) prior to use of a nonformulary test strip in all current and new users of a nonformulary test strip.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) designating FreeStyle Lite (Abbott) with BCF status, based on clinical and cost-effectiveness, and removing Precision Xtra (Abbott) from the BCF. Note: Precision Xtra (Abbott) is designated with Uniform Formulary status and is step-preferred on the UF.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1abstained, 1 absent) manual PA criteria for all new and current users of a nonformulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a nonformulary SMBG test strip. (See Appendix E for full criteria).

4 ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs/days

supply limits for the SMBGS test strips, limiting use to 150 strips/30-day supply in the Retail Network, and 450 strips/90-day supply via Mail Order.

5. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for the NF SMBGS test strips. (See Appendix D for full MN criteria.)

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD*** The P&T Committee recommended (11 for, 1 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is March 12, 2014.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

Considering the comments of the Beneficiary Advisory Panel, implementation period is 180 days. Effective date is May 7, 2014.

II. UTILIZATION MANAGEMENT

A. Prior Authorizations

1. **Injectable Corticotropin (HP Acthar Gel)**— The P&T Committee established manual PA criteria for all new and current users of HP Acthar Gel, limiting use to infantile spasms (West Syndrome) for patients less than 24 months old at initiation of treatment and not previously treated with corticotropin. Additional uses for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies may be permitted on appeal.

   The following uses for Acthar Gel are considered unsupportable: dermatomyositis, polymyositis, psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis), sarcoidosis, serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis.

   a) ***COMMITTEE ACTION: HP ACTHAR GEL PA CRITERIA*** The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) manual PA criteria for all current and new users of HP Acthar

Gel, limiting use to the specific FDA-approved indication of infantile spasms (West Syndrome). Prior Authorization will expire after 30 days for infantile spasms; retreatment is not covered. Use for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies will be on appeal only. Other uses of HP Acthar Gel are considered unsupportable and not covered. (See Appendix E for full criteria.)

b) ***COMMITTEE ACTION: HP ACTHAR GEL PA IMPLEMENTATION***—The P&T Committee recommended (8 for, 3 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 30-day implementation period in all POS; and 2) TMA send a letter to beneficiaries affected by this PA decision. Based on the P&T Committee's recommendation, the effective date is December 11, 2013.

2. **Doxylamine/Pyridoxine (Diclegis)**—Diclegis contains 10 mg of doxylamine and 10 mg of pyridoxine and is FDA-approved for treating pregnant women experiencing nausea and vomiting.

   a) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (DICLEGIS) PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) that manual PA criteria apply to new users of Diclegis who are being treated for nausea and vomiting during pregnancy. The PA will expire after nine months. (See Appendix E for full criteria.)

   b) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (DICLEGIS) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

3. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara) and Golimumab (Simponi)**—PA criteria currently apply to the Targeted Immunomodulatory Biologics (TIBs). Ustekinumab 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 plaque psoriasis. Also, the FDA recently approved a new indication for golimumab for treatment of moderate to severe ulcerative colitis.

a) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI) PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) PA criteria for ustekinumab for plaque psoriasis and golimumab for ulcerative colitis, consistent with the products' labeling. (See Appendix E for full criteria.)

b) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

B. Quantity Limits

1. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara) and Golimumab (Simponi)**—QLs currently apply to the TIBs. The P&T Committee evaluated QLs for ustekinumab for the new indication of plaque psoriasis for patient self administration, and for golimumab for the new indication of ulcerative colitis.

   a) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI) QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for Stelara and Simponi, as outlined in Appendix F, consistent with FDA-approved product labeling.

2. **Oral Chemotherapy Drugs: Dabrafenib (Tafinlar), Trametinib (Mekinist), and Afatinib (Glotrif)**—The P&T Committee evaluated QLs for several oral chemotherapy drugs, including dabrafenib (Tafinlar), indicated for treatment of treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations; trametinib (Mekinist) for treatment of unresectable or metastatic melanoma with BRAF V600E mutations; and afatinib (Glotrif) for first-line treatment of metastatic non-small cell lung cancer whose tumors have specific mutations. QLs exist for several other oral chemotherapy agents.

   a) ***COMMITTEE ACTION: TAFINLAR, MEKINST, AND GLOTRIF QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for dabrafenib (Tafinlar), trametinib (Mekinist), and afatinib (Glotrif) as outlined in Appendix F, consistent with FDA-approved product labeling.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

III. Fiscal Year 2008 National Defense Authorization Act, Section 703

A. Section 703—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.

1. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) to designate the products in Appendix G (listed by manufacturer) as nonformulary on the Uniform Formulary.

2. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) the following Pre-Authorization Criteria for the drugs listed as nonformulary in Appendix G: 1) obtaining the product from 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.

3. ***COMMITTEE ACTION: UF AND PRE-AUTHORIZATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and 2) TMA send a letter to beneficiaries affected by the these decisions. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

Patriot Pharmaceuticals has now signed a pricing agreement for all of its covered drugs. Qutenza patch and Zyclara cream are also now covered by a pricing agreement. Therefore, the Patriot Pharmaceuticals products listed in Appendix G, Qutenza patch, and Zyclara cream are excluded from this action.

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

7 NOV 2013
Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE MINUTES AND RECOMMENDATIONS

August 2013

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 14 and 15, 2013, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May Minutes**—Jonathon Woodson M.D., Director, TRICARE® Management Activity (TMA), approved the minutes for the May 2013 DoD P&T Committee meeting on August 6, 2013.
2. **Changes to the May 2013 Minutes:**
    a) **Emergency Contraceptives**—The Director's decision was that due to over-the-counter availability of levonorgestrel 1.5 mg (Plan B One-Step) without age restrictions, no emergency contraceptives shall be included on the Basic Core Formulary (BCF). However, Military Treatment Facilities (MTFs) shall carry Plan B One-Step and provide it no cost.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and BCF recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. UF DRUG CLASS REVIEWS

A. Corticosteroid Immune Modulators (Topical Steroids)

Background and Relative Clinical Effectiveness—The P&T Committee evaluated the Corticosteroid Immune Modulators (Topical Steroids) Drug Class. The drug

class is comprised of 22 individual chemical entities, available in over 100 different formulations and vehicles. The Stoughton-Cornell classification system, which divides the drugs into seven classes based on their vasoconstrictive properties, was used to further divide the drugs into high- (classes 1 and 2), medium- (classes 3, 4, and 5), and low-potency agents (classes 6 and 7). Over-the-counter (OTC) products are excluded from the class. Appendix B lists all products in the Corticosteroid Immune Modulators (Topical Steroids) Drug Class and their respective potency classifications, formulations, and generic availability.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the following conclusions:

- For all of the topical steroids, there is very limited generalizable data. Heterogeneity of the data precludes direct and indirect comparisons. A product formulated for hair (e.g., foam, shampoo) from each potency class is desirable for inclusion on the UF.
- Safety issues are considered class effects.
- A Coopman Class C product (e.g., desoximetasone, clocortolone) is less likely to cause an allergic response, compared with Coopman Classes A (hydrocortisone, hydrocortisone acetate) and D1 (clobetasol, betamethasone, diflurasone, fluticasone, mometasone, aclometasone) agents, and is required for inclusion on the UF.
- For the high-potency topical steroids, none of the products offer unique advantages in terms of efficacy or safety over other agents in the high-potency class.
    - Clobetasol is offered in more vehicles and is more extensively studied than the other high-potency products.
    - Fluocinonide was frequently mentioned as required for inclusion on the UF in a survey of Military Health System (MHS) providers.
    - Flurandrenolide tape has several unique therapeutic uses.
    - Clobetasol, halobetasol, augmented betamethasone dipropionate, and fluocinonide 1% cream products have package-labeled weekly exposure limits.
- For the medium-potency topical steroids, the following conclusions were made:
    - Triamcinolone is offered in more vehicles, is more extensively studied, and more frequently mentioned as required for inclusion on the UF in the MHS

provider survey than the other medium-potency agents. It has a modest risk of skin atrophy.

- Triamcinolone (Kenalog Spray) is the only spray product in the medium-potency class.
- The Pediaderm TA combination product co-packages triamcinolone with an emollient vehicle. There are no compelling advantages to using the co-packaged product versus using triamcinolone and a comparable emollient sold separately.
- There is weak evidence that clocortolone may have less risk of hypothalamic-pituitary-adrenal axis suppression than other medium- potency steroids.
- Hydrocortisone butyrate and fluticasone propionate are the only medium-potency agents labeled for use in children as young as three months of age.
- Fluticasone propionate, mometasone, and prednicarbate have the most favorable therapeutic indices among the medium-potency steroids.
- Desonide ointment and lotion, betamethasone valerate, and hydrocortisone valerate were frequently favorably mentioned in the MHS provider survey as required for inclusion on the UF.

- For the low-potency topical steroids, there is no evidence to support clinically meaningful differences in efficacy or safety among the agents.
  - Hydrocortisone was more frequently favorably mentioned in the MHS provider survey than the other low-potency agents.
  - The Pediaderm HC combination product co-packages hydrocortisone with an emollient vehicle. There are no compelling advantages to using the co-packaged product versus using hydrocortisone and a comparable emollient sold separately.
  - Derma-Smoothe/FS, a fluocinolone acetonide shampoo product, has the theoretical risk of inducing a peanut allergy.
  - Desonate Gel, Verdeso Foam, and Capex Shampoo all remain uniquely branded, without clinical advantages over the other generic low-potency topical steroids.

Relative Cost-Effectiveness Analysis and Conclusion—A pharmacoeconomic analysis, including cost minimization analysis (CMA), was performed for the topical steroids within each potency class (high, medium, and low). CMA results showed that designating cost-effective agents from within each potency class as formulary on the UF yielded the most cost-effective results for the MHS.

The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 1 absent) that, for each topical steroid potency class, there were specific agents, strengths, and dosage forms determined to be cost-effective based on the weighted average cost per day of treatment across all three points of service (POS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (9 for, 3 opposed, 1 abstained, 1 absent) all topical steroid products be designated formulary on the UF, with the exception of the products listed below that are designated NF (See Appendix G):

    - **NF High Potency products:** amcinonide 0.1% ointment (Cyclocort, generics); diflorasone 0.05% cream and ointment (Apexicon, generics); fluocinonide 0.1% cream (Vanos); halcinonide 0.1% cream and ointment (Halog);

    - **NF Medium Potency products:** amcinonide 0.1% cream and lotion (Cyclocort, generics); betamethasone valerate 0.12% foam (Luxiq, generics); clocortolone 0.1% cream (Cloderm); desonide 0.05% lotion (Desowen, generics); hydrocortisone probutate 0.1% cream (Pandel); hydrocortisone butyrate 0.1% cream and lotion (Locoid); triamcinolone with emollient #45, 0.1% cream kit (Pediaderm TA);

    - **NF Low Potency products:** desonide 0.05% foam (Verdeso) and 0.05% gel (Desonate); fluocinolone 0.01% shampoo (Capex); hydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC).

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) maintaining fluocinonide 0.05% cream and triamcinolone acetate 0.1% cream on the BCF. Additionally, the P&T Committee recommended adding fluocinonide 0.05% ointment, clobetasol 0.05% cream, clobetasol 0.05% ointment, and triamcinolone acetate 0.1% ointment to the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for all topical steroids that were designated as NF. (See Appendix D for full MN criteria.)

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (12 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) TMA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

B. Self-Monitoring Blood Glucose System (SMBGS) Test Strips

Background and Relative Clinical Effectiveness—The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips, including the attributes of the test strips and glucometers. The SMBGS test strips were previously reviewed for UF placement in August 2008. The primary goal for this review is to ensure uniform availability of quality SMBGS test strips across the MHS (MTF, Retail, and Mail Order POS). SMBGS glucometers are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review; however, provisions have been made to provide SMBGS glucometers at no cost to MHS beneficiaries. Appendix C lists the products in the SMBGS Test Strips Drug Class.

The FDA classifies SMBGS test strips and glucometers as medical devices, rather than drugs, thus the focus of the clinical effectiveness review centers on differences in the technical aspects/attributes among the products. Candidates for inclusion on the UF must meet all minimum required technical standards and U.S. Federal Government contracting requirements. The P&T Committee reviewed the existing technical requirements approved in May 2007, and recommended updates to the criteria.

Relative Clinical Effectiveness Conclusion—The full clinical effectiveness evaluation was presented at the May 2013 P&T Committee meeting. During the May 2013 meeting, the P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following for the minimum technical requirements and U.S. Federal Government contracting requirements for the SMBGS test strips.

- *U.S. Federal Government contracting requirements*: SMBGS test strips eligible for inclusion on the UF must be available at all three POS and must be compliant with the Trade Agreements Act. Corresponding SMBGS glucometers must also be compliant with the Trade Agreements Act. Manufacturers of SMBGS glucometers will be required to provide DoD beneficiaries with a no-cost glucometer.
- *Minimum technical requirements*: Candidate SMBGS test strips eligible for inclusion on the UF must meet the following minimum technical requirements:
    - Accuracy: must meet FDA standards for accuracy based on the International Organization for Standardization (ISO) 15197 guidelines. During the August 2013 meeting, newly proposed ISO standards were

presented to the P&T Committee. However, the current 2003 ISO 15197 standard remains effective and there is no change regarding this minimum technical requirement.

- Sample size of ≤ 1 microliter
- Alternate site testing: more than one alternate site approved.
- Result time: ≤ 10 seconds
- Memory capacity: ≥ 250 readings
- Ease of use: glucometer must be easy to code/calibrate, have a large visual display, and be easy to handle for patients with dexterity issues.
- Customer support: 24-hour helpline available, for beneficiaries residing outside the continental United States.
- Downloading capabilities: results must be downloadable
- Data management capabilities: data management capabilities required (e.g., software, cloud computing).

- *SMBG strips meeting the final technical and U.S. Federal Government contracting requirements*: The SMBG test strips meeting the final technical and U.S. Federal Government contracting requirements are Abbott FreeStyle Lite, Abbbot FreeStyle InsuLinx, Abbott Precision Xtra; Roche ACCU-CHEK Aviva Plus; Bayer CONTOUR NEXT; Nipro Diagnostics TRUEtest; Nova Nova Max; Arkray Glucocard 01-Sensor, Akray Glucocard Vital; and Prodigy Prodigy No Coding.
- *MHS Provider Opinion*: MTF and Managed Care Support Contractors (MCSCs) were surveyed for their opinions on the SMBGS test strips and glucometers. The majority of the respondents ranked meter accuracy as the most important attribute. The majority of MTF respondents stated one glucometer was adequate to meet their needs, while the MCSCs requested availability of more than one glucometer to allow the patient options.
- *Overall relative clinical effectiveness conclusion:* The Committee concluded that any of the 10 final SMBGS test strip candidates were acceptable for inclusion on the UF. There are no clinically relevant differences between the 10 SMBGS test strips meeting the final technical and U.S. Federal Government contracting requirements set forth by the P&T Committee.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed for SMBGS test strips that met all minimum required technical standards and U.S. Federal Government contracting requirements. CMA was performed for the following manufacturer's products: Abbott (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra), Roche (ACCU-CHEK Aviva Plus), Bayer

(CONTOUR NEXT), Nipro Diagnostics (TRUEtest), Nova (Nova Max), ARKRAY (GLUCOCARD 01-SENSOR, GLUCOCARD Vital), and Prodigy (Prodigy No Coding) test strips. For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted.

The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 2 absent) the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) were the most cost-effective SMBGS products, based on the weighted average cost per strip across all three POS, followed by (ranked in order from most cost effective to least cost effective). Arkray (GLUCOCARD 01-SENSOR, GLUCOCARD Vital), Bayer (CONTOUR NEXT), Nipro (TRUEtest), Roche (ACCU-CHEK Aviva Plus), Prodigy (Prodigy No Coding), and Nova (Nova Max) products.

Among the formulary options evaluated, CMA and BIA results showed the most cost-effective scenario designated Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra) as the UF step-preferred test strip "suite" with all other SMBGS test strips designated NF and non-preferred, where all current and new users are required to first try an Abbott test strip.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) the following:
    - Formulary and step-preferred on the UF:
        - Precision Xtra (Abbott)
        - FreeStyle Lite (Abbott)
        - FreeStyle InsuLinx (Abbott)
    - Nonformulary and non-step preferred on the UF:
        - ACCU-CHEK Aviva Plus (Roche)
        - GLUCOCARD 01-Sensor (Arkray)
        - GLUCOCARD Vital (Arkray)
        - CONTOUR NEXT (Bayer)
        - NovaMax (Nova)
        - TRUEtest (Nipro Diagnostics)
        - Prodigy No Coding (Prodigy)
        - One Touch Verio
        - One Touch Ultra
        - All other test strips listed in Appendix C (with the exception of FreeStyle Lite, FreeStyle InsuLinx, Precision Xtra)
    - This recommendation includes step therapy, which requires a trial of one of the Abbott test strips (FreeStyle Lite, FreeStyle InsuLinx, or

Precision Xtra) prior to use of a nonformulary test strip in all current and new users of a nonformulary test strip.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) designating FreeStyle Lite (Abbott) with BCF status, based on clinical and cost-effectiveness, and removing Precision Xtra (Abbott) from the BCF. Note: Precision Xtra (Abbott) is designated with Uniform Formulary status and is step-preferred on the UF.

3. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1abstained, 1 absent) manual PA criteria for all new and current users of a nonformulary SMBG test strip, requiring a trial of FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra prior to the use of a nonformulary SMBG test strip. (See Appendix E for full criteria).

4 ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs/days supply limits for the SMBGS test strips, limiting use to 150 strips/30-day supply in the Retail Network, and 450 strips/90-day supply via Mail Order.

5. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) MN criteria for the NF SMBGS test strips. (See Appendix D for full MN criteria.)

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD*** The P&T Committee recommended (11 for, 1 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 120-day implementation period in all POS; 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is March 12, 2014.
See p 6. Considering the commentsof the Beneficiary Advisory Panel, implementation period is 180 days.

V. UTILIZATION MANAGEMENT

A. PAs

1. **Injectable Corticotropin (HP Acthar Gel)**—Injectable corticotrophin has been commercially available since 1952, but now is only marketed as a proprietary product, HP Acthar Gel. The P&T Committee established manual PA criteria for all new and current users of HP Acthar Gel, limiting use to infantile spasms (West Syndrome) for patients less than 24 months

old at initiation of treatment and not previously treated with corticotropin. Additional uses for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies may be permitted on appeal.

The following uses for Acthar Gel are considered unsupportable: dermatomyositis, polymyositis, psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis), sarcoidosis, serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis.

a) ***COMMITTEE ACTION: HP ACTHAR GEL PA CRITERIA***
The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) manual PA criteria for all current and new users of HP Acthar Gel, limiting use to the specific FDA-approved indication of infantile spasms (West Syndrome). Prior Authorization will expire after 30 days for infantile spasms; retreatment is not covered. Use for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout, and protein-wasting nephropathies will be on appeal only. Other uses of HP Acthar Gel are considered unsupportable. (See Appendix E for full criteria.)

b) ***COMMITTEE ACTION: HP ACTHAR GEL PA IMPLEMENTATION***—The P&T Committee recommended (8 for, 3 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by this PA decision. Based on the P&T Committee's recommendation, the effective date is December 11, 2013.

2. **Doxylamine/Pyridoxine (Diclegis)**—Diclegis contains 10 mg of doxylamine and 10 mg of pyridoxine and is FDA-approved for treating pregnant women experiencing nausea and vomiting. The P&T Committee recommended manual PA criteria for all new users of Diclegis. Diclegis is limited to use for management of nausea and vomiting during pregnancy (NVP) and excluded for the treatment of hyperemesis gravidarum. Patients must have tried at least one nonpharmacologic treatment (e.g., ginger, acupressure, high-protein bedtime snack) and OTC pyridoxine. An alternate antiemetic (e.g., ondansetron) should be considered prior to Diclegis.

   a) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (DICLEGIS) PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) that manual PA criteria apply to new users of

Diclegis who are being treated for nausea and vomiting during pregnancy. The PA will expire after nine months. (See Appendix E for full criteria.)

b) ***COMMITTEE ACTION: PYRIDOXINE/DOXYLAMINE (DICLEGIS) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

3. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara) and Golimumab (Simponi)**—PA criteria currently apply to the Targeted Immunomodulatory Biologics (TIBs). Ustekinumab 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 plaque psoriasis. Also, the FDA recently approved a new indication for golimumab for treatment of moderate to severe ulcerative colitis.

   a) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI) PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) PA criteria for ustekinumab for plaque psoriasis and golimumab for ulcerative colitis, consistent with the products' labeling. (See Appendix E for full criteria.)

   b) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

B. QLs

1. **Targeted Immunomodulatory Biologics: Ustekinumab (Stelara) and Golimumab (Simponi)**—QLs currently apply to the TIBs. The P&T Committee evaluated QLs for ustekinumab for the new indication of plaque psoriasis for patient self administration, and for golimumab for the new indication of ulcerative colitis.

a) ***COMMITTEE ACTION: USTEKINUMAB (STELARA) AND GOLIMUMAB (SIMPONI) QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for Stelara and Simponi, as outlined in Appendix F, consistent with FDA-approved product labeling.

2. **Oral Chemotherapy Drugs: Dabrafenib (Tafinlar), Trametinib (Mekinist), and Afatinib (Glotrif)**—The P&T Committee evaluated QLs for several oral chemotherapy drugs, including dabrafenib (Tafinlar), indicated for treatment of treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations; trametinib (Mekinist) for treatment of unresectable or metastatic melanoma with BRAF V600E mutations; and afatinib (Glotrif) for first-line treatment of metastatic non-small cell lung cancer whose tumors have specific mutations. QLs exist for several other oral chemotherapy agents.

   a) ***COMMITTEE ACTION: TAFINLAR, MEKINST, AND GLOTRIF QLs***—The P&T Committee recommended (11 for, 0 opposed, 1 abstained, 2 absent) QLs for dabrafenib (Tafinlar), trametinib (Mekinist), and afatinib (Glotrif) as outlined in Appendix F, consistent with FDA-approved product labeling.

VI. SECTION 703

A. Section 703—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.

1. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) to designate the products in Appendix G (listed by manufacturer) as nonformulary on the Uniform Formulary

2. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) the following Pre-Authorization Criteria for the drugs listed as nonformulary in Appendix G: 1) Obtaining the product from the 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.

3. ***COMMITTEE ACTION: UF AND PRE-AUTHORIZATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS; and 2) TMA send a letter to beneficiaries affected by the these decisions. Based on the P&T Committee's recommendation, the effective date is January 8, 2014.

See p 10. Patriot Pharmaceuticals has now signed a pricing agreement for all of its covere drugs. Qutenza patch and Zyclara cream are excluded from this action.

VII. OVERVIEWS

Overviews of the following four drug class were presented to the P&T Committee: the Inhaled Corticosteroids/Long-Acting Beta Agonists, the Inhaled Short-Acting Beta Agonists, the Antilipidemic-1 Agents (LIP-1s), and the Benign Prostatic Hyperplasia drugs comprised of the 5-alpha-reductase inhibitors and alpha blockers. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important for the PEC to use in contract solicitation, and for completing the clinical effectiveness reviews and developing the appropriate cost-effectiveness models. The clinical and economic analyses of these classes will be presented at an upcoming meeting.

VIII. ITEMS FOR INFORMATION

A. Bulk Chemicals In Compounded Medications—The P&T Committee was presented with an update and will be given a full presentation at an upcoming meeting.

B. FY13 TRICARE Pharmacy Copayments—The P&T Committee was briefed on the initial impact of new pharmacy copayments implemented in February 2013 on pharmaceutical utilization in the Military Health System. The analysis included the first 5 months of data following copayment increases for Tier 2 products (preferred brands) and Tier 3 products (non-preferred brands) in the Retail Network and at Mail Order. The results showed preliminary evidence that the increase in copays (from $25 to $43 in Mail Order/$44 in the Retail Network) for Tier 3 medications appeared to be associated with declining use of these products, with about a 10% reduction over the first 5 months. However, the new copays did not appear to be associated with any major changes in use of medications overall (i.e., across all Tiers). Additional updates will be provided to the P&T Committee as data becomes available.

C. Angiotensin Receptor Blockers (ARBs)/Direct Renin Inhibitor—The P&T committee considered the merits of formulary action in the Angiotensin Receptor Blockers, Direct Renin Inhibitors and respective fixed dose combination products drug

classes. Based on current pricing agreements and pending availability of new generic entrants, the P&T committee opted not to take any formulary action at this time.

D. **Prior Authorization (PA) Implementation date for canagliflozin (Invokana)**—The implementation date for PA criteria applicable to canagliflozin (Invokana) was changed to September 25, 2013.

IX. ADJOURNMENT

The meeting adjourned at 1015 hours on August 15, 2013. The next meeting will be in November 2013.

Appendix A—Attendance: August 2013 P&T Committee Meeting

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drug Class

Appendix C—Self-Monitoring Blood Glucose System Test Strips Products in Class

Appendix D—Table of Medical Necessity

Appendix E—Table of Prior Authorization Criteria

Appendix F—Table of Quantity Limits

Appendix G—Table of Drugs Designated NF due to Section 703

Appendix H—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix I—Table of Abbreviations

Appendix A—Attendance: August 2013 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CDR Joe Lawrence, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
COL John Spain, MS	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
LTC Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Dr. Miguel Montalvo	TRICARE Regional Office-South Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, TMA
LCDR Tiffany Scott, MSC, via DCO	Defense Logistics Agency Troop Support
Capt Richard Caballero, via DCO	Defense Logistics Agency Troop Support
Capt Randall Sweeney, via DCO	Defense Logistics Agency Troop Support
Guests	
Mr. Bill Davies via DCO	TRICARE Management Activity, Pharmaceutical Operations Directorate
CDR Matthew Baker, USPHS, by phone	Indian Health Service
CAPT Jamie Kersten	Navy Medicine Training Support Center
LCDR David Sohl	University of Texas Masters Student

Appendix A—Attendance (continued)

Others Present	
LTC Chris Conrad, MS	DoD Pharmacoeconomic Center
LCDR Marisol Martinez, USPHS	DoD Pharmacoeconomic Center
LCDR Joshua Devine, USPHS	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
LCDR Linh Quach, MSC	DoD Pharmacoeconomic Center
Lt Col Melinda Henne, MC	DoD Pharmacoeconomic Center
Maj David Folmar, BSC	DoD Pharmacoeconomic Center
MAJ Misty Cowan, MC	DoD Pharmacoeconomic Center
LT Kendra Jenkins, USPHS	DoD Pharmacoeconomic Center
HM1 Nichole Moraldo	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Dean Valibhai	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
Dr. Amy Lugo via DCO	DoD Pharmacoeconomic Center
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Mr. Kirk Stocker	DoD Pharmacy Outcomes Research Team contractor
Andrew Delgado	University of Texas Health Science Center/University of Texas College of Pharmacy Student
Yuna Bae via DCO	University of Maryland School of Pharmacy Student
Christopher Bender via DCO	Lake Erie College of Osteopathic Medicine School of Pharmacy Student

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drugs in the Class (For UF decision see Appendix H)

Generic	Brand Generic	Strengths & formulations	Patent Exp
High-Potency Steroids (Classes 1 and 2)			
Clobetasol Propionate	Clobex Temovate/-E Olux/-E Generics: Yes (lotion/ointment/solution/ shampoo/ ointment/gel/foam)	0.05% Lotion, Shampoo, Spray 0.05% Oint, Soln, Gel, Cream 0.05% Foam 0.05% Ointment, Soln, Gel, Cream 0.05% Cream	9/2017–6/2019 -- 3/2016–9/2019 -- -- --
Diflorasone diacetate	*Psorcon/-E; Apexicon E** Generic: Yes	0.05% Ointment 0.05% Cream 0.05% Cream with Emollient	-- -- --
Halobetasol propionate	*Halac, Halonate, Halonate PAC** Ultravate/-PAC Generics: Yes	0.05% Cream, Ointment, Foam Combinations with Lactates	-- --
Flurandrenolide	Cordran Generics: No	4mcg/sq cm Tape	--
Desoximetasone	Topicort Generics: Yes	0.25% Cream, Ointment, Spray 0.05% Gel	-- --
Fluocinonide/-Emollient	Vanos, *Lidex/-E** Generics: Yes	0.1% Cream 0.05% Gel, Cream, Oint, Soln	-- --
Halcinonide	Halog Generics: Halog is generic	0.1% Cream, Ointment	--
Betamethasone dipropionate augmented	Diprolene/-AF Generics: Yes	0.05% Cream, Lotion, Ointment 0.05% Gel (generic only)	
Amcinonide	Cyclocort Generics: Yes	0.1% Ointment	--

*** Italicized medications are branded products (reference listed drugs) that are not currently marketed.**

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drugs in the Class (For UF decision see Appendix H)

Generic	Brand Generic	Strengths & formulations	Patent Exp
Medium-Potency Steroids (Classes 3, 4, 5)			
Amcinonide	Cyclocort Generics: Yes	0.1% Cream, Lotion	
Betamethasone dipropionate	Diprosone Generics: Yes	0.05% Cream 0.05% Lotion (generic only)	---
Betamethasone valerate	Beta-Val, Luxiq, Valisone Generics: Yes (ointment)	0.1% Cream, Lotion 0.12% Foam	Luxiq: 3/2016–5/2017 ---
Clocortalone pivalate	Cloderm Generics: No	0.1% Cream	---
Desonide	Desowen Generics: Yes	0.05% Ointment, Lotion	---
Desoximetasone	Topicort Generics: Yes	0.05% Cream	---
Fluocinolone	Synalar Generics: Yes (cream/ointment)	0.025% Cream	---
Flurandrenolide	Cordran Generics: No	0.05% Cream, Lotion	---
Fluticasone propionate	Cutivate Generics: Yes	0.05% Cream, Lotion 0.005% Ointment	---
Hydrocortisone butyrate	Locoid Locoid Lipocream Generics: Yes (lotion/ointment/solution)	0.1% Cream (brand only), Ointment, Solution, Lotion 0.1% Cream	Lotion: 1/2025–12/2026 Cream: 6/2014
Hydrocortisone probutate	Pandel Generics: No	0.1% Cream	---
Hydrocortisone valerate	Brand: *Westcort** Generics: Yes	0.2% Cream, Ointment	---
Mometasone furoate	Elocon Generics: Yes	0.1% Ointment, Cream, Solution	---
Prednicarbate	Dermatop Generics: Yes	0.1% Cream, Ointment	---
Triamcinolone acetate	Aristocort HP Kenalog Trianex Kenalog Triderm Triacet Generics: Yes (cream/ointment/lotion)	0.5% Cream 0.025%, 0.1%, 0.5% Cream 0.025%, 0.1% Lotion 0.025%; 0.1% Ointment 0.147 mg/g Topical Spray 0.1% Cream 0.05% Ointment	--- --- --- --- --- --- ---
Triamcinolone Acetonide	Aristocort A Pediaderm TA Generics: Yes	0.5% Cream 0.1% Cream	--- ---

*** italicized medications are branded products (reference listed drugs) that are not currently marketed.**

Appendix B—Corticosteroid Immune Modulators (Topical Steroids) Drugs in the Class (For UF decision see Appendix H)

Generic	Brand Generic	Strengths & formulations	Patent Exp
Low Potency Steroids (Class 6 and 7)			
Alclometosone dipropionate	Aclovate Generics: Yes	0.05% Cream, Ointment	--
Desonide	Desonate Desowen Verdeso Generics: Yes	0.05% Gel 0.05% Cream 0.05% Foam	08/2020 -- 09/2016
Fluocinolone acetonide	Capex Derma-Smoothe/FS Synalar Generics: Yes	0.01% Shampoo 0.01% Oil 0.01% Solution	-- -- --
Hydrocortisone	Ala-Cort Ala-Scalp Nutracort, Stie-Cort Synacort Texacort Pediaderm HC Generics: Yes	1% Lotion, Cream 2% Lotion 1%, 2.5% Lotion 1%, 2% Cream 2.5% Solution 2% Lotion + Emollient	-- -- -- -- -- --
Hydrocortisone acetate	Microcort Carmol HC, U-Cort Pramosone Epifoam Generics: Yes	2%, 2.5% Cream 1% Cream + 10% Urea 0.5%, 1% Cream + 1% Pramoxine 1%, 2.5% Lotion + 1% Pramoxine 1% Aerosol +1% Pramoxine	-- -- -- -- --

Appendix C—Self-Monitoring Blood Glucose System Test Strips Products in the Class

FREESTYLE LITE (ABBOTT)	ACCU-CHEK AVIVA
FREESTYLE INSULINX (ABBOTT)	ACCU-CHEK COMFORT CURVE
PRECISION XTRA (ABBOTT)	ACCU-CHEK SMARTVIEW
ACCU-CHEK AVIVA PLUS (ROCHE)	ACCUTREND GLUCOSE
GLUCOCARD 01-SENSOR (ARKRAY)	ACURA TEST STRIPS
GLUCOCARD (ARKRAY)	ADVANCE TEST STRIPS
CONTOUR NEXT (BAYER)	ADVOCATE REDI-CODE
NOVAMAX (NOVA)	ADVOCATE REDI-CODE+
TRUETEST (NIPRO DIAGNOSTICS)	ADVOCATE TEST STRIP
PRODIGY NO CODING (PRODIGY)	ASSURE 4
ACCU-CHEK	BG-STAR
ACCU-CHEK ACTIVE	BLOOD GLUCOSE TEST
ACCU-CHEK ADVANTAGE	CLEVER CHECK
ACCU-CHEK INSTANT	CLEVER CHOICE PRO
ASCENSIA ELITE	CONTOUR
ASSURE 3	CONTROL
ASSURE PLATINUM	EASY TOUCH
ASSURE PRO	EASYGLUCO
BD TEST STRIPS	EMBRACE
CHEMSTRIP BG	GE100 BLOOD GLUCOSE TEST STRIP
CLEVER CHOICE TEST STRIPS	GLUCOCARD EXPRESSION
DEXTROSTIX REAGENT	GLUCOCARD X SENSOR
EASY PRO PLUS	GLUCOLAB
EASYMAX	INFINITY
ELEMENT TEST STRIPS	INFINITY TEST STRIPS
EVENCARE G2	KEYNOTE
EZ SMART	LIBERTY TEST STRIPS
EZ SMART PLUS	MICRO
FAST TAKE	ONE TOUCH ULTRA
FIFTY50 TEST STRIP	ONE TOUCH VERIO
FORA G20	OPTIUM
FORA TEST STRIP	POCKETCHEM EZ
FORA V10	PRECISION PCX PLUS
FORA V30A	PRECISION Q-I-D
GLUCOMETER ENCORE	RELION CONFIRM MICRO
GLUCOSE TEST STRIP	RELION PRIME
GLUCOSTIX	RIGHTEST GS300 TEST STRIPS
MICRODOT	SMARTDIABETES XPRES
OPTIUM EZ	SOLUS V2 TEST STRIPS
PRECISION PCX	SURESTEP
PRECISION POINT OF CARE	TELCARE
PRESTIGE SMART SYSTEM	TEST STRIP
PRESTIGE TEST	TRUE TRACK
PRODIGY	TRUETRACK SMART SYSTEM
RIGHTEST GS100 TEST STRIPS	ULTIMA
RIGHTEST GS550 TEST STRIPS	ULTRATRAK
SMARTEST TEST	ULTRATRAK PRO
SURECHEK TEST STRIPS	VICTORY
SURESTEP PRO	WAVESENSE AMP
TRACER BG	WAVESENSE JAZZ
	WAVESENSE PRESTO

Appendix D—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Amcinonide 0.1% ointment (Cyclocort, generics) • Diflorasone 0.05% cream and ointment (Apexicon, generics) • Fluocinonide 0.1% cream (Vanos) • Halcinonide 0.1% cream and ointment (Halog) **High Potency Topical Steroids**	• Use of the formulary agent is contraindicated • All other formulary agents have resulted in therapeutic failure. Formulary alternatives include the high potency topical steroids - clobetasol, augmented betamethasone dipropionate, desoximetasone, fluocinonide 0.05%, halobetasol propionate.
• Amcinonide 0.1% cream and lotion (Cyclocort, generics) • Betamethasone valerate 0.12% foam (Luxiq, generics) • Clocortolone 0.1% cream (Cloderm) • Desonide 0.05% lotion (Desowen, generics) • Hydrocortisone probutate 0.1% cream (Pandel) • Hydrocortisone butyrate 0.1% cream and lotion (Locoid) • Triamcinolone with emollient #45, 0.1% cream kit (Pediaderm TA) **Medium Potency Topical Steroids**	• Use of all other medium potency formulary agents is contraindicated, and using a high potency agent would incur unacceptable risk. • All other Mid Potency formulary agents have resulted in therapeutic failure and using a High Potency agent would incur unacceptable risk. • For clocortolone, the patient requires a Coopman Class C agent, and desoximetasone is contraindicated. Formulary alternatives include the high potency and medium potency topical steroids
• Desonide 0.05% foam (Verdeso) • Desoinde 0.05 gel (Desonate) • Fluocinolone 0.01% shampoo (Capex) • Hydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC) **Low Potency Topical Steroids**	• Use of all other low potency formulary agents, including over-the-counter topical steroids are contraindicated and using a higher potency agent would incur unacceptable risk. • All other low potency formulary topical steroids have resulted in therapeutic failure and using a higher potency agent would incur unacceptable risk. • For Desonide 0.05% foam (Verdeso) and fluocinolone 0.01% shampoo (Capex), requires a trial of fluocinolone oil (Derma-Smoothe/FS) unless patient has a contraindication specifically to Derma-Smoothe/FS Formulary alternatives include high, medium, and low potency topical steroids
• ACCU-CHEL Aviva Plus (Roche) • GLUCOCARD 01-Sensor (Arkray) • GLUCOCARD Vital (Arkray) • CONTOUR NEXT (Bayer) • NovaMAx (Nova) • TRUEtest (Nipro Diagnostics) • Prodigy No Coding (Prodigy) • One Touch Ultra (Lifescan) • One Touch Verio (Lifescan) • All other test strips listed in Appendix C with the exception of FreeStyle Lite, FreeStyle InsuLinx, and Precision Xtra **SMBG System Test Strips**	• No alternative formulary agent. o Patient is blind/severely visually impaired and requires a test strip used in a talking meter - Prodigy Voice, Prodigy AutoCode, Advocate Redicode. o Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter. o The patient has a documented physical or mental health disability requiring a special strip meter. o Provider is concerned about the glucose dehydrogenase-pyrroloquinolinequinone interaction (GDH-PQQ) and the patient is taking IVIG Octagam.

Appendix E—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• ACCU-CHEK Aviva Plus (Roche) • GLUCOCARD 01-Sensor (Arkray) • GLUCOCARD Vital (Arkray) • CONTOUR NEXT (Bayer) • NovaMax (Nova) • TRUEtest (Nipro Diagnostics) • Prodigy No Coding (Prodigy) • One Touch Ultra (Lifescan) • One Touch Verio (Lifescan) • All other SMBG test strips listed in Appendix C, with the exception of FreeStyle Lite, FreeStyle InsuLinx, and Precision Xtra **Self-Monitoring Blood Glucose (SMBG) Test Strips**	New and current users of the nonformulary test strips are required to try FreeStyle Lite, FreeStyle InsuLinx, or Precision Xtra <u>Manual PA Criteria</u>—Non-Preferred test strip allowed if: • Patient is blind/severely visually impaired and requires a test strip used in a talking meter - Prodigy Voice, Prodigy AutoCode, Advocate Redicode • Patient uses an insulin pump and requires a specific test strip that communicates wirelessly with a specific meter o Contour NEXT strip with CONTOUR NEXT Link meter for Medtronic pump o NovaMax strip with NovaMax Link meter for Medtronic pump o OneTouch Ultra test strips with One Touch Ultra Link meter for Medtronic Mini Med Paradigm insulin pump o OneTouch Ultra test strips with One Touch Ping meter and using the One Touch Ping insulin pump • The patient has a documented physical or mental health disability requiring a special strip or meter. • The patient is receiving peritoneal dialysis or the intravenous immune globulin (IVIG) preparation Octagam and the provider is concerned about the glucose dehydrogenase-pyrroloquinolinequinone interaction (GDH-PQQ)
• Injectable Corticotropin (HP Acthar Gel)	All new and current users of HP Acthar Gel are required to undergo Prior Authorization. <u>Manual PA Criteria</u> • Coverage is approved for infantile spasms (West Syndrome) in the following patients: Patient is less than 24 months old at initiation of treatment, and has no previous treatment with corticotrophin. Prior Authorization will expire in 30 days. Retreatment is not covered. • Coverage for acute exacerbations of multiple sclerosis and/or optic neuritis, acute gout and protein-wasting nephropathies—may be permitted on appeal. Prior Authorization will expire in 21 days for multiple sclerosis; 14 days for acute gout; and 6 months for protein-wasting nephropathies. • Coverage is not provided for the following uses: dermatomyositis, polymyositis, psoriatic arthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis and ankylosing spondylitis), sarcoidosis, serum sickness, Stevens-Johnson Syndrome (severe erythema multiforme), and systemic lupus erythematosis

Drug / Drug Class	Prior Authorization Criteria
• pyridoxine/doxylamine (Diclegis) **Antiemetics**	All new users of Diclegis are required to try a nonpharmacologic method for management of nausea and vomiting during pregnancy AND OTC pyridoxine before receiving pyridoxine/doxylamine (Diclegis). Manual PA criteria—Pyridoxine/doxylamine (Diclegis) is approved if: • The patient has not had relief of symptoms after trying a nonpharmacologic method to manage nausea and vomiting during pregnancy, AND • The patient has not had relief of symptoms after trying OTC pyridoxine for management of nausea and vomiting during pregnancy • Providers are encouraged to consider an alternate antiemetic (e.g., ondansetron) prior to prescribing pyrodixone/doxylamine. Prior Authorization will expire after 9 months.
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy No expiration date for Prior Authorization
• Golimumab (Simponi) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with • Moderate to severely active rheumatoid arthritis and active psoriatic arthritis, active ankylosing spondylitis • **Moderate to severely active ulcerative colitis that has not responded to other treatments or who require continuous steroids** • Coverage NOT provided for concomitant use with other TIBs, Kineret, Enbrel, Remicade, Orencia, or Rituxan No expiration date for Prior Authorization

Appendix F—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
Self-Monitoring Blood Glucose Test Strips (all products)	▪ Retail: 150 strips/30-day supply ▪ Mail Order and MTF: 450 strips/90-day supply
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail: 2 pre-filled syringes (45 mg/0.5 mL; 90 mg/1.0 mL) or 2 vials (45 mg; 90 mg) /30 days ▪ Mail: 2 pre-filled syringes (45 mg/0.5 mL; 90 mg/1.0 mL) or 2 vials (45 mg; 90 mg) /56 days
• Golimumab (Simponi) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail: 3 syringes (3 mL) /30 days ▪ Mail: 4 syringes (4mL) /56 days
• Dabrafenib (Tafinlar) **Oral chemotherapy drug**	50 mg and 75 mg capsules ▪ Retail: 120 capsules/30 days ▪ Mail Order: 240 capsules/60 days
• Trametinib (Mekinist) **Oral chemotherapy drug**	2 mg tablets ▪ Retail: 30 tablets/30 days ▪ Mail Order: 60 tablets/60 days 0.5 mg ▪ Retail: 120 tablets/30 days ▪ Mail Order 240 tablets/60 days
• Afatinib (Giotrif) **Oral chemotherapy drug**	40mg, 30mg, 20mg tablets ▪ Retail: 30 tablets/30 days ▪ Mail Order: 60 tablets/60 days

Appendix G—Drugs Designated as NF due to Section 703

Manufacturer	Drugs
Bausch & Lomb Rx	Besivance ophthalmic suspension
Fougera	methscopolamine tablets
Graceway Pharma	Zyclara cream
Kedrion	Gammaked injection
Meda Pharma	Dymista nasal spray
Neurogesx, Inc	Qutenza patch
Novartis Consumer	Transderm Scop
Otsuka America	Pletal
Patriot Pharma	Haldol injection; Itraconazole tabs/caps; Ketoconazole Shampoo; Galantamine Tabs; Tramadol ER Tabs
Pharmaderm	Oxistat products; Cutivate lotion; Temovate products
Rhodes Pharm	Hydromorphone; Tramadol ER
Sandoz	Calcitonin Nasal Spray; Calcium Acetate; Carbamazepine XR; Lansoprazole; Losartan; Losartan/HCTZ; Oxcarbazepine Susp; Sumatriptan Nasal Spray; Valsartan/HCTZ; Metoprolol/HCTZ; Rivastigmine
Stiefel Labs	Veltin
United Research Lab	Glycopyrrolate Tabs; Nisoldipine ER
Viropharma Inc	Vancocin Caps

See p 10. Patriot Pharmaceuticals has now signed a pricing agreement for all of its covered drugs. Qutenza patch and Zyclara cream are excluded from this action.

Appendix H—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2013	**Topical Steroids**	UF Class Review	▪ clobetasol 0.05% cream and ointment ▪ fluocinonide 0.05% cream and ointment ▪ triamcinolone acetate 0.1% cream and ointment	▪ aclometasone 0.05% cream, ointment (Aclovate, generics) ▪ augmented betamethasone dipropionate 0.05% cream, ointment, gel & lotion (Diprolene, Diprolene AF, generics) ▪ betamethasone dipropionate 0.05% cream & lotion (Diprosone, generics) ▪ betamethasone valerate 0.1% cream, ointment & lotion (Valisone, generics) ▪ clobetasol 0.05% solution, foam, gel, shampoo, lotion & spray (Clobex, Olux, Temovate, generics) ▪ desonide 0.05% cream & ointment (Desowen, generics) ▪ desoximetasone 0.05% & 0.25% cream, ointment, gel, & spray (Topicort, generics) ▪ fluocinonide 0.05%, gel, and solution (Lidex, generics) ▪ fluocinolone acetonide 0.01% oil, solution (Derma-Smoothe/FS, generics) ▪ fluocinolone 0.025% cream & ointment (Synalar, generics) ▪ flurandrenolide 4mcg/sq cm tape (Cordran) ▪ flurandrenolide 0.05% cream, lotion (Cordran, generics) ▪ fluticasone 0.005% ointment, & 0.05% cream & lotion (Cutivate, generics)	**High potency** ▪ mcinonide 0.1% ointment (Cyclocort, generics) ▪ iflorasone 0.05% cream & ointment (Apexicon, generics) ▪ luocinonide 0.1% cream (Vanos) ▪ alcinonide 0.1% cream & ointment (Halog) **Medium potency** ▪ mcinonide 0.1% cream & lotion (Cyclocort, generics) ▪ etamethasone valerate 0.12% foam (Luxiq, generics) ▪ locortolone 0.1% cream (Cloderm) ▪ esonide 0.05% lotion (Desowen, generics) ▪ hydrocortisone probutate 0.1% cream (Pandel) ▪ ydrocortisone butyrate 0.1% cream & lotion (Locoid) ▪	Pending signing of the minutes/ 60 days	N/A	-

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
				▪ halobetasol 0.05% cream, ointment, lotion foam, & combinations (Halonate, Ultravate, generics) ▪ hydrocortisone 1%, 2% &2.5% cream, solution & lotion (excludes Pediaderm HC) ▪ hydrocortisone acetate 2% & 2.5% cream (Microcort-HC) generics ▪ hydrocortisone butyrate 0.1% ointment & solution (Locoid) ▪ hydrocortisone valerate 0.2% cream and ointment (Westcort, generics) ▪ mometasone 0.1% cream, ointment & solution (Elocon, generics) ▪ prednicarbate 0.1% cream & ointment (Dermatop, generics) ▪ triamcinolone acetate 0.025%, 0.05%, 0.1%, & 0.5% cream, ointment & lotion (excludes Pediaderm TA) ▪ triamcinolone acetate 0.015% spray (Kenalog) ▪ triamcinolone acetonide 0.5% cream (Artistocort A, generics)	riamcinolone acetonide with emollient #45, 0.1% cream kit (Pediaderm TA) **Low potency** ▪ esonide 0.05% foam (Verdeso) & 0.05% gel (Desonate) ▪ luocinolone 0.01% shampoo (Capex) **Low potency (continued)** ▪ ydrocortisone with emollient #45, 2% lotion kit (Pediaderm HC)			

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2013	**Self-Monitoring Blood Glucose System (SMBS) test strips**	UF Class Review	▪ FreeStyle Lite (Abbott)	Uniform Formulary and Step-Preferred ▪ FreeStyle Lite (Abbott) ▪ FreeStyle InsuLinx (Abbott) ▪ Precision Xtra (Abbott)	Nonformulary and non-step preferred ▪ACCU-CHEK Aviva Plus (Roche) ▪GLUCOCARD 01-SENSOR (Arkray) ▪GLUCOCARD (Arkray) ▪CONTOUR NEXT (Bayer) ▪NovaMax (Nova) ▪TRUEtest (Nipro) ▪Prodigy No Coding (Prodigy) ▪One Touch Ultra (Lifescan) ▪One Touch Verio (Lifescan) ▪All other test strips listed in Appendix C, with the exception of Freestyle Lite, Freestyle InsuLinx, and Precision Xtra	Pending signing of the minutes / 120 days	Step therapy requires a trial of an Abbott test strip (FreeStyle Lite, FreeStyle InsunLinx, or Precision Xtra) in all new and current users of the nonformulary strips	▪ FreeStyle Lite added to the BCF ▪ PrecisionXtra removed from the BCF, but still UF and step-preferred

Appendix I—Table of Abbreviations

ARBs	Angiotensin Receptor Blockers
ASD(HA)	Assistant Secretary of Defense for Health Affairs
BCF	Basic Core Formulary
BIA	budget impact analysis
BPH	benign prostatic hyperplasia
CMA	cost minimization analysis
DoD	Department of Defense
DRIs	Direct Renin Inhibitors
FDA	U.S. Food and Drug Administration
GDH-PQQ	glucose dehydrogenase-pyrroloquinolinequinone
ISO	International Organization for Standardization
LIP-1s	Antilipidemic-1s Drug Class
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
MCSCs	Managed Care Support Contractors
NF	nonformulary
NVP	nausea and vomiting in pregnancy
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PEC	Pharmacoeconomic Center
PORT	Pharmacy Outcomes Research Team
POS	points of service
QLs	quantity limits
SMBGS	Self-Monitoring Blood Glucose System (SMBGS)
TMA	TRICARE Management Activity
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary

DECISION PAPER

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

May 2013

I. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2)Inhibitors—Canagliflozin (Invokana)

Relative Clinical Effectiveness Conclusion—Canagliflozin (Invokana) is a new diabetes drug with a novel mechanism of action and the first FDA-approved SGLT2 inhibitor. SGLT2 inhibitors are a new subclass of the Non-Insulin Diabetes Drug Class. The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee concluded (15 for, 1 opposed, 0 abstained, 1 absent) that despite its unique mechanism of action to increase urinary glucose excretion, canagliflozin (Invokana) does not offer a clinically compelling advantage over the other non-insulin drugs included on the Uniform Formulary (UF). Canagliflozin has several safety concerns in the setting of modest decreases in hemoglobin A1c.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that canagliflozin (Invokana) is not cost-effective compared to other non-insulin diabetes drugs currently available on the UF. Cost minimization analysis (CMA) showed canagliflozin is more costly than metformin, glyburide, pioglitazone (Actos, generic), sitagliptin (Januvia), and exenatide (Byetta), in terms of cost per day of therapy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 1 opposed, 1 abstained, 2 absent) canagliflozin (Invokana) be designated nonformulary (NF) due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes and adverse event data, and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***
The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) the following MN criteria for canagliflozin (Invokana): use of formulary agents is contraindicated. (See Appendix B for full criteria.)

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***
In the Non-Insulin Diabetes Drug Class, existing automated prior authorization (step therapy) requires a trial of metformin or a sulfonylurea, prior to the use of a dipeptidyl-dipeptidase-4 (DPP-4) inhibitor, a thiazolidinedione (TZD), or a glucagon-like peptide-1 receptor agonist (GLP1RA), based on positive efficacy and long-term outcomes data with metformin and the sulfonylureas.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor in all new and current users of SGLT2 inhibitors, canagliflozin (Invokana), due to the modest hemoglobin A1c lowering and safety concerns. (See Appendix C for full criteria.)

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) 1) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is September 11, 2013.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

II. UF DRUG CLASS REVIEWS

A. Anti-Gout Drugs

Relative Clinical Effectiveness Conclusion—The P&T Committee evaluated the Anti-Gout Drug Class. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following clinical effectiveness conclusions:

- Colchicine is a very old drug that is available in one branded formulation, (Colcrys), which has a patent extending to 2029.
- For an acute gout attack, clinical practice guidelines support colchicine as first line treatment, along with non-steroidal anti-inflammatory drugs (NSAIDs) or prednisone. Treatment should be initiated within the first 24 hours of symptom onset.

- For chronic gout, urate lowering therapy (ULT) with allopurinol or febuxostat is recommended as first line. Based on head-to-head trials, febuxostat (Uloric) 40 mg and allopurinol 300 mg were equally efficacious in lowering serum uric acid (sUA) to less than 6mg/dL in one study (CONFIRMS). Febuxostat 80 mg was superior to allopurinol 300 mg in lowering sUA to less than 6mg/dL in two studies (FACT and APEX).
- Higher doses of allopurinol (doses > 300mg), although not well studied, may be required in some patients to decrease sUA.
- Systematic reviews from the Cochrane group, and evidence-based organizations from Canada, the United Kingdom, and Europe recommend febuxostat as an alternative ULT in patients who cannot tolerate allopurinol.
- In terms of clinical coverage, one anti-inflammatory agent (colchicine) and one xanthine oxidase inhibitor (allopurinol or febuxostat) is required on the UF to meet the needs of the majority of DoD beneficiaries.

Relative Cost-Effectiveness Conclusion—Pharmacoeconomic analyses were performed for the Anti-Gout Drug Class, including CMA and budget impact analysis (BIA). The class was subdivided into chronic drugs (allopurinol and febuxostat) and acute drugs (colchicine).

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) generic allopurinol (Zyloprim) was the most cost-effective of the chronic drugs, followed by branded febuxostat (Uloric), based on the weighted average cost per day of treatment across all three POS. Branded colchicine (Colcrys) was the only acute agent examined in the analysis; a cost analysis was conducted. Results from the CMA and BIA showed that among available formulary options examined, scenarios where allopurinol (Zyloprim) is the Basic Core Formulary (BCF) step-preferred agent, febuxostat (Uloric) is the NF non-preferred agent (with all current and new users required to try allopurinol first), and colchicine (Colcrys) is UF presented a maximum cost-avoidance projection.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:
    - allopurinol be designated UF and step-preferred (e.g., "in front of the step");
    - febuxostat (Uloric) be designated NF and non step-preferred (e.g., "behind the step"); and

- colchicine (Colcrys), probenecid, and the fixed dose combination of colchicine/probenecid be designated formulary on the UF and exempt from step therapy.
- This recommendation includes step therapy, which requires a trial of allopurinol prior to using febuxostat (Uloric) in all current and new users of febuxostat.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) maintaining allopurinol as BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for febuxostat (Uloric). (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—After extensive discussion, the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) PA criteria for all current and new users of febuxostat (Uloric), requiring a trial of allopurinol prior to use of febuxostat. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Additional recommendations made by the P&T Committee were to provide messaging to retail pharmacies to designate that PA and step therapy is required, with a trial of allopurinol prior to febuxostat (Uloric); and that the Anti-Gout Drug Class be added to the Rapid Response Program for the Retail Network and Mail Order Pharmacy. Based on the P&T Committee's recommendation, the effective date is November 6, 2013.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Pulmonary II Drugs

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following at the February 2013 meeting:

- Aclidinium inhaler (Tudorza) is the second long-acting muscarinic agent (LAMA) on the market. Three clinical trials reported statistically significant improvement in spirometric endpoints, and two of the trials reported significantly fewer chronic obstructive pulmonary disease (COPD) exacerbations, compared to placebo.
- For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.
- Several trials have shown the LAMA tiotropium (Spiriva) is associated with clinically significant improvements in spirometric endpoints and reductions in risk for COPD exacerbations. Tiotropium is also reported to reduce the proportion of patients hospitalized for COPD exacerbations.
- Reports of a possible link between tiotropium and adverse cardiovascular events including death, stroke, and myocardial infarction have not been confirmed in prospective trials.
- Roflumilast (Daliresp) is the first oral selective inhibitor of phosphodiesterase type 4 (PDE-4) marketed in the United States. In two clinical trials, roflumilast was associated with statistically significant reductions in the rate of COPD exacerbations.
- For roflumilast, safety issues identified by the FDA included psychiatric events (including suicide), weight loss, gastrointestinal upset and severe diarrhea, and nasal tumors. However, the FDA did not require additional prospective safety studies.
- Albuterol/ipratropium soft mist inhaler (Combivent Respimat) is the new propellant-free inhaler that is replacing the ozone-depleting chlorofluorocarbon (CFC)-containing Combivent metered dose inhaler (MDI). The clinical trial used to obtain FDA approval showed Combivent Respimat was non-inferior to Combivent CFC MDI in terms of improvements in spirometric endpoints.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- CMA within the LAMA subclass showed that tiotropium (Spiriva) was more cost-effective than aclidinium (Tudorza). BIA results where Spiriva was designated BCF and Tudorza designated UF resulted in the greatest cost-avoidance to the MHS.

- CMA was conducted within the COPD subclass, which includes the short-acting muscarinic agents (SAMA), short-acting beta agonist (SABA)/SAMA combination drugs, and PDE-4 inhibitors. The results showed that ipratropium nebulized solution (Atrovent; generic) was the most cost-effective agent, followed by ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium hydrofluoroalkane MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp). Ipratropium/albuterol (Combivent) was not included in the cost-effectiveness analysis due to market discontinuation by December 2013. BIA projections for all scenarios were very similar.

    1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (12 for, 1 opposed, 2 abstained, 2 absent) aclidinium inhaler (Tudorza), tiotropium inhaler (Spiriva), ipratropium nebulized solution (Atrovent; generic), ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium HFA MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp) remain designated Uniform Formulary. Ipratropium/albuterol MDI (Combivent) will remain designated UF, pending discontinuation in December 2013.

    2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) maintaining ipratropium HFA MDI (Atrovent HFA) and ipratropium/albuterol nebulized solution (DuoNeb; generic), on the BCF, and recommended adding tiotropium (Spiriva) to the BCF, upon signing of the minutes.

Director, TMA, Decision: ☒Approved □ Disapproved

Approved, but modified as follows:

C. Self-Monitoring Blood Glucose System (SMBGS) Test Strips

Background and Relative Clinical Effectiveness—The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips, including the attributes of the test strips and glucometers. Candidates for inclusion on the UF must meet all minimum required technical standards and United States Federal Government contracting requirements.

The P&T Committee reviewed the existing technical requirements approved in May 2007, and recommended updates to the criteria.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following for the minimum technical requirements and U.S. Federal Government contracting requirements for the SMBGS test strips. The full clinical effectiveness conclusion will be presented at the August 2013 meeting:

- *U.S Federal Government contracting requirements*: SMBGS test strips eligible for inclusion on the Uniform Formulary must be available at all 3 POS and must be compliant with the Trade Agreements Act. Corresponding SMBGS glucometers must also be compliant with the Trade Agreements Act. Manufacturers of SMBGS glucometers will be required to provide DoD beneficiaries with a no-cost glucometer.
- *Minimum technical requirements*: Candidate SMBGS test strips eligible for inclusion on the Uniform Formulary must meet minimum technical requirements in the areas of accuracy, sample size, alternate site testing, results time, memory capacity, ease of use, customer support, downloading capabilities, and data management capabilities. See pages 19-20 for detailed technical requirements.

Relative Cost-Effectiveness Conclusion—The P&T Committee reviewed proposed condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

D. Corticosteroid Immune Modulators (Topical Steroids)

The P&T Committee evaluated the Corticosteroid Immune Modulators (Topical Steroids) Drug Class. The class is comprised of 22 individual chemical entities, available in over 100 different formulations and vehicles. The Stoughton-Cornell classification system, which divides the drugs into seven classes based on their vasoconstrictive properties, was used to further divide the drugs into high- (classes 1 and 2 steroids), medium- (classes 3, 4, and 5), and low-potency agents (classes 6 and 7). Over-the-counter (OTC) products are excluded from the class.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the clinical effectiveness conclusion. The full clinical effectiveness evaluation will be reported in the August meeting minutes.

Relative Cost-Effectiveness Conclusion—The P&T Committee reviewed proposed condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

III. BCF ISSUES

A. Emergency Contraceptives

The Emergency Contraceptives were last reviewed by the P&T Committee in August 2011. Levonorgestrel 0.75 mg (Next Choice, the generic for Plan B) was designated as BCF. Next Choice was discontinued by the manufacturer in early 2013. The currently available emergency contraceptives include levonorgestrel 0.75 mg available from a generic manufacturer; levonorgestrel 1.5 mg (Next Choice One Dose, Plan B One Step); and ulipristal (Ella). A prescription is required for all ages for Ella; and for patients under age 17 for generic levonorgestrel 0.75 mg, and levonorgestrel 1.5 mg (Next Choice One Dose). On April 15, 2013, the age restriction was lowered to under age 15 for Plan B One Step by the FDA. A cost analysis showed that Plan B One Step has the lowest cost of the currently available emergency contraceptives.

1. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee voted (15 for, 0 opposed, 2 abstained, 0 absent) upon signing of the minutes, to:
   a) remove levonorgestrel 0.75 mg (Next Choice) from the BCF; and
   b) add levonorgestrel 1.5 mg (Plan B One Step) to the BCF.
   c) No other changes to the Uniform Formulary are recommended; generic levonorgestrel 0.75 mg, levonorgestrel 1.5 mg (Next Choice One Dose, generic Plan B One Step), and ulipristal (Ella) remain UF.

2. ***COMMITTEE ACTION: QLs AND AGE LIMITS***—The P&T Committee voted (15 for, 0 opposed, 2 abstained, 0 absent) upon signing of the minutes, to:
   a) maintain the current QLs at all three POS of one fill per prescription, with no refills (new prescription required for every fill).
   b) For the current age limits, MTFs should follow their individual service policies, and for the Mail Order and Retail points of service, the FDA labeling should be followed.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

As the FDA has now approved emergency contraceptive Plan B One-Step to be available over the counter without restrictions, and as regulations required by section 702 of the FY13 NDAA to include OTCs on the uniform formulary have not yet been

prescribed, no emergency contraceptive shall be included on the BCF. Nevertheless, MTFs shall ~~treat~~ carry Plan B One-Step as ~~any other OTC in deciding whether to~~ provide it, and at no cost.

B. Gastrointestinal-1 (GI-1) Drug Class—Mesalamine (Asacol)

The GI-1 Drug Class was previously reviewed by the P&T Committee in February 2011. Mesalamine delayed release tablets (Asacol) were designated as BCF. In March 2013, Asacol tablets were discontinued by the manufacturer, Warner Chilcott, and supplies have been depleted. Warner Chilcott subsequently received FDA approval for a new formulation, Delzicol capsules, which is substantially more costly than Asacol. Several other mesalamine delayed release tablets are on the UF, including Asacol HD, Apriso, Lialda, and Pentasa. These products use different proprietary methods to delay release of the drug into the large intestine and, therefore, are not interchangeable and have different FDA-approved indications and dosing.

1. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee voted (16 for, 0 opposed, 1 abstained, 0 absent) upon signing of the minutes, to:
   a) remove mesalamine delayed release tablets (Asacol) from the BCF.
   b) The GI-1 Drug Class will not have a designated BCF product until the class can be re-reviewed for UF status. MTFs are advised to order what they need to meet local needs.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IV. UTILIZATION MANAGEMENT

A. PA

1. **Injectable Gonadotropins**—The P&T Committee clarified the PA criteria to set a 60-day expiration date for the PA, to help ensure that an authorization memorandum is included with each assisted reproductive technology (ART) cycle. A 60-day expiration is sufficient for a patient to complete an ART cycle.

   a) ***COMMITTEE ACTION: INJECTABLE GONADOTROPINS***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) clarifying the existing PA criteria for the injectable gonadotropins to have a 60-day expiration date for the PA.

2. **Proton Pump Inhibitors: Pantoprazole Change from Non-Preferred to Step-Preferred Status**—In November 2012, the P&T Committee recommended reclassification of pantoprazole as formulary on the UF, due to availability of cost-effective generic formulations; pantoprazole remained non-preferred. The cost of generic pantoprazole tablets has continued to decline since November 2012. The P&T Committee recommended revising the PA criteria to designate pantoprazole as step preferred (i.e., in front of the step).

    a) ***COMMITTEE ACTION: PANTOPRAZOLE PA CRITERIA/ STEP-PREFERRED STATUS***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) designating pantoprazole as step-preferred (i.e., in front of the step) on the UF.

3. **Antilipidemics-2: Icosapent ethyl (Vascepa)**—Icosapent ethyl (Vascepa) is the second prescription fish oil product marketed. The P&T Committee recommended manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication; the manual PA criteria for Vascepa will be the same as criteria for Lovaza.

    a) ***COMMITTEE ACTION: ICOSAPENT ETHYL (VASCEPA) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication. (See Appendix C for full criteria.)

4. **Abiraterone (Zytiga)**—PA criteria for abiraterone (Zytiga) were recommended at the November 2012 meeting, consistent with the FDA labeling. The FDA has subsequently updated the approved labeling for patients with metastatic castration-resistant prostate cancer with concomitant prednisone.

    a) ***COMMITTEE ACTION: ABIRATERONE (ZYTIGA) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) revising the abiraterone (Zytiga) PA criteria for use in patients with a documented diagnosis of metastatic castration-resistant prostate cancer on concomitant prednisone. The previous criterion for prior chemotherapy containing docetaxel is no longer required.

B. Quantity Limits (QLs)

1. **Oral tretinoin 10 mg capsules (Vesanoid)**—Oral tretinoin 10 mg capsules are approved for inducing remission in acute promyelocytic leukemia. Quantity limits are in place for several oral chemotherapy agents. The P&T Committee recommended QLs for oral tretinoin 10 mg capsules due to the high cost and adverse event profile.

   a) ***COMMITTEE ACTION: ORAL TRETINOIN 10MG CAPSULES (VESANOID) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs/days supply limits for oral tretinoin 10 mg capsules (Vesanoid), based on FDA-approved labeling, limiting use to a 30-day supply in the Retail Network, and a 45-day supply in the Mail Order.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Jonathan Woodson, M.D.
Director

8/6/2013
Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE MINUTES AND RECOMMENDATIONS

May 2013

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 15, 2013, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of February 2013 Minutes**—Jonathon Woodson, M.D., Director, approved the minutes for the February 2013 DoD P&T Committee meeting on May 13, 2013.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors—Canagliflozin (Invokana)

Relative Clinical Effectiveness Conclusion—Canagliflozin (Invokana) is a new diabetes drug with a novel mechanism of action and the first FDA-approved SGLT2 inhibitor. SGLT2 inhibitors are a new subclass of the Non-Insulin Diabetes Drug Class, which was originally reviewed in November 2010. The Non-Insulin Diabetes Drug Class also includes the following subclasses: biguanides (metformin), sulfonylureas,

thiazolidinedione (TZD), dipeptidyl-dipeptidase-4 (DPP-4) inhibitors, glucagon-like peptide-1 receptor agonists (GLP1RAs), pramlintide, dopamine agonists, meglitinides, and alpha glucosidase inhibitors.

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

- Efficacy of canagliflozin is limited to eight clinical trials, showing moderate decreases in hemoglobin A1c from baseline ranging from 0.63% (with insulin) to 1.11% (monotherapy in treatment-naïve patients).
- Canagliflozin has safety concerns of hypotension, impaired renal function, hyperkalemia, hypermagnesemia, hyperphosphatemia, increases in low-density lipoprotein (LDL) cholesterol and hemoglobin, hypoglycemia, urinary tract infections in both men and women, and genital mycotic infections.
- There is limited safety information available and no long-term outcomes trials have been completed to date with canagliflozin.
- Despite its unique mechanism of action to increase urinary glucose excretion, canagliflozin (Invokana) does not offer a clinically compelling advantage over the other non-insulin drugs included on the UF.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that canagliflozin (Invokana) is not cost-effective compared to other non-insulin diabetes drugs currently available on the UF. Cost minimization analysis (CMA) showed canagliflozin is more costly than metformin, glyburide, pioglitazone (Actos, generic), sitagliptin (Januvia), and exenatide (Byetta), in terms of cost per day of therapy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 1 opposed, 1 abstained, 2 absent) canagliflozin (Invokana) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes and adverse event data, and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) the following MN criteria for canagliflozin (Invokana): use of formulary agents is contraindicated. (See Appendix B for full criteria.)

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***—In the Non-Insulin Diabetes Drug Class, existing automated prior authorization (step therapy) requires a trial of metformin or a

sulfonylurea, prior to the use of a DPP-4 inhibitor, a TZD, or a GLP1RA, based on positive efficacy and long-term outcomes data with metformin and the sulfonylureas.

The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor in all new and current users of SGLT2 inhibitors, canagliflozin (Invokana), due to the modest hemoglobin A1c lowering and safety concerns. (See Appendix C for full criteria.)

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent) 1) an effective date of the first Wednesday after a 30-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is September 11, 2013.

V. UF DRUG CLASS REVIEWS

A. Anti-Gout Drugs

Background and Relative Clinical Effectiveness—The P&T Committee evaluated the Anti-Gout Drug Class. This class has not been previously reviewed for UF placement. Drugs in the class include allopurinol (Zyloprim, generic), probenecid, colchicine (Colcrys), colchicine/probenecid, and febuxostat (Uloric). Allopurinol is currently designated as a BCF product (pre-UF Rule decision).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following clinical effectiveness conclusions:

- Colchicine is a very old drug that is available in one branded formulation, (Colcrys), which has a patent extending to 2029.
- For an acute gout attack, clinical practice guidelines support colchicine as first line treatment, along with non-steroidal anti-inflammatory agents (NSAIDs) or prednisone. Treatment should be initiated within the first 24 hours of symptom onset.
- For chronic gout, urate-lowering therapy (ULT) with allopurinol or febuxostat is recommended as first line. Based on head-to-head trials, febuxostat (Uloric) 40 mg and allopurinol 300 mg were equally efficacious in lowering serum uric acid (sUA) to less than 6mg/dL in one study

(CONFIRMS). Febuxostat 80 mg was superior to allopurinol 300 mg in lowering sUA to less than 6mg/dL in two studies (FACT and APEX).

- Higher doses of allopurinol (doses > 300mg), although not well studied, may be required in some patients to decrease sUA.
- Systematic reviews from the Cochrane group, and evidence-based organizations from Canada, the UK, and Europe recommend febuxostat as an alternative ULT in patients who cannot tolerate allopurinol.
- Use of colchicine for prophylaxis helps prevent gout flares during initiation of ULT. However, in published trials, gout flares increased when prophylaxis was discontinued. Guidelines recommend administering colchicine or NSAID prophylaxis for up to 6 months.
- Head-to-head studies show similar rates of adverse events with febuxostat and allopurinol.
- Febuxostat warnings from the FDA include liver enzyme elevations. Liver function tests should be tested at initiation of therapy and monitored throughout treatment.
- Febuxostat warnings from the European Medicines Association (EMA) include the potential for increased cardiovascular (CV) events. According to the EMA, febuxostat should not be used in patients with ischemic heart disease or congestive heart failure, due to increased risk of CV events.
- In terms of clinical coverage, one anti-inflammatory agent (colchicine) and one xanthine oxidase inhibitor (allopurinol or febuxostat) are required on the UF to meet the needs of the majority of DoD beneficiaries.

Relative Cost-Effectiveness Analysis and Conclusion—Pharmacoeconomic analyses were performed for the Anti-Gout Drug Class, including CMA and budget impact analyses (BIAs). The class was subdivided into chronic drugs (allopurinol and febuxostat) and acute drugs (colchicine). For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted.

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) generic allopurinol (Zyloprim) was the most cost-effective of the chronic drugs, followed by branded febuxostat (Uloric), based on the weighted average cost per day of treatment across all three POS. Branded colchicine (Colcrys) was the only acute agent examined in the analysis; a cost analysis was conducted. CMA and BIA results showed that among available formulary options examined, scenarios where allopurinol (Zyloprim) is the BCF step-preferred agent, febuxostat (Uloric) is the NF non-preferred agent (with all current and new users required to try allopurinol first), and colchicine (Colcrys) is UF presented a maximum cost-avoidance projection.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) the following scenario for the UF, which is the most clinically and cost-effective option for the MHS:
    - allopurinol be designated UF and step-preferred (e.g., "in front of the step") ;
    - febuxostat (Uloric) be designated NF and non step-preferred (e.g., "behind the step"); and
    - colchicine (Colcrys), probenecid, and the fixed dose combination of colchicine/probenecid be designated formulary on the UF and exempt from step therapy.
    - This recommendation includes step therapy, which requires a trial of allopurinol prior to using febuxostat (Uloric) in all current and new users of febuxostat.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) maintaining allopurinol as BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for febuxostat (Uloric). (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—After extensive discussion, the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) PA criteria for all current and new users of febuxostat (Uloric), requiring a trial of allopurinol prior to use of febuxostat. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Additional recommendations made by the P&T Committee were to provide messaging to retail pharmacies to designate that PA and step therapy is required, with a trial of allopurinol prior to febuxostat (Uloric) and that the Anti-Gout Drug Class be added to the Rapid Response Program for the Retail Network and Mail Order Pharmacy. Based on the P&T Committee's recommendation, the effective date is November 6, 2013.

B. Pulmonary II Drugs

Background and Relative Clinical Effectiveness—The Pulmonary II Drug Class is comprised of two subclasses, the long-acting muscarinic agents (LAMAs), aclidinium inhaler (Tudorza) and tiotropium inhaler (Spiriva), and the chronic obstructive pulmonary disease (COPD) drugs [comprised of the short-acting muscarinic agents (SAMAs), short-acting beta agonist (SAMA/SABA) combinations and the phosphodiesterase type 4 (PDE-4) inhibitors].

Combivent metered dose inhaler (MDI) is one of the last available chlorofluorocarbon (CFC) MDIs on the market and will have supplies exhausted by December 2013. Its replacement is Combivent Respimat, a new CFC- and propellant-free formulation.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following at the February 2013 meeting:

- Aclidinium inhaler (Tudorza) is the second LAMA on the market. The three clinical trials used to obtain FDA approval reported statistically significant improvement in spirometric endpoints, and two of the trials reported significantly fewer COPD exacerbations with aclidinium, compared to placebo.
- For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. However, there is limited safety data with the 400 mcg approved dose. The FDA requires a prospective clinical trial to assess CV safety. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.
- Several trials have shown the LAMA tiotropium (Spiriva) is associated with clinically significant improvements in spirometric endpoints and reductions in risk for COPD exacerbations. Tiotropium is also reported to reduce the proportion of patients hospitalized for COPD exacerbations.
- Reports of a possible link between tiotropium and adverse CV events including death, stroke, and myocardial infarction have not been confirmed in prospective trials.
- Roflumilast (Daliresp) is the first oral selective inhibitor of PDE-4 marketed in the United States. Its FDA indication is limited to reducing the incidence of COPD exacerbations in patients with severe COPD. In two clinical trials, roflumilast was associated with statistically significant reductions in the rate of COPD exacerbations.
- For roflumilast, safety issues identified by the FDA included psychiatric events (including suicide), weight loss, gastrointestinal upset and severe diarrhea, and

nasal tumors. However, the FDA did not require additional prospective safety studies. A risk evaluation and mitigation strategy program was not required.

- Albuterol/ipratropium inhaler (Combivent Respimat) is the new propellant-free inhaler that is replacing the ozone-depleting CFC-containing Combivent MDI. The clinical trial used to obtain FDA approval showed Combivent Respimat was non-inferior to Combivent CFC MDI in terms of improvements in spirometric endpoints.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- CMA within the LAMA subclass showed that tiotropium (Spiriva) was more cost-effective than aclidinium (Tudorza). BIA results where Spiriva was designated BCF and Tudorza designated UF resulted in the greatest cost-avoidance to the MHS.
- CMA was conducted within the COPD subclass, which includes the SAMAs, SABA/SAMA combination drugs, and PDE-4 inhibitors. The results showed ipratropium nebulized solution (Atrovent; generic) was the most cost-effective agent, followed by ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium hydrofluoroalkane (HFA) MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp). Ipratropium/albuterol (Combivent) was not included in the cost-effectiveness analysis due to market discontinuation by December 2013. BIA projections for all scenarios were very similar.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (12 for, 1 opposed, 2 abstained, 2 absent) aclidinium inhaler (Tudorza), tiotropium inhaler (Spiriva), ipratropium nebulized solution (Atrovent; generic), ipratropium/albuterol nebulized solution (DuoNeb; generic), ipratropium HFA MDI (Atrovent HFA), ipratropium/albuterol soft mist inhaler (Combivent Respimat), and roflumilast (Daliresp) remain designated UF. Ipratropium/albuterol MDI (Combivent) will remain designated UF, pending discontinuation in December 2013.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) maintaining ipratropium HFA MDI (Atrovent HFA) and ipratropium/albuterol nebulized solution (DuoNeb; generic) on the BCF, and recommended adding tiotropium (Spiriva) the BCF, upon signing of the minutes.

C. Self-Monitoring Blood Glucose System (SMBGS) Test Strips

Background and Relative Clinical Effectiveness—The P&T Committee reviewed the clinical effectiveness of the SMBGS test strips, including the attributes of the test strips and glucometers. The SMBGS test strips were previously reviewed for UF placement in August 2008. The primary goal for this review is to ensure uniform availability of quality SMBGS test strips across the MHS (MTF, Retail, and Mail Order points of service). SMBGS glucometers are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review; however, provisions have been made to provide SMBGS glucometers at no cost to MHS beneficiaries.

The FDA classifies SMBGS test strips and glucometers as medical devices, rather than drugs, thus the focus of the clinical effectiveness review centers on differences in the technical aspects/attributes among the products. Candidates for inclusion on the UF must meet all minimum required technical standards and United States Federal Government contracting requirements. The P&T Committee reviewed the existing technical requirements approved in May 2007, and recommended updates to the criteria.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following for the minimum technical requirements and U.S. Federal Government contracting requirements for the SMBGS test strips. The full clinical effectiveness conclusion will be presented at the August 2013 meeting:

- *U.S Federal Government contracting requirements*: SMBGS test strips eligible for inclusion on the Uniform Formulary must be available at all 3 POS and must be compliant with the Trade Agreements Act. Corresponding SMBGS glucometers must also be compliant with the Trade Agreements Act. Manufacturers of SMBGS glucometers will be required to provide DoD beneficiaries with a no-cost glucometer.
- *Minimum technical requirements*: Candidate SMBGS test strips eligible for inclusion on the Uniform Formulary must meet the following minimum technical requirements:
    - Accuracy: Must meet FDA standards for accuracy based on the International Organization for Standardization (ISO) 15197 guidelines.
    - Sample size of $\leq$ 1 microliter
    - Alternate site testing: more than one alternate site approved.
    - Result time: $\leq$ 10 seconds
    - Memory capacity: $\geq$ 250 readings

- Ease of use: glucometer must be easy to code/calibrate, have a large visual display, and be easy to handle for patients with dexterity issues.
- Customer support: 24-hour helpline available, for beneficiaries residing outside the continental United States.
- Downloading capabilities: results must be downloadable
- Data management capabilities: data management capabilities required (e.g., software, cloud computing).

Relative Cost-Effectiveness Conclusion—The P&T Committee reviewed proposed condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

D. Corticosteroid Immune Modulators (Topical Steroids)

The P&T Committee evaluated the Corticosteroid Immune Modulators (Topical Steroids) Drug Class. The class is comprised of 22 individual chemical entities, available in over 100 different formulations and vehicles. The Stoughton-Cornell classification system, which divides the drugs into seven classes based on their vasoconstrictive properties, was used to further divide the drugs into high- (classes 1 and 2 steroids), medium- (classes 3, 4, and 5), and low-potency agents (classes 6 and 7). Over-the-counter (OTC) products are excluded from the class.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the clinical effectiveness conclusion. The full clinical effectiveness evaluation will be reported in the August meeting minutes.

Relative Cost-Effectiveness Conclusion—The P&T Committee reviewed proposed condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

VI. BCF ISSUES

A. Emergency Contraceptives

The Emergency Contraceptives were last reviewed by the P&T Committee in August 2011. Levonorgestrel 0.75 mg (Next Choice, the generic for Plan B) was designated as BCF. Next Choice was discontinued by the manufacturer in early 2013. The currently available emergency contraceptives include levonorgestrel 0.75 mg available from a

generic manufacturer; levonorgestrel 1.5 mg (Next Choice One Dose, Plan B One Step); and ulipristal (Ella). A prescription is required for all ages for Ella; and for patients under age 17 for generic levonorgestrel 0.75 mg, and levonorgestrel 1.5 mg (Next Choice One Dose). On April 15, 2013, the age restriction was lowered to under age 15 for Plan B One Step by the FDA. A cost analysis showed that Plan B One Step has the lowest cost of the currently available emergency contraceptives.

1. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee voted (15 for, 0 opposed, 2 abstained, 0 absent) upon signing of the minutes, to:
   a) remove levonorgestrel 0.75 mg (Next Choice) from the BCF; and
   b) add levonorgestrel 1.5 mg (Plan B One Step) to the BCF.
   c) No other changes to the Uniform Formulary are recommended; generic levonorgestrel 0.75 mg, levonorgestrel 1.5 mg (Next Choice One Dose, generic Plan B One Step), and ulipristal (Ella) remain UF.

2. ***COMMITTEE ACTION: QLs AND AGE LIMITS***—The P&T Committee voted (15 for, 0 opposed, 2 abstained, 0 absent) upon signing of the minutes, to:
   a) maintain the current QLs at all three POS of one fill per prescription, with no refills (new prescription required for every fill).
   b) For the current age limits, MTFs should follow their individual service policies, and for the Mail Order and Retail points of service, the FDA labeling should be followed.

Note from Decision Paper on p 8: As the FDA has now approved emergency contraceptive Plan B One-Step to be available over the counter without restrictions, and as regulations required by section 702 of the FY13 NDAA to include OTCs on the uniform formulary have not yet been prescribed, no emergency contraceptive shall be included on the BCF. MTFs shall ~~treat~~ Plan B One-Step ~~as any other OTC in deciding~~ and ~~whether to~~ provide it at no cost. carry JPK nevertheless,

B. Gastrointestinal-1 (GI-1) Drug Class—Mesalamine (Asacol)

The GI-1 Drug Class was previously reviewed by the P&T Committee in February 2011. Mesalamine delayed release tablets (Asacol) were designated as BCF. In March 2013, Asacol tablets were discontinued by the manufacturer, Warner Chilcott, and supplies have been depleted. Warner Chilcott subsequently received FDA approval for a new formulation, Delzicol capsules, which is substantially more costly than Asacol.

Several other mesalamine delayed release tablets are on the UF, including Asacol HD, Apriso, Lialda, and Pentasa. These products use different proprietary methods to delay release of the drug into the large intestine and, therefore, are not interchangeable and have different FDA-approved indications and dosing.

1. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee voted (16 for, 0 opposed, 1 abstained, 0 absent) upon signing of the minutes, to:
   a) remove mesalamine delayed release tablets (Asacol) from the BCF.
   b) The GI-1 Drug Class will not have a designated BCF product until the class can be re-reviewed for UF status. MTFs are advised to order what they need to meet local needs.

VII. UTILIZATION MANAGEMENT

A. PA

1. **Injectable Gonadotropins**—In November 2012, PA criteria for the injectable gonadotropins was revised to allow for use in conjunction with a noncoital reproductive technology, as outlined in the ASD(HA) April 2012 "Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members." A Signed Authorization Memorandum from TMA must be included with the prescription, and a new prescription is required for each assisted reproductive technology (ART) cycle. The P&T Committee clarified the PA criteria to set a 60-day expiration date for the PA, to help ensure that an authorization memorandum is included with each ART cycle. A 60-day expiration is sufficient for a patient to complete an ART cycle.

   a) ***COMMITTEE ACTION: INJECTABLE GONADOTROPINS***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) clarifying the existing PA criteria for the injectable gonadotropins to have a 60-day expiration date for the PA.

2. **Proton Pump Inhibitors (PPIs): Pantoprazole Change from Non-Preferred to Step-Preferred Status**—The PPIs currently have PA criteria (step therapy) requiring a trial of omeprazole or esomeprazole (Nexium) prior to use of the other PPIs. Omeprazole and esomeprazole are BCF and step-preferred. In November 2012, the P&T Committee

recommended reclassification of pantoprazole as formulary on the UF, due to availability of cost-effective generic formulations; pantoprazole remained non-preferred. The other PPIs, lansoprazole (Prevacid), rabeprazole (Aciphex), and omeprazole/sodium bicarbonate (Zegerid), are NF and non-preferred. The cost of generic pantoprazole tablets has continued to decline since November 2012. The P&T Committee recommended revising the PA criteria to designate pantoprazole as step-preferred (i.e., in front of the step).

a) ***COMMITTEE ACTION: PANTOPRAZOLE PA CRITERIA/ STEP-PREFERRED STATUS***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) designating pantoprazole as step-preferred (i.e., in front of the step) on the UF.

3. **Antilipidemics-2: Icosapent ethyl (Vascepa)**—Icosapent ethyl (Vascepa) is the second prescription fish oil product marketed. Icosapent ethyl has the same FDA-approved labeling and dosing as omega-3-acid ethyl esters (Lovaza). Vascepa is not as effective as Lovaza at lowering triglycerides, but does not adversely affect LDL levels. PA criteria apply to Lovaza, limiting use to the FDA-approved indications, due to the large number of off-label, non-supportable uses. The P&T Committee recommended manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication; the manual PA criteria for Vascepa will be the same as criteria for Lovaza.

   a) ***COMMITTEE ACTION: ICOSAPENT ETHYL (VASCEPA) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for all current and new users of Vascepa, limiting use to the FDA-approved indication. (See Appendix C for full criteria.)

4. **Abiraterone (Zytiga)**— Zytiga is an inhibitor of CYP 17 (an enzyme expressed in testicular, adrenal, and prostatic tumor tissues that is required for androgen biosynthesis). PA criteria for abiraterone (Zytiga) were recommended at the November 2012 meeting, consistent with the FDA labeling. At that time, Zytiga was FDA-approved for treatment of patients with metastatic castration-resistant prostate cancer who had previously received docetaxel. The FDA has subsequently updated the approved labeling for patients with metastatic castration-resistant prostate cancer with concomitant prednisone.

a) ***COMMITTEE ACTION: ABIRATERONE (ZYTIGA) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) revising the abiraterone (Zytiga) PA criteria for use in patients with a documented diagnosis of metastatic castration-resistant prostate cancer on concomitant prednisone. The previous criterion for prior chemotherapy containing docetaxel is no longer required.

B. Quantity Limits (QLs)

1. **Oral tretinoin 10 mg capsules (Vesanoid)**—Oral tretinoin 10 mg capsules are approved for inducing remission in acute promyelocytic leukemia. The product was previously available under the trade name Vesanoid, but now only generic formulations are available. Quantity limits are in place for several oral chemotherapy agents. The P&T Committee recommended QLs for oral tretinoin 10 mg capsules due to the high cost and adverse event profile.

a) ***COMMITTEE ACTION: ORAL TRETINOIN 10MG CAPSULES (VESANOID) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs/days supply limits for oral tretinoin 10 mg capsules (Vesanoid), based on FDA-approved labeling, limiting use to a 30-day supply in the Retail Network, and a 45-day supply in the Mail Order.

VIII. ADJOURNMENT

The meeting adjourned at 1630 hours on May 15, 2013. The next meeting will be in August 2013.

Appendix A—Attendance: May 2013 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix E—Table of Abbreviations

Appendix A—Attendance: May 2013 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CDR Joe Lawrence, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
COL Peter Bulatao, MS for COL John Spain, MS	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CDR Aaron Middlekauf for CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
COL Ted Cieslak, MC	Army, Physician at Large
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CAPT Walter Downs, MC	Navy, Internal Medicine Physician
COL Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
COL Bruce Lovins, MC	Army, Family Practice Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Jeremy King, MC	Air Force, OB/GYN Physician
LCDR Christine Olsen, MC	Navy, Pediatrics
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, TMA
COL Todd Williams, MS	Defense Medical Materiel Program Office
Maj Dan Castiglia via DCO	Defense Logistics Agency Troop Support
Guests	
Mr. Bill Davies via DCO	TRICARE Management Activity, Pharmaceutical Operations Directorate
CAPT Joel A. Roos	Navy Medicine Training Support Center
LCDR David Sohl	University of Texas Masters Student
Maj Ellen Roska	University of Texas PhD Student

Appendix A—Attendance (continued)

Others Present	
LCDR Marisol Martinez, USPHS	DoD Pharmacoeconomic Center
LCDR Joshua Devine, USPHS	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
LCDR Ola Ojo, MSC	DoD Pharmacoeconomic Center
LCDR Linh Quach, MSC	DoD Pharmacoeconomic Center
Maj David Folmar, BSC	DoD Pharmacoeconomic Center
MAJ Misty Cowan, MC	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Amy Lugo	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe via DCO	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
LT Kendra Jenkins, USPHS	Pharmacy Resident
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Mr. Kirk Stocker	DoD Pharmacy Outcomes Research Team contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Canagliflozin (Invokana) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	• Use of the formulary agent is contraindicated
• Febuxostat (Uloric) **Anti-gout Drugs**	• Use of allopurinol is contraindicated. • The patient has experienced significant adverse effects from allopurinol that are not expected to occur with the non-formulary medication. • Use of allopurinol has resulted in therapeutic failure. • The patient previously responded to non-formulary agent and changing to allopurinol would incur unacceptable risk.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Canagliflozin (Invokana) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	All new and current users of an SLGPT2 inhibitor are required to try metformin, a sulfonylurea (SU), or a DPP-4 inhibitor before receiving canagliflozin (Invokana). Automated PA criteria—The patient has filled a prescription for metformin, a SU, or a DPP-4 inhibitor 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, canagliflozin (SGLT2 inhibitor) is approved (e.g., trial of metformin or SU or DPP-4 inhibitor is NOT required) if: • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis • The patient has experienced any of the following issues on a sulfonylurea: o hypoglycemia requiring medical treatment • The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor • The patient has a contraindication to metformin or a SU or DPP-4 inhibitor
• Febuxostat (Uloric) **Anti-gout Drugs**	New and current users of febuxostat (Uloric) are required to try allopurinol. Automated PA Criteria—The patient has received a prescription for allopurinol at any Military Health System pharmacy point service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria—If automated criteria are not met, febuxostat (Uloric) is approved (e.g., a trial of allopurinol is not required) if: • The patient has experienced any of the following issues with at least one of the following with allopurinol, which is not expected to occur with febuxostat (Uloric): o The patient has had an inadequate response to allopurinol (failure to achieve serum uric acid levels < 6 mg/day) after an adequate trial (at least 300 mg per day of allopurinol) o The patient has had intolerable adverse effects (e.g., hypersensitivity) to allopurinol o The patient has a contraindication to allopurinol (e.g., renal impairment)

• icosapent ethyl (Vascepa) **Antilipidemic-2s**	New and current users of Vascepa are required to undergo the PA process. <u>Manual PA Criteria</u>—Vascepa is approved if: • Patients Receiving Statins: o Patients with triglyceride (TG) Levels > 500 mg/dL AND o Inadequate TG-lowering response to a therapeutic trial of niacin (1-g/day), unable to tolerate niacin/fibrate or who are not a candidate for niacin/fibrate therapy * ** • Patients NOT Receiving Statins: o Patients with TG Levels > 500 mg/dL AND o Inadequate response to a therapeutic trial of monotherapy with both a fibrate and niacin (1-2 g/day), unable to tolerate a fibrate and niacin or who are not candidates for fibrates** and niacin therapy • Patients with TG <500 mg/dL or <500 mg/dL with an inadequate TG-lowering response to niacin or fibrates or who are unable to tolerate/are not candidates for niacin or fibrates • Coverage is not approved for the use of Vascepa for the treatment of other conditions, including: ADHD, Alzheimer's disease, bipolar disorder, Crohn's disease, cystic fibrosis, dementia, depression, inflammatory bowel disease, intermittent claudication, metabolic syndrome, osteoporosis, PTSD, renal disease (IgA nephropathy), rheumatoid arthritis, schizophrenia, Type 2 diabetes mellitus, and ulcerative colitis *Not candidates for niacin: patients with a history of confirmed PUD (perforation, ulceration, or upper GIB), gouty attacks (presence of intra-articular uric acid crystals in the affected joint), and/or poorly controlled diabetes **Not candidates for fibrates: patients with hepatic or severe renal dysfunction, including primary biliary cirrhosis and preexisting gallbladder disease
• abiraterone (Zytiga) **Oral Chemotherapy Drugs for Prostate Cancer**	<u>Manual PA Criteria</u>—Coverage approved for treatment of patients: • With a documented diagnosis of metastatic castration-resistant prostate cancer AND • Patient is receiving concomitant prednisone

Appendix D—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2013	**Pulmonary II Drugs**	UF Class Review	▪ Ipratropium HFA MDI (Atrovent HFA) ▪ Ipratropium/ albuterol nebulized solution (DuoNeb) ▪ Tiotropium inhaler (Spiriva)	▪ Aclidinium inhaler (Tudorza) ▪ Ipratropium nebulized solution (Atrovent) ▪ Ipratropium / albuterol soft mist inhaler (Combivent Respimat) ▪ Roflumilast (Daliresp)	▪ None	Pending signing of the minutes	None	▪ Combivent Respimat added to the BCF
May 2013	**Anti-Gout Drugs**	UF class review	▪ Allopurinol	▪ colchicine (Colcrys) ▪ probenecid ▪ colchicine/probenecid	▪ Febuxostat (Uloric)	Pending signing of the minutes / 90 days	Step therapy (automated PA); requires a trial of allopurinol prior to use of Uloric in all new and current users of Uloric.	▪ Step therapy does not apply to colchicine, probenecid, or colchicine/ probenecid
May 2013	**Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	New Drug review	▪ None	▪ None	▪ **Canagliflozin (Invokana) recommended for NF May 2013**	Pending signing of the minutes / 30 days	Step therapy (automated PA); requires a trial of metformin, an SU, or a DPP-4 inhibitor in all new and current users of a SGLT2 inhibitor	BCF, UF, and NF drugs are designated for the non-insulin diabetes drugs for metformin, sulfonylureas, DPP-4 inhibitors, GLP1RA agonists, TZDs, meglitinides, and alpha glucosidase inhibitors (see Minutes November 2010, August 2012, and November 2012).

TRICARE Formulary Search tool: http://www.pec.ha.osd.mil/formulary_search.php

Appendix E—Table of Abbreviations

ASD(HA)	Assistant Secretary of Defense for Health Affairs
ART	assisted reproductive technology
BCF	Basic Core Formulary
BIA	budget impact analysis
CFC	chlorofluorocarbon
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
CV	cardiovascular
DCO	Defense Connect Online
DoD	Department of Defense
DPP-4	dipeptidyl-dipeptidase-4
EMA	European Medicines Association
FDA	U.S. Food and Drug Administration
GI-1	Gastrointestinal-1 Drug Class
GLP1RA	glucagon-like peptide-1 receptor agonist
HFA	hydrofluoroalkane
LAMA	long-acting muscarinic agent
LDL	low-density lipoprotein cholesterol
MDI	metered dose inhaler
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NF	nonformulary
NSAIDs	nonsteroidal anti-inflammatory drugs
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PDE-4	phosphodiesterase-4
PEC	Pharmacoeconomic Center
POS	points of service
PPIs	proton pump inhibitors
QLs	quantity limits
SABA	short-acting beta agonist
SAMA	short-acting muscarinic agent
SGLT2	sodium glucose co-transporter 2
SMBGS	self-monitoring blood glucose system
SU	sulfonylurea
sUA	serum uric acid
TG	triglyceride
TZD	thiazolidinedione
ULT	urate-lowering therapy
UF	Uniform Formulary

DECISION PAPER

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

February 2013

I. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Newer Sedative Hypnotic-1 (SED-1s) Agents—Zolpidem Sublingual Low-Dose Tablets (Intermezzo)

Relative Clinical Effectiveness Conclusion—Intermezzo is a new low-dose zolpidem sublingual (SL) formulation available in 1.75 mg and 3.5 mg tablets. The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that despite its unique FDA labeling for middle-of-the-night awakening compared to the other SED-1s and the potential for less next-day impairment, zolpidem SL low dose (Intermezzo) does not offer a clinically compelling advantage over the other SED-1s included on the Uniform Formulary (UF).

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that zolpidem SL low dose (Intermezzo) is not cost-effective when compared to other SED-1s included on the UF. The relative cost minimization analysis (CMA) ranking of the comparator SED-1s (ranked from most cost-effective to least cost-effective) revealed that zolpidem immediate release (IR) (Ambien IR, generics) < zaleplon (Sonata, generics) < zolpidem ER (Ambien CR, generics) < zolpidem SL (Edluar)< ramelteon (Rozerem) < zolpidem SL low dose (Intermezzo).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) zolpidem sublingual low dose (Intermezzo) be designated nonformulary (NF) due to the lack of compelling clinical advantages and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following MN criteria for zolpidem SL low dose (Intermezzo): there is no alternative formulary agent—the patient has swallowing difficulties and requires a product for middle-of-the-night awakening.

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***
Existing automated prior authorization (step therapy) requires a trial of generic zolpidem IR or zaleplon, the step-preferred agents, prior to the other SED-1s in new users. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria should apply to Intermezzo. Coverage would be approved if the patient met any of the following criteria:

   a) Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any Military Health System (MHS) pharmacy point of service (POS) [military treatment facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

   b) Manual PA criteria: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is July 17, 2013.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

II. UF DRUG CLASS REVIEWS

A. Topical Pain Agents

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Lidocaine 5% patch (Lidoderm) is effective for the management of its orphan indication, postherpetic neuralgia (PHN). There is insufficient evidence supporting use of Lidoderm for other neuropathies (e.g., diabetic neuropathy, HIV-associated neuropathy, complex regional pain syndrome); however, several professional guidelines support its use. There is a paucity of data regarding use

of Lidoderm for other off-label conditions, including widespread or deep pain conditions such as fibromyalgia or chronic pain associated with osteoarthritis.

- A review of MHS prescribing trends showed a high discontinuation rate for Lidoderm, with a similar prevalence between unique user new starts and discontinuations. A Pharmacy Outcomes Research Team (PORT) analysis showed that Lidoderm is commonly prescribed in the MHS for off-label, non-supportable uses (e.g., musculoskeletal pain) that are not associated with neuropathic pain.
- There are no head-to-head trials comparing the topical diclofenac products (Voltaren gel, Pennsaid drops, and Flector patch) in terms of efficacy or safety. However, indirect evidence suggests the agents are highly interchangeable with regard to efficacy. Limited evidence suggests the agents are as effective as oral diclofenac.
- The incidence of gastrointestinal (GI) adverse events is lower with the topical diclofenac products compared to oral nonsteroidal anti-inflammatory drugs (NSAIDs), offering a potential advantage for patients with a history of GI bleeding or peptic ulcers.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that among topical diclofenac products, diclofenac gel (Voltaren) was the most cost-effective, based on the weighted average cost per day of treatment across all three POS, followed by diclofenac drops (Pennsaid) and diclofenac patch (Flector). Results from the CMA and budget impact analyses (BIAs) showed that the scenario where Lidocaine patch (Lidoderm) and diclofenac gel (Voltaren) were designated UF, with diclofenac drops (Pennsaid) and patch (Flector) designated NF, was the most cost-effective for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) lidocaine 5% patch (Lidoderm) and diclofenac 1% gel (Voltaren) remain designated with formulary status on the UF, and recommended NF status for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector), based on clinical and cost effectiveness.
2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) that none of the topical pain agents be designated BCF. Because the topical pain agents are a subclass of the Pain Agents, there is no requirement to designate a topical agent with BCF status. Several pain agents (narcotic analgesics and oral NSAIDs) are included on the BCF. The cost-effectiveness analysis revealed no financial benefit to the MHS for placement of the topical pain agents on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector). (See Appendix B for full MN criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—After extensive discussion, the P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) manual PA criteria apply to all current and new users of lidocaine 5% patch (Lidoderm). Coverage is approved for patients who have a diagnosis of postherpetic neuralgia, other peripheral neuropathic pain, and for patients with non-neuropathic pain where an occupational or clinical reason exists and other analgesics are contraindicated. Coverage is not approved for other uses of Lidoderm. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is August 14, 2013.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Pulmonary II Drugs

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Aclidinium inhaler (Tudorza) is the second long-acting muscarinic agent (LAMA) on the market. The three clinical trials used to obtain FDA approval reported statistically significant improvement in spirometric endpoints, and two of the trials reported significantly fewer chronic obstructive pulmonary disease (COPD) exacerbations with aclidinium, compared to placebo.
- For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. However, there is limited safety data with the 400 mcg approved dose. The FDA is requiring a prospective clinical trial to

assess cardiovascular safety. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.

- Several trials have shown the LAMA tiotropium (Spiriva) is associated with clinically significant improvements in spirometric endpoints and reductions in risk for COPD exacerbations. Tiotropium is also reported to reduce the proportion of patients hospitalized for COPD exacerbations.

- Reports of a possible link between tiotropium and adverse cardiovascular (CV) events including death, stroke, and myocardial infarction have not been confirmed in prospective trials.

- Roflumilast (Daliresp) is the first oral selective inhibitor of phosphodiesterase type 4 marketed in the United States. Its FDA indication is limited to reducing the incidence of COPD exacerbations in patients with severe COPD. In two clinical trials, roflumilast was associated with statistically significant reductions in the rate of COPD exacerbations.

- For roflumilast, safety issues identified by the FDA included psychiatric events (including suicide), weight loss, GI upset and severe diarrhea, and nasal tumors. However, the FDA did not require additional prospective safety studies. A risk evaluation and mitigation strategy program was not required.

- Albuterol/ipratropium inhaler (Combivent Respimat) is the new propellant-free inhaler that is replacing the ozone-depleting chlorofluorocarbon (CFC)-containing Combivent metered dose inhaler (MDI). The clinical trial used to obtain FDA approval showed Combivent Respimat was non-inferior to Combivent CFC MDI in terms of improvements in spirometric endpoints.

Relative Cost-Effectiveness Conclusion—The P&T Committee reviewed proposed condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

C. Oral Anticoagulants

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following for warfarin, dabigatran (Pradaxa), and rivaroxaban (Xarelto). Apixaban (Eliquis) will be reviewed at an upcoming P&T meeting due to recent FDA approval in late 2012.

- The newer oral anticoagulants (NOACs) dabigatran and rivaroxaban have advantages of predictable anticoagulant effect, fixed dosing, and fewer drug interactions compared to warfarin (Coumadin, generic). Advantages of warfarin

include its long history of use, reliable reversal agent (vitamin K), and adverse effects that are predictable and manageable.

- The NOACs offer a convenience to patients; laboratory monitoring for efficacy and dietary restrictions are not required. More data is needed in patients with renal and hepatic impairment. No reversal agent is available with the NOACs.
- In non-valvular atrial fibrillation (Afib), dabigatran and apixaban were superior to poorly controlled warfarin at preventing stroke and systemic embolism, including hemorrhagic stroke; rivaroxaban was non-inferior to poorly controlled warfarin for these outcomes. Intracranial bleeding was lower with dabigatran, rivaroxaban, and apixaban compared to warfarin.
- For venous thromboembolism (VTE) prevention following orthopedic surgery, rivaroxaban was superior to enoxaparin at preventing symptomatic deep venous thrombosis (DVT), but at the cost of increased bleeding. For prevention of VTE recurrence following DVT or pulmonary embolism (PE), rivaroxaban in two trials was non-inferior to enoxaparin/warfarin for preventing recurrent VTE, with no difference in bleeding, and was superior to placebo in one trial for extended therapy for 6–12 months.
- Due to a lack of head-to-head trials, there is insufficient evidence to determine if one NOAC has advantages over the others.
- Patients require education and clinical monitoring to ensure appropriate use and avoid adverse reactions with the NOACs. Bleeding is a concern with all the NOACs, and dabigatran is associated with dyspepsia and major GI bleeding. For warfarin, a high risk of falls is not associated with risk of subsequent major bleeding.
- It remains to be determined whether the NOACs will increase the numbers of patients currently undertreated for stroke prevention in Afib. Also unknown is whether NOACs will improve persistence rates for anticoagulation therapy.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Anticoagulant agents for stroke prevention in non-valvular AFib—CMA results showed that, in all scenarios, warfarin, including drug monitoring costs, was the least costly agent. Cost-effectiveness analysis (CEA) results showed that the incremental cost-effectiveness ratios per life year gained with dabigatran and rivaroxaban in relation to warfarin were in a range that could be considered cost-effective to the MHS.
- Anticoagulant agents for DVT/PE prophylaxis in hip and knee replacement surgery—CMA results demonstrated that rivaroxaban was a cost-effective

alternative compared to enoxaparin, based on analysis of the average weighted price per day of therapy at all three POS.

- BIA results—Scenarios where all drugs remain on the UF resulted in the greatest cost-avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) warfarin (Coumadin, generic), dabigatran (Pradaxa), and rivaroxaban (Xarelto) remain formulary on the UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining warfarin (Coumadin, generic) on the BCF. MTFs are highly encouraged to purchase the contracted warfarin generic product.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

III. UTILIZATION MANAGEMENT

A. PA

1. **Tretinoin Age Limits**—The P&T Committee reviewed the current age limits for tretinoin, which does not allow use in patients older than 35 years. While treatment for acne is covered by TRICARE benefits, cosmetic services and supplies are excluded from the benefit, including treatments for photoaging of the skin.

   a) ***COMMITTEE ACTION: TRETINOIN AGE LIMITS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing the age limit for tretinoin products that are not exclusively labeled for cosmetic use at all 3 MHS POS (MTF, Mail Order, and the Retail Network). Acne can occur beyond age 35. Treatment for acne is covered by TRICARE benefits and low-cost tretinoin generic formulations are available. Tretinoin products/derivatives specifically indicated for cosmetic use as a result of the aging process (e.g., Renova, Refissa, Avage) remain excluded from the Pharmacy benefit.

2. **Zolpidem Gender-Based Dosing**—The P&T Committee discussed whether PA criteria are needed for zolpidem products, given new recommendations from the FDA in January 2013 regarding dosing in women. For women, lower dosing is recommended, as blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. A review of MHS prescriptions in the last six months of 2012 showed significant use of the higher zolpidem dosages in women.

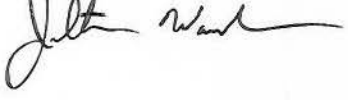
    a) ***COMMITTEE ACTION: ZOLPIDEM GENDER-BASED DOSING*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to not institute gender-based dosing PA criteria for zolpidem products, and to instead educate providers of the new recommendations, and notify patients via beneficiary newsletters of the concerns regarding impaired driving and activities requiring mental alertness the morning after use. The P&T Committee recommended re-evaluating this issue in six months to review MHS prescribing trends and whether additional measures are necessary.

B. Quantity Limits (QLs)

1. The P&T Committee reviewed quantity limit proposals for four products: aclidinium oral inhaler (Tudorza) for COPD, beclomethasone dipropionate nasal inhaler (Qnasl) for seasonal and perennial allergic rhinitis, ponatinib (Iclusig) tablets for treatment of patients with chronic myelogenous leukemia (CML), and cabozantinib (Cometriq) for patients with progressive, metastatic medullary thyroid cancer. QLs are recommended due to either existing QLs in the class to prevent wastage (inhalers) or due to high cost/adverse event profiles with subsequent need for dosage changes.

    a) ***COMMITTEE ACTION: ACLIDINIUM (TUDORZA), BECLOMETHASONE (QNASAL), PONATINIB (ICLUSIG) and CABOZANTINIB (COMETRIQ) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for aclidinium oral inhaler (Tudorza), beclomethasone dipropionate nasal inhaler (Qnasl), ponatinib tablets (Iclusig), and cabozantinib (Cometriq), based on FDA-approved labeling. (See Appendix D.)

Director, TMA, Decision: ☒ Approved ☐ Disapproved



Approved, but modified as follows:

VI. ITEMS FOR INFORMATION

A. Options for Future DoD P&T Committee Meetings—Given the current budget restrictions regarding travel, the P&T Committee discussed options for future meetings, including Defense Connect Online (DCO) web conferences. Items of concern voiced by the P&T Committee if DCO teleconferences were implemented in lieu of in-person meetings included maintaining confidentiality of the contracted pricing solicitations, likelihood of interruption/inattention, decreased engagement by P&T Committee members, and potential lost opportunities for cost-avoidance, which would ultimately negatively impact TRICARE beneficiaries.

B. Cost-Effectiveness Modeling Review—The P&T Committee reviewed an analysis of previous UF economic evaluations that compared the performance of cost modeling projections and budget impact analyses to actual observed costs in the MHS. Overall, the evaluated cost-effectiveness models performed suitably, demonstrating expenditure and utilization trends that were similar between modeled outcomes and actual results. Possible factors contributing to variance between the modeled outcomes and actual results were discussed. Potential improvements identified during the review will be incorporated into future cost modeling scenarios and processes.

C. Smoking Cessation Program Final Rule—As of the meeting date, the Smoking Cessation Final Rule has not yet been published in the Code of Federal Regulations. The Proposed Rule provides that smoking cessation pharmaceutical agents, including FDA-approved over-the-counter pharmaceutical agents, will be available through the TRICARE Mail Order Pharmacy or the MTF. Until publication of the Final Rule, all UF/BCF recommendations for smoking cessation products from the May 2012 DoD P&T Committee meeting remain on hold.

D. POS Analysis Update—The PORT provided an update on MHS prescribing trends by point of service. The results showed that for branded medications considered maintenance products (e.g., used for chronic conditions and not specialty medications), drug costs (30-day equivalent prescriptions) would have been about 27%–31% lower, if all prescriptions that were filled and dispensed in the Retail Network had instead been dispensed at the MTFs or at the Mail Order. In contrast, drug costs would have been about 13%–18% higher if generic drugs dispensed in the Retail Network had instead been dispensed in the MTFs or Mail Order.

E. **New TRICARE Pharmacy Copayments**—The P&T Committee was briefed on new pharmacy co-pays that were implemented in February 2013. At the Mail Order POS, co-pays for Tier 1 drugs (generics) remain $0, with co-pays of $13 for Tier 2 products (preferred brands) and $43 for Tier 3 products (non-preferred brands). The new co-pays in the Retail Network are $5 (Tier 1), $17 (Tier 2) and $44 (Tier 3). In the Mail Order, one co-pay applies for up to a 90-day supply, and one co-pay applies for up to a 30-day supply in the Retail Network.

F. **Step Therapy Safety Net**—The P&T Committee was briefed on the Rapid Response Step Therapy "Safety Net" Program implemented in September 2012. The program was initiated to educate beneficiaries affected by a step therapy reject and to educate providers regarding step-preferred drugs. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non step-preferred drug, after the initial reject. Since implementation, the MHS successful cases averaged 38.30%, which is similar to successful cases reported in commercial programs. Updates on the program will be periodically provided to the P&T Committee.

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Jonathan Woodson, M.D.
Director

13 May 2013
Date

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE MINUTES AND RECOMMENDATIONS

February 2013

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 20 and 21, 2013, at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2012 Minutes**—Jonathon Woodson M.D., Director, approved the minutes for the November 2012 DoD P&T Committee meeting on February 13, 2013.
2. **Clarification to the November 2012 Minutes—Prior Authorization (PA) Implementation Date for enzalutamide (Xtandi) and abiratone (Zytiga):** The November minutes were clarified to state March 20, 2013, is the effective implementation date for PA criteria applicable to enzalutamide (Xtandi) and abiratone (Zytiga).

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Newer Sedative Hypnotic-1 (SED-1s) Agents—Zolpidem Sublingual Low Dose Tablets (Intermezzo)

Relative Clinical Effectiveness—Intermezzo is a new low-dose zolpidem sublingual

(SL) formulation available in 1.75 mg and 3.5 mg tablets. Women should not receive Intermezzo doses larger than 1.75 mg. Intermezzo is specifically approved for treatment of insomnia characterized by middle-of-the-night waking followed by difficulty returning to sleep. In one study, there was a statistically significant improvement in sleep latency and total sleep time with Intermezzo versus placebo for middle-of-the-night awakening, but another placebo-controlled trial found no differences in total sleep time. No studies have been completed with an active comparator.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) despite its unique FDA labeling for middle-of-the-night awakening compared to the other SED-1s and the potential for less next-day impairment, zolpidem SL low dose (Intermezzo) does not offer a clinically compelling advantage over the other SED-1s included on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that zolpidem SL low dose (Intermezzo) is not cost-effective when compared to other SED-1s included on the UF. The relative cost minimization analysis (CMA) ranking of the comparator SED-1s (ranked from most cost-effective to least cost-effective) revealed that zolpidem immediate release (IR) (Ambien IR, generics) < zaleplon (Sonata, generics) < zolpidem ER (Ambien CR, generics) < zolpidem SL (Edluar)< ramelteon (Rozerem) < zolpidem SL low dose (Intermezzo).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) zolpidem sublingual low dose (Intermezzo) be designated NF due to the lack of compelling clinical advantages and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following MN criteria for zolpidem SL low dose (Intermezzo): there is no alternative formulary agent—the patient has swallowing difficulties and requires a product for middle-of-the-night awakening.

3. ***COMMITTEE ACTION: PA CRITERIA***—Existing automated prior authorization (step therapy) requires a trial of generic zolpidem IR or zaleplon, the step-preferred agents, prior to the other SED-1s in new users. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria should apply to Intermezzo. Coverage would be approved if the patient met any of the following criteria:

a) Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any Military Health System (MHS) pharmacy point of service (POS) [military treatment facilities (MTFs), retail network pharmacies, or mail order] during the previous 180 days.

b) Manual PA criteria: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is July 17, 2013.

V. UF DRUG CLASS REVIEWS

A. Topical Pain Agents

Background and Relative Clinical Effectiveness—The P&T Committee evaluated the Topical Pain agents subclass, which is comprised of lidocaine 5% patch (Lidoderm), diclofenac 1% gel (Voltaren), diclofenac 1.5% solution (Pennsaid), and diclofenac 1.3% patch (Flector).

The Topical Pain agents are a subclass of the Pain Agents UF drug class, which includes the Narcotic Analgesics and oral Non-Steroidal Anti-Inflammatory drugs (NSAIDs).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Extensive review of the literature provided limited evidence regarding efficacy and safety of the topical pain agents.
- Lidoderm is effective as first line and/or combination therapy for the management of its orphan indication—postherpetic neuralgia (PHN). There is insufficient evidence supporting use of Lidoderm for other neuropathies (e.g., diabetic neuropathy, HIV-associated neuropathy, complex regional pain syndrome); however, several professional guidelines support its use. There is a paucity of data regarding use of Lidoderm for other off-label conditions, including widespread or deep pain conditions such as fibromyalgia or chronic pain associated with osteoarthritis.

- A review of MHS prescribing trends showed a high discontinuation rate for Lidoderm, with a similar prevalence between unique user new starts and discontinuations.
- Topical diclofenac formulations (Voltaren gel, Pennsaid drops, and Flector patch) are effective in managing superficial pain associated with osteoarthritis of the knee and wrist, and superficial pain associated with sprains, strains, and contusions.
- There are no head-to-head trials comparing the topical diclofenac products in terms of efficacy or safety. However, indirect evidence suggests the agents are highly interchangeable with regard to efficacy. Limited evidence suggests the agents are as effective as oral diclofenac.
- The incidence of gastrointestinal (GI) adverse events is lower with the topical diclofenac products compared to oral NSAIDs, offering a potential advantage for patients with a history of GI bleeding or peptic ulcers.
- Systemic side effects are uncommon and the most common adverse events are application site reactions, including pruritis with Lidoderm, and dry skin, erythema and pruritis with the topical diclofenac products.
- Flector is indicated for short-term use associated with acute musculoskeletal injury and is likely to be used in a younger population than Voltaren gel or Pennsaid drops.
- Pennsaid is indicated only for osteoarthritis of the knee and clinical usefulness may be limited by multiple daily dosing (four times daily).
- A Pharmacy Outcomes Research Team (PORT) analysis reviewing ICD-9 codes associated with Lidoderm prescriptions in the MHS revealed significant overlap for diagnoses associated with neuropathic and musculoskeletal pain. Only 3% of prescriptions were written for patients with the FDA-approved PHN indication. Up to 49% of patients receiving Lidoderm prescriptions had no neuropathic diagnosis: 39% had musculoskeletal diagnoses without neuropathic diagnoses and 10% had neither neuropathic nor musculoskeletal diagnostic codes. This suggests that Lidoderm is commonly used in the MHS for off-label use that is not associated with neuropathic pain.

Relative Cost-Effectiveness Analysis and Conclusion—Pharmacoeconomic analyses were performed for the Topical Pain Agent subclass, including CMA and budget impact analyses (BIAs). For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted.

The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that among topical diclofenac products, diclofenac gel (Voltaren) was the most cost-effective, based

on the weighted average cost per day of treatment across all three POS, followed by diclofenac drops (Pennsaid), and diclofenac patch (Flector). Results from the CMA and BIAs showed that the scenario where Lidocaine patch (Lidoderm) and diclofenac gel (Voltaren) were designated UF, with diclofenac drops (Pennsaid) and patch (Flector) designated NF, was the most cost-effective for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) lidocaine 5% patch (Lidoderm) and diclofenac 1% gel (Voltaren) remain designated with formulary status on the UF, and recommended NF status for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector), based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) that none of the topical pain agents be designated BCF. Because the topical pain agents are a subclass of the Pain Agents, there is no requirement to designate a topical agent with BCF status. Several pain agents (narcotic analgesics and oral NSAIDs) are included on the BCF. The cost-effectiveness analysis revealed no financial benefit to the MHS for placement of the topical pain agents on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for diclofenac 1.5% solution (Pennsaid drops) and diclofenac 1.3% patch (Flector). (See Appendix B for full MN criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—After extensive discussion, the P&T Committee recommended (12 for, 4 opposed, 1 abstained, 0 absent) manual PA criteria apply to all current and new users of lidocaine 5% patch (Lidoderm). Coverage is approved for patients who have a diagnosis of postherpetic neuralgia, other peripheral neuropathic pain, and for patients with non-neuropathic pain where an occupational or clinical reason exists and other analgesics are contraindicated. Coverage is not approved for other uses of Lidoderm. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS, and 2) TMA send a letter to beneficiaries affected by the UF and PA decisions. Based on the P&T Committee's recommendation, the effective date is August 14, 2013.

B. Pulmonary II Drugs

Background and Relative Clinical Effectiveness—The Pulmonary II Drug Class is comprised of aclidinium inhaler (Tudorza), tiotropium inhaler (Spiriva), roflumilast tablets (Daliresp), ipratropium (Atrovent HFA inhaler; Atrovent nebulized solution), and ipratropium/albuterol (Combivent, Combivent Respimat and DuoNeb nebulized solution). The two inhalation solutions, ipratropium (Atrovent) and ipratropium/ albuterol (DuoNeb), are available in generic formulations.

Combivent metered dose inhaler (MDI) is one of the last available chlorofluorocarbon (CFC) MDIs on the market and will have supplies exhausted by December 2013. Its replacement is Combivent Respimat, a new CFC- and propellant-free formulation.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following clinical effectiveness conclusions:

- With regard to the long-acting muscarinic agents (LAMAs), aclidinium (Tudorza) and tiotropium (Spiriva), and the short-acting muscarinic agent (SAMA), ipratropium (Atrovent HFA), the P&T Committee concluded the following:
  - Aclidinium (Tudorza) is a dry powder inhaler (DPI) administered twice daily. The three clinical trials used to obtain FDA approval reported statistically significant improvement in lung function/spirometric endpoints [forced expiratory volume in 1 second (FEV_1)] compared with placebo at 12 weeks. Two of the trials reported statistically significant reductions in chronic obstructive pulmonary disease (COPD) exacerbations versus placebo.
  - In a small-dose ranging trial with 30 participants lasting for 15 days, there was no significant difference between aclidinium and tiotropium in terms of improvements in spirometric endpoints (FEV_1).
  - For aclidinium, the adverse event profile appears minimal, with primarily anticholinergic events reported. However, there is limited safety data with the approved 400 mcg dose. The FDA is requiring a prospective clinical trial to assess cardiovascular (CV) safety. Longer duration and larger comparative trials are needed to determine aclidinium's place in therapy.
  - Tiotropium is formulated as a DPI administered once daily. Several trials have documented tiotropium is associated with clinically significant improvements in FEV_1 and forced vital capacity compared with placebo or ipratropium. Additional benefits include reductions in the risk for COPD exacerbations as well as reduced hospitalizations due to COPD exacerbations.
  - Reports of a possible link between tiotropium and adverse CV events including death, stroke, and myocardial infarction (MI) were first raised in

2008, based on meta-analysis and retrospective analyses of health claims data. New data based on a large 4-year prospective trial (UPLIFT) and other analyses does not support an association with tiotropium and CV adverse events.

  - The other common adverse effects of tiotropium are anticholinergic in nature. There are reports of incorrect administration of the inhaler, with patients swallowing the capsule, instead of administering it via the HandiHaler device.
  - Ipratropium has been marketed since 1995. Review of the clinical literature for efficacy did not add substantial new information. For safety, while there may be a possible signal between ipratropium use and CV adverse events, the data is limited due to study design (cohort studies), influence of underlying CV disease, and presence of underlying pulmonary cancers.

- With regard to the SAMA/LAMA combination products, Combivent Respimat demonstrated similar improvements in FEV_1 as Combivent CFC MDI in the clinical trial used to obtain FDA approval. Some older patients or those with hand joint problems may require assistance for the initial assembly of the Combivent Respimat inhaler and cartridge. Combining bronchodilators may improve efficacy and decrease the risk of side effects, as compared to maximizing the dose of a single bronchodilator, and also provide a convenience to the patient. The safety profile of Combivent Respimat is similar to Combivent CFC MDI.
- Roflumilast (Daliresp) is the first oral phosphodiesterase type 4 inhibitor marketed in the United States, and is administered once daily. It has a narrow FDA indication, limited to reducing the incidence of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.
- Roflumilast should not be used to treat acute bronchospasm, as it has modest effects on FEV_1, is not a bronchodilator, and instead has anti-inflammatory actions. Combining roflumilast with a long-acting bronchodilator [salmeterol (Serevent) or tiotropium] results in improvements in FEV_1. The two trials used to obtain FDA approval reported roflumilast reduced COPD exacerbation rates by 15%–19% compared to placebo.
- For roflumilast, safety issues identified by the FDA included psychiatric events (including suicide), weight loss, GI upset and severe diarrhea, and nasal tumors. However, the FDA did not require additional prospective safety studies. A risk evaluation and mitigation strategy program was not required.

Relative Cost-Effectiveness Analysis, Relative Cost-Effectiveness Conclusion, UF Recommendation, BCF Recommendation—The P&T Committee reviewed proposed

condition sets for contract solicitation. The cost-effectiveness analysis and UF and BCF recommendations will be presented at an upcoming meeting.

C. Oral Anticoagulants

Background and Relative Clinical Effectiveness—The Oral Anticoagulant Drug Class is comprised of warfarin (Coumadin, generic), and the newer oral anticoagulants (NOACs) dabigatran (Pradaxa) and rivaroxaban (Xarelto). Another NOAC, apixaban (Eliquis) was approved in December 2012, and will be evaluated as a new drug at an upcoming meeting. Warfarin has been designated a BCF drug since before 1998, prior to implementation of the Uniform Formulary Rule in 2005.

Dabigatran, rivaroxaban, and apixaban are approved for stroke prevention in patients with non-valvular atrial fibrillation (Afib). Rivaroxaban has additional indications for prophylaxis of venous thromboembolism (VTE) in patients following hip or knee replacement surgery, and is also indicated to prevent recurrent VTE in patients with deep vein thrombosis (DVT) or pulmonary embolism (PE).

A PORT analysis showed that MHS users of dabigatran have a mean age of 76 years and 91% of patients have an ICD-9 diagnosis code for Afib. MHS users of rivaroxaban have a mean age of 70 years and 41% of patients have an ICD-9 diagnosis code for Afib versus 39% of patients with a diagnosis code for hip of knee replacement surgery.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) on the following clinical effectiveness conclusions:

- The NOACs dabigatran and rivaroxaban have advantages of predictable anticoagulant effect, fixed dosing, and fewer drug interactions compared to warfarin (Coumadin, generic). Advantages of warfarin include its long history of use, reliable reversal agent (vitamin K), and adverse effects that are predictable and manageable.
- The NOACs offer a convenience to patients; laboratory monitoring for efficacy and dietary restrictions are not required. More data is needed in patients with renal and hepatic impairment. No reversal agent is available with the NOACs.
- In non-valvular Afib, dabigatran and apixaban were superior to poorly controlled warfarin (time in therapeutic range < 65.5%) at preventing stroke and systemic embolism, including hemorrhagic stroke; rivaroxaban was non-inferior to poorly controlled warfarin for these outcomes. Intracranial bleeding was lower with dabigatran, rivaroxaban, and apixaban compared to warfarin.
- For VTE prevention following orthopedic surgery, rivaroxaban was superior to enoxaparin at preventing symptomatic DVT, but at the cost of increased bleeding. Dabigatran and apixaban were similar to enoxaparin at VTE

prevention; no difference in bleeding was noticed with dabigatran, but a lower risk of bleeding was shown with apixaban versus enoxaparin.

- For prevention of VTE recurrence following DVT or PE, rivaroxaban in two trials was non-inferior to enoxaparin/warfarin for preventing recurrent VTE, with no difference in bleeding, and was superior to placebo in one trial for extended therapy. Dabigatran in one trial was non-inferior to enoxaparin/warfarin for preventing recurrent VTE, with no difference in bleeding. Apixaban was superior to placebo for prevention of recurrent VTE over 12 months (extended therapy) in one trial.
- Due to a lack of head-to-head trials, there is insufficient evidence to determine if one NOAC has advantages over the others for stroke prevention in non-valvular Afib, prophylaxis of VTE following hip or knee replacement surgery, or for prevention of VTE recurrence following DVT or PE.
- Patients require education and clinical monitoring to ensure appropriate use and avoid adverse reactions with the NOACs. Bleeding is a concern with all the NOACs, and dabigatran is associated with dyspepsia and major GI bleeding. For warfarin, a high risk of falls is not associated with risk of subsequent major bleeding.
- It remains to be determined whether the NOACs will increase the numbers of patients currently undertreated for stroke prevention in Afib. Also unknown is whether NOACs will improve persistence rates for anticoagulation therapy.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee evaluated the relative cost-effectiveness of the anticoagulant agents for stroke prevention in non-valvular Afib and for prophylaxis of VTE in patients undergoing knee or hip replacement surgery. CMAs were performed for both indications. Additionally, a cost-effectiveness analysis (CEA) evaluated the agents for stroke prevention in Afib.

- For the anticoagulant drugs, CMAs were used to compare the anticoagulant drug costs including relevant drug monitoring costs (e.g., international normalized ratio testing for warfarin and office visits).
- The CEA model was constructed based on comparisons of relevant clinical trial data from systematic reviews. The CEA model assessed the potential impact of anticoagulant treatment on the occurrence of stroke, bleeding, MI, and mortality. Results were reported as an incremental cost-effectiveness ratio (ICER) comparing the additional costs per life year gained with the NOACs dabigatran (Pradaxa) and rivaroxaban (Xarelto) in relation to warfarin.
- For the BIAs, several of the model's key assumptions were varied, with corresponding sensitivity analyses conducted. BIA results were presented to

the P&T Committee. The MHS projected budgetary impact varied depending on which medication was selected for BCF, UF, or NF status.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 0 absent) the following:

- Anticoagulant agents for stroke prevention in non-valvular AFib—CMA results showed that, in all scenarios, warfarin (Coumadin, generic), including drug monitoring costs, was the least costly agent. CEA results showed that the ICERs per life year gained with dabigatran and rivaroxaban in relation to warfarin were in a range that could be considered cost-effective to the MHS.
- Anticoagulant agents for DVT/PE prophylaxis in hip and knee replacement surgery—CMA results demonstrated that rivaroxaban (Xarelto) was a cost-effective alternative compared to enoxaparin (Lovenox), based on analysis of the average weighted price per day of therapy at all three POS.
- BIA results—Scenarios where all drugs remain on the UF resulted in the greatest cost-avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) warfarin (Coumadin, generic), dabigatran (Pradaxa), and rivaroxaban (Xarelto) remain formulary on the UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining warfarin (Coumadin, generic) on the BCF. MTFs are highly encouraged to purchase the contracted warfarin generic product.

VI. UTILIZATION MANAGEMENT

A. PAs

1. **Tretinoin Age Limits**—The P&T Committee reviewed the current age limits for tretinoin, which does not allow use in patients older than 35 years. While treatment for acne is covered by TRICARE benefits, cosmetic services and supplies are excluded from the benefit, including treatments for photoaging of the skin.

a) ***COMMITTEE ACTION: TRETINOIN AGE LIMITS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing the age limit for tretinoin products that are not exclusively labeled for cosmetic use at all 3 MHS POS (MTF, Mail Order, and the Retail Network). Acne can occur beyond age 35 years. Treatment for acne is covered by TRICARE benefits and low-cost tretinoin generic formulations are available. Tretinoin products/derivatives specifically indicated for cosmetic use as a result of the aging process (e.g., Renova, Refissa, Avage) remain excluded from the Pharmacy benefit.

2. **Zolpidem Gender-Based Dosing**—The P&T Committee discussed whether PA criteria are needed for zolpidem products, given new recommendations from the FDA in January 2013 regarding dosing in women. For women, lower dosing is recommended, as blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. A review of MHS prescriptions in the last six months of 2012 showed significant use of the higher zolpidem dosages in women.

   a) ***COMMITTEE ACTION: ZOLPIDEM GENDER-BASED DOSING*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to not institute gender-based dosing PA criteria for zolpidem products, and to instead educate providers of the new recommendations, and notify patients via beneficiary newsletters of the concerns regarding impaired driving and activities requiring mental alertness the morning after use. The P&T Committee recommended re-evaluating this issue in six months to review MHS prescribing trends and whether additional measures are necessary.

B. Quantity Limits (QLs)

1. The P&T Committee reviewed quantity limit proposals for four products: aclidinium oral inhaler (Tudorza) for COPD, beclomethasone dipropionate nasal inhaler (Qnasl) for seasonal and perennial allergic rhinitis, ponatinib (Iclusig) tablets for treatment of patients with chronic myelogenous leukemia (CML), and cabozantinib (Cometriq) for patients with progressive, metastatic medullary thyroid cancer. QLs are recommended due to either existing QLs in the class to prevent wastage (inhalers) or due to high cost/adverse event profiles with subsequent need for dosage changes.

a) ***COMMITTEE ACTION: ACLIDINIUM (TUDORZA), BECLOMETHASONE (QNASAL) PONATINIB (ICLUSIG) and CABOZANTINIB (COMETRIQ) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for aclidinium oral inhaler (Tudorza), beclomethasone dipropionate nasal inhaler (Qnasl), ponatinib tablets (Iclusig), and cabozantinib (Cometriq), based on FDA-approved labeling. (See Appendix D.)

VII. ITEMS FOR INFORMATION

A. Options for Future DoD P&T Committee Meetings—Given the current budget restrictions regarding travel, the P&T Committee discussed options for future meetings, including Defense Connect Online (DCO) web conferences. Items of concern voiced by the P&T Committee if DCO teleconferences were implemented in lieu of in-person meetings included maintaining confidentiality of the contracted pricing solicitations, likelihood of interruption/inattention, decreased engagement by P&T Committee members, and potential lost opportunities for cost-avoidance, which would ultimately negatively impact TRICARE beneficiaries.

B. Cost-Effectiveness Modeling Review—The P&T Committee reviewed an analysis of previous UF economic evaluations that compared the performance of cost modeling projections and budget impact analyses to actual observed costs in the MHS. Overall, the evaluated cost-effectiveness models performed suitably, demonstrating expenditure and utilization trends that were similar between modeled outcomes and actual results. Possible factors contributing to variance between the modeled outcomes and actual results were discussed. Potential improvements identified during the review will be incorporated into future cost modeling scenarios and processes.

C. Smoking Cessation Program Final Rule—As of the meeting date, the Smoking Cessation Final Rule has not yet been published in the Code of Federal Regulations. The Proposed Rule provides that smoking cessation pharmaceutical agents, including FDA-approved over-the-counter pharmaceutical agents, will be available through the TRICARE Mail Order Pharmacy or the MTF. Until publication of the Final Rule, all UF/BCF recommendations for smoking cessation products from the May 2012 DoD P&T Committee meeting remain on hold.

D. POS Analysis Update—The PORT provided an update on MHS prescribing trends by point of service. The results showed that for branded medications considered maintenance products (e.g., used for chronic conditions and not specialty

medications), drug costs (30-day equivalent prescriptions) would have been about 27%–31% lower, if all prescriptions that were filled and dispensed in the Retail Network had instead been dispensed at the MTFs or at the Mail Order. In contrast, drug costs would have been about 13%–18% higher if generic drugs dispensed in the Retail Network had instead been dispensed in the MTFs or Mail Order.

E. **New TRICARE Pharmacy Copayments**—The P&T Committee was briefed on new pharmacy co-pays that were implemented in February 2013. At the Mail Order POS, co-pays for Tier 1 drugs (generics) remain $0, with co-pays of $13 for Tier 2 products (preferred brands) and $43 for Tier 3 products (non-preferred brands). The new co-pays in the Retail Network are $5 (Tier 1), $17 (Tier 2) and $44 (Tier 3). In the Mail Order, one co-pay applies for up to a 90-day supply, and one co-pay applies for up to a 30-day supply in the Retail Network.

F. **Step Therapy Safety Net**—The P&T Committee was briefed on the Rapid Response Step Therapy "Safety Net" Program implemented in September 2012. The program was initiated to educate beneficiaries affected by a step therapy reject and to educate providers regarding step-preferred drugs. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non step-preferred drug, after the initial reject. Since implementation, the MHS successful cases averaged 38.30%, which is similar to successful cases reported in commercial programs. Updates on the program will be periodically provided to the the P&T Committee.

VIII. ADJOURNMENT

The meeting adjourned at 1145 hours on February 21, 2013. The next meeting will be in May 2013.

Appendix A—Attendance: February 2013 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix F—Table of Abbreviations

Appendix A—Attendance: February 2013 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CDR Joe Lawrence, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
COL Peter Bulatao, MS for COL John Spain, MS	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
COL Ted Cieslak, MC	Army, Physician at Large
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CDR Brian King, MC for CAPT Walter Downs, MC	Navy, Internal Medicine Physician
LTC Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
COL Bruce Lovins, MC	Army, Family Practice Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Jeremy King, MC	Air Force, OB/GYN Physician
CDR Eileen Hoke, MC	Navy, Pediatrics
Dr. Miguel Montalvo	TRICARE Regional Office-South Chief of Clinical Operations Division and Medical Director
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, TMA
COL Todd Williams, MS	Defense Medical Materiel Program Office
CDR Jay Peloquin, MSC via DCO	Defense Logistics Agency Troop Support
Guests	
Mr. Bill Davies via DCO	TRICARE Management Activity, Pharmaceutical Operations Directorate
CDR Matthew Baker, USPHS	Indian Health Service

Appendix A—Attendance (continued)

Guests	
Stephani Folts	Student, University of Incarnate Word Feik School of Pharmacy
Brian Hettler	Student, University of Incarnate Word Feik School of Pharmacy
Others Present	
LTC Chris Conrad, MS	DoD Pharmacoeconomic Center
LCDR Marisol Martinez, USPHS	DoD Pharmacoeconomic Center
LCDR Joshua Devine, USPHS	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
Lt Col Melinda Henne, MC	DoD Pharmacoeconomic Center
LCDR Ola Ojo, MSC	DoD Pharmacoeconomic Center
LCDR Linh Quach, MSC	DoD Pharmacoeconomic Center
Maj David Folmar, BSC	DoD Pharmacoeconomic Center
MAJ Misty Cowan, MC	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Amy Lugo via DCO	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe via DCO	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Dean Valibhai	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
LT Kendra Jenkins, USPHS	Pharmacy Resident
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Mr. Kirk Stocker	DoD Pharmacy Outcomes Research Team contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Zolpidem sublingual low dose (Intermezzo) **Newer Sedative Hypnotic-1 (SED-1s)**	• No alternative formulary agent – patient has swallowing difficulties and requires a product for middle-of-the-night awakening.
• Diclofenac 1.5% solution (Pennsaid) **Topical Pain Medications**	• Patient has experienced significant adverse effects from ALL of the formulary medications that are not expected to occur with the nonformulary topical pain medication (e.g., patient had intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs). • Formulary agents result or are likely to result in therapeutic failure (e.g., patient had intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs). • No alternative formulary agent – patient requires topical agent with dimethyl sulfoxide (DMSO) to aid in skin absorption.
• Diclofenac 1.3% patch (Flector) **Topical Pain Medications**	• Patient has experienced significant adverse effects from ALL of the formulary medications that are not expected to occur with the nonformulary topical pain medication (e.g., patient experienced intolerable dry skin with use of diclofenac gel and has gastrointestinal or cardiovascular risk factors that preclude use of oral NSAIDs). • No alternative formulary agent – patient requires use of patch for treatment of pain associated with acute strain/sprain and cannot use oral NSAIDs or diclofenac gel products.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
▪ Zolpidem sublingual low dose (Intermezzo) **Newer Sedative Hypnotics-1 (SED-1s)**	A trial of generic zolpidem IR or zaleplon is required for new users of Intermezzo. Automated PA criteria – The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria – The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon.
▪ Lidocaine 5% patch (Lidoderm) **Topical Pain Medications**	New and current users of Lidoderm are required to undergo the PA process. Manual PA criteria Lidoderm is approved if: – The patient has a diagnosis of postherpetic neuropathy – The patient has a diagnosis of another form of peripheral neuropathy – The patient has a diagnosis of other pain (non-neuropathic) and an occupational or clinical reason exists and other analgesics are contraindicated • Coverage for other uses of Lidoderm is not approved.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• aclidinium oral inhaler (Tudorza) **Pulmonary Disease II Drugs – Long-Acting Muscarinic Agent**	• Retail: 1 inhalers/30 days • Mail Order and MTF: 3 inhalers/90 days
• beclomethasone dipropionate aerosol nasal inhaler (Qnasl) **Nasal Allergy Drugs**	• Retail: 1 inhalers/30 days • Mail Order and MTF: 3 inhalers/90 days
• ponatinib (Iclusig) **Oral Chemotherapy Agents for chronic myelogenous leukemia**	• 15 mg tablets: – Retail: 90 tabs/30 days – Mail Order and MTF: 135 tabs/45 days • 45 mg tablets: – Retail: 30 tabs/30 days – Mail order and MTF: 45 tabs/45 days
• cabozantinib (Cometriq) **Oral Chemotherapy Agents for metastatic medullary thyroid cancer**	• 140, 100 and 60 mg daily dose cartons – Retail: 4 packs/30 days – Mail Order: 8 packs /45 days

Appendix E—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2013	**Topical Pain Medications**	UF Class Review	None	▪ Lidocaine 5% patch (Lidoderm) ▪ Diclofenac 1% gel (Voltaren)	▪ Diclofenac 1.3% patch (Flector) ▪ Diclofenac 1.5% solution (Pennsaid)	Pending signing of the minutes/ 90 days	PA applies	PA for Lidoderm applies to new and current users (see Appendix C)
Feb 2013	**Oral Anticoagulants**	UF Class review	Warfarin	▪ Dabigatran (Pradaxa) ▪ Rivaroxaban (Xarelto)	▪ N/A (no drugs designated nonformulary	Pending signing of the minutes	-	-
Feb 2013	**Newer Sedative Hypnotics-1 (SED-1s)**	New Drug	Zolpidem IR	▪ Zolpidem ER ▪ Eszopiclone (Lunesta) ▪ Doxepin (Silenor) ▪ Zaleplon	▪ **Zolpidem sublingual low dose (Intermezzo) recommended for NF placement Feb 2013** ▪ Rozerem (Ramelteon) ▪ Zolpidem sublingual (Edluar)	Pending signing of the minutes/ 60 days	PA applies	Step therapy (Automated PA); requires trial of zolpidem IR or zaleplon before any other SED-1

TRICARE Formulary Search tool: http://www.pec.ha.osd.mil/formulary_search.php

Appendix F—Table of Abbreviations

Afib	atrial fibrillation
ASD(HA)	Assistant Secretary of Defense for Health Affairs
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	cost-effectiveness analysis
CFC	chlorofluorocarbon
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
CV	cardiovascular
DCO	Defense Connect Online
DoD	Department of Defense
DMSO	dimethyl sulfoxide
DPI	dry powder inhaler
DVT	deep vein thrombosis
ER	extended release
FDA	U.S. Food and Drug Administration
FEV_1	forced expiratory volume in 1 second
GI	gastrointestinal
ICER	incremental cost-effectiveness ratio
IR	immediate release
MI	myocardial infarction
MDI	metered dose inhaler
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NAOCs	newer oral anticoagulants
NF	nonformulary
NSAIDs	nonsteroidal anti-inflammatory drugs
P&T	Pharmacy and Therapeutics
PA	prior authorization
PE	pulmonary embolism
PEC	Pharmacoeconomic Center
PHN	postherpetic neuralgia
PORT	Pharmacy Outcomes Research Team
POS	points of service
QLs	quantity limits
SED-1s	newer sedative hypnotic-1 agents
LAMA	long-acting muscarinic agent
SAMA	short-acting muscarinic agent
SL	sublingual
UF	Uniform Formulary
VTE	venous thromboembolism