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 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
VITAMIN D
HECTOROL
ROCALTROL
ZEMPLAR
VASODILATING AGENTS, MISCELLANEOUS
AGGRENOX
PERSANTINE
VITAMIN B COMPLEX
NASCOBAL
PHOSPHODIESTERASE-5 INHIBITORS
VIAGRA
PLATELET-REDUCING AGENTS
AGRYLIN

SOMATOSTATIN AGONISTS
SANDOSTATIN
SANDOSTATIN LAR
SULFONAMIDES (SYSTEMIC)
AZULFIDINE
SULFONYLUREAS
AMARYL
DIABETA
GLUCOTROL
GLUCOTROL XL
GLUCOVANCE
GLYNASE
METAGLIP
THIAZIDE DIURETICS
DIURIL
MICROZIDE
THIAZIDE-LIKE DIURETICS
THALITONE
ZAROXOLYN
THIAZOLIDINEDIONES
ACTOPLUS MET
ACTOPLUS MET XR
ACTOS
DUETACT
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