DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

May 2011

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 11 and 12, 2011, 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, approved the minutes for the February 2011 DoD P&T Committee meeting on May 9, 2011.

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

A. Non-Insulin Diabetes Drugs: Dipeptidyl Peptidase-4 Inhibitor (DPP-4)/Biguanide Fixed-Dose Combination (FDC)—Saxagliptin/Metformin XR (Kombiglyze XR)

Relative Clinical Effectiveness—Kombiglyze XR is a FDC product containing the DPP-4 inhibitor saxagliptin (Onglyza) and the biguanide metformin extended-release (ER) (generic Glucophage XR) in one tablet. This drug is the second FDA-approved DPP-4/metformin FDC product. The Non-Insulin Diabetes drug class, which included the DPP-4s and biguanides separately, as well as combinations, was reviewed during the November 2010 P&T Committee meeting. The clinical evaluation for Kombiglyze XR included, but was not limited to, the requirements stated in 32 Code of Federal Regulations (CFR) 199.21(e)(1).

Kombiglyze XR is approved for use as adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. In November 2010, sitagliptin (Januvia) and sitagliptin/metformin immediate-release (IR) (Janumet) were designated with Basic Core Formulary (BCF) status and saxagliptin was designated with Uniform Formulary (UF) status. Automated Prior Authorization or Step Therapy applies to the DPP-4 subclass, which requires a trial of metformin alone or a sulfonylurea (SU) prior to use of sitagliptin, sitagliptin/metformin IR, or saxagliptin. The generic metformin ER component of Kombiglyze XR is available on the BCF as a single agent.

Clinical trials with sitagliptin and saxagliptin when used as monotherapy show reduction in hemoglobin A1C (HbA1C) of 0.4 - 0.79%. The saxagliptin/metformin FDC provides a 2.5% decrease in HbA1c from baseline. There are no head-to-head trials comparing saxagliptin/metformin ER (Kombiglyze XR) and sitagliptin/metformin IR (Janumet). However, in a head-to-head non-inferiority trial, sitagliptin/metformin IR lowered HbA1c by approximately 0.1% more from baseline than saxagliptin/metformin IR. Saxagliptin was considered non-inferior to sitagliptin. While statistical significance was achieved, the difference between the two agents is not clinically significant. There are no clinically relevant differences between sitagliptin and saxagliptin when combined with metformin in terms of glycemic control, and changes in lipid profile, weight, or blood pressure.

The product labeling for Kombiglyze XR contains the same contraindications and warnings as metformin. Renal and hepatic impairment remains a concern as well as other conditions that increase the risk of developing lactic acidosis. Kombiglyze XR can be dosed once daily. To achieve the target dose of metformin, patients can take an additional dose of metformin or take two 2.5mg/1000mg Kombiglyze XR tablets together once daily.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) saxagliptin/metformin XR (Kombiglyze XR) offers no clinically meaningful therapeutic advantage over sitagliptin/metformin IR (Januvia) in terms of efficacy, safety, or tolerability.

Relative Cost-Effectiveness—Cost-minimization analysis (CMA) was performed to evaluate the cost of saxagliptin/metformin ER (Kombiglyze XR) in relation to the other UF DPP-4 inhibitor/biguanide FDC agent, sitagliptin/metformin IR (Janumet), and to generic metformin IR or ER in combination with sitagliptan (Januvia) or saxagliptan (Onglyza). Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

Relative Cost-Effectiveness Conclusion—Based on the results of the cost analysis and other clinical and cost considerations, the P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that saxagliptin/metformin ER (Kombiglyze XR) tablets were more costly, compared with the other DPP-4s currently designated with BCF or UF status.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (16 for, 0 opposed, 1 abstained, 0 absent) saxagliptin/metformin ER (Kombiglyze

XR) remain formulary on the UF. Prior authorization/step therapy for the DPP-4s would require a trial of metformin or sulfonylurea prior to use of Kombiglyze XR for new patients.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (16 for, 0 opposed, 1 abstained, 0 absent) saxagliptin/metformin ER (Kombiglyze XR) be excluded from the BCF.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following PA criteria should apply to Kombiglyze XR. Coverage would be approved if the patient met any of the following criteria:

   a) Automated PA criteria:

      (1) The patient has received a prescription for metformin or sulfonylurea at any Military Health Service (MHS) pharmacy point of service [Military Treatment Facilities (MTFs), retail network pharmacies, or mail order) during the previous 180 days. OR

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

b) Manual PA criteria, if automated criteria are not met:

(1) The patient has experienced the following adverse event while receiving a SU: hypoglycemia requiring medical treatment.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

4. ***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 60-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is October 5, 2011

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows

B. Ophthalmic-1 Class—Bromfenac 0.09% Ophthalmic Solution (Bromday)

Relative Clinical Effectiveness—Bromfenac 0.09% ophthalmic solution (Bromday) is a non-steroidal anti-inflammatory drug (NSAID). It is the only ophthalmic NSAID approved for once daily dosing. Bromday is the same formulation of bromfenac (Xibrom) that was previously a twice daily dosed product. The branded formulation Xibrom was withdrawn from the market in February 2011 by the manufacturer. At the time of the May 2011 P&T Committee meeting, no generic formulations of Xibrom were approved. The Ophthalmic-1 Class was reviewed at the August 2010 P&T Committee meeting. All the ophthalmic NSAIDs are designated with formulary status on the UF; none are designated with BCF status. The clinical evaluation included, but was not limited to, the requirements stated in 32 CFR 199.21(e)(1).

Bromday was approved under a Supplemental New Drug Application using the data from Xibrom to change the dosing regimen to once daily dosing. Two Phase III placebo-controlled studies concluded that bromfenac dosed once daily for 16

days is effective for treating inflammation and pain in patients who have undergone cataract extraction with intraocular lens implantation. There are no head-to-head clinical trials comparing the bromfenac once-a-day formulation with the twice-a-day formulation. There are no studies comparing the bromfenac once daily formulation with any other ophthalmic NSAIDs. The safety profile of bromfenac is consistent with the other ophthalmic NSAIDs. The most common adverse events in the Phase III clinical trials that led to drug discontinuation and which occurred in a higher incidence than placebo were eye inflammation, photophobia, and eye pain. Based on the safety data from two Phase III studies, there are no clinically relevant differences between bromfenac ophthalmic solution and other ophthalmic NSAIDs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) there is no published evidence to suggest that bromfenac ophthalmic solution 0.09% (Bromday) has a compelling clinical advantage over other ophthalmic NSAID products currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the cost of bromfenac 0.09% ophthalmic solution (Bromday) in relation to the efficacy, safety, tolerability, and clinical outcomes of the other Ophthalmic-1 NSAIDs prescribed for postoperative pain and inflammation following cataract surgery. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the relative cost-effectiveness of Bromday compared to other UF agents. CMA results showed the projected weighted average cost per day for Bromday is higher than generic ophthalmic NSAIDs, but comparable in price to brand name ophthalmic NSAIDs.

Relative Cost-Effectiveness Conclusion—Based on the results of the cost analysis and other clinical and cost considerations, the P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) bromfenac 0.09% ophthalmic solution (Bromday) is cost-effective relative to the other branded Ophthalmic-1 NSAIDs in this class.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (15 for, 0 opposed, 1 abstained, 1 absent) bromfenac 0.09% ophthalmic solution (Bromday) remain formulary on the UF.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (15 for, 0 opposed, 1 abstained, 1 absent) bromfenac 0.09% ophthalmic solution (Bromday) be excluded from the BCF.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Alpha Blockers for Benign Prostatic Hyperplasia (BPH)—Tamsulosin/Dutasteride (Jalyn)

Relative Clinical Effectiveness—Tamsulosin/dutasteride (Jalyn) is a FDC product containing tamsulosin (Flomax, generics), an uroselective alpha-1 blocker (A1B) and dutasteride (Avodart), a 5-alpha reductase inhibitor (5-ARI). Jalyn is the first combination product for BPH. The drug is indicated for treatment of symptomatic BPH in men who have an enlarged prostate (>30 mL prostate volume). Jalyn is classified in the A1B subclass of the BPH agents, which was last reviewed in May 2010. Automated PA/Step Therapy applies to the A1B subclass, which requires a trial of generic tamsulosin or alfuzosin (Uroxatral) for new patients. For the 5-ARI subclass, finasteride (Proscar, generics) is designated with BCF status, and dutasteride (Avodart) is nonformulary on the UF. The clinical evaluation for Jalyn included, but was not limited to, the requirements stated in 32 CFR 199.21(e)(1).

FDA approval for Jalyn is based on the large randomized controlled four-year study, Combination of Avodart and Tamsulosin (CombAT), which evaluated the combination versus individual components. Results from the CombAT study showed the combination of dutasteride and tamsulosin (Jalyn) was not superior to dutasteride monotherapy for males with BPH with an enlarged prostate (>30ml), in terms of objective clinical progression to acute urinary retention (AUR) or BPH-related surgery.

The combination was superior to both tamsulosin and dutasteride monotherapy in terms of improvement of BPH-related symptoms.

The safety and tolerability data from the ComBAT study did not show a clinically relevant difference with Jalyn as compared to monotherapy with tamsulosin or dutasteride. There was a numerical increase in the incidence of cardiac failure with combination tamsulosin/dutasteride, however the FDA determined that co-morbidities were more likely the cause than the drug effect. There was a higher incidence of sexual adverse events (e.g., erectile dysfunction, retrograde ejaculation) with Jalyn, but these did not lead to a higher discontinuation rate with Jalyn, compared to the single agents administered as monotherapy.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that the FDC tamsulosin/dutasteride (Jalyn) is superior to tamsulosin and dutasteride monotherapy in terms of delaying BPH symptoms. However, it was not superior to dutasteride in delaying clinical progression to AUR and BPH-related surgery. There were no clinically relevant differences for Jalyn as compared to tamsulosin or dutasteride monotherapy in terms of safety and tolerability. The P&T Committee also agreed there is a high degree of therapeutic interchangeability between Jalyn and other combinations of selective A1B and a 5-ARI (e.g., tamsulosin/finasteride).

Relative Cost-Effectiveness—The P&T Committee evaluated the cost of tamsulosin/dutasteride (Jalyn) in relation to the efficacy, safety, tolerability, and clinical outcomes of the other uroselective A1Bs and 5-ARIs used for BPH. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA was used to evaluate the relative cost-effectiveness of Jalyn compared to other UF agents. Results from the CMA showed the projected weighted average cost per day for Jalyn was higher than the most cost-effective combination—generic tamsulosin and generic finasteride. However, Jalyn was more cost-effective than its individual components taken separately.

Relative Cost-Effectiveness Conclusion—Based on the results of the cost analysis and other clinical and cost considerations, the P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the combination of tamsulosin and finasteride administered together represents the most cost-effective combination of uroselective A1Bs and 5-ARIs for treatment of BPH. The FDC tamsulosin/dutasteride (Jalyn) is a cost-effective alternative relative to other combinations of A1Bs and dutasteride (Avodart).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (14 for, 1 opposed, 1 abstained, 1 absent) tamsulosin/dutasteride (Jalyn) remain formulary on the UF, with automated PA/Step Therapy requiring generic tamsulosin or alfuzosin (Uroxatral) for new patients.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (15 for, 0 opposed, 1 abstained, 1 absent) tamsulosin/dutasteride (Jalyn) be excluded from the BCF.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: PA CRITERIA***—Prior authorization for the A1Bs requires a trial of a step-preferred drug [tamsulosin or alfuzosin (Uroxatral)] prior to a non-step-preferred A1B [silodosin (Rapaflo)]. Tamsulosin/dutasteride (Jalyn) would be designated non-step-preferred. The P&T Committee recommended (13 for, 1 opposed, 2 abstained, 1 absent) the following PA criteria apply to tamsulosin/dutasteride (Jalyn):

    a) Automated PA criteria:
        (1) The patient has received a prescription for a preferred agent in the A1B subclass at any MHS pharmacy point of service (MTFs, retail network pharmacies, or home delivery) during the previous 180 days.

b) Manual (paper) PA criteria, if automated criteria are not met:

(1) The patient has received a trial of tamsulosin or alfuzosin and had an inadequate response and requires therapy with both an A1B and 5-ARI.
(2) The patient has received a trial of alfuzosin but was unable to tolerate it due to adverse effects but is expected to tolerate tamsulosin and requires therapy with both an A1B and 5-ARI.
(3) Treatment with alfuzosin is contraindicated for this patient (e.g., due to hypersensitivity) but tamsulosin is not contraindicated, and the patient requires therapy with both an A1B and 5-ARI.
(4) The patient requires therapy with both an A1B and 5-ARI and requires a fixed-dose combination (e.g., swallowing difficulties).

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 2 abstained, 1 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is October 5, 2011.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

IV. UF DRUG CLASS REVIEWS

A. Atypical Antipsychotic Drugs

Background Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the drugs in the atypical antipsychotics (AAP) Drug Class. The clinical review for the oral AAP drugs included, but was not limited to,

sources of information listed in 32 CFR 199.21(e)(1). The injectable AAPs were not included in the review.

The class is comprised of the following agents: clozapine (Clozaril, generics; Fazaclo), risperidone (Risperdal, Risperdal orally disintegrating tablet (ODT), generics), aripiprazole (Abilify, Abilify Discmelt), asenapine (Saphris), iloperidone (Fanapt), lurasidone (Latuda), olanzapine (Zyprexa, Zyprexa Zydis), olanzapine/fluoxetine (Symbyax), paliperidone (Invega), quetiapine IR and ER (Seroquel; Seroquel XR), and ziprasidone (Geodon).

The AAP Drug Class has not previously been reviewed for UF status, although quetiapine IR (Seroquel) and risperidone tablets were added to the BCF in May 2003 (prior to implementation of the Uniform Formulary Rule). Clarifications were made in August 2007 to include quetiapine ER (Seroquel XR) on the BCF and to exclude risperidone ODT. Currently, risperidone is the only AAP drug available in a generic formulation. The anticipated generic entries in the class are Zyprexa, Geodon, Abilify, and Seroquel IR, with patents set to expire in 2011 to 2014.

The AAP Drug Class is associated with a significant cost within the MHS; expenditures exceed $200 million annually. In terms of MHS utilization, quetiapine is the most utilized AAP, followed by generic risperidone. Aripiprazole is the third most utilized agent but accounts for most of the expenditures in the class.

The Pharmacy Outcomes Research Team (PORT) analyzed utilization and prescribing patterns in the MHS and noted that approximately 60% of AAP use in the MHS appears to be consistent with FDA-approved labeling. This estimate is higher than noted in the literature and may be overstated. The most common diagnosis codes for the AAPs differed by the population studied. For the active duty population, depression was the most commonly reported diagnosis code (53%, although it is unclear whether AAP use was for insomnia or to augment antidepressant effect). In the non-active duty population (ages 18–64 years), depression was the most commonly reported diagnosis code (61%). In contrast, attention deficit hyperactivity was the most commonly reported diagnosis code in the pediatric population (62%), compared with the over-65 population, where dementia was the most common diagnosis code (52%).

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (16 for, 0 against, 0 abstained, 1 absent) the following conclusions for the AAPs:

1. Schizophrenia: All AAPs are efficacious in treating schizophrenia. Data from the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) trial suggests that olanzapine is superior to the other AAPs in efficacy, but use is limited by adverse events. The four newest AAPs (asenapine, iloperidone, lurasidone, and paliperidone) are superior to placebo in treating schizophrenia, but the data is limited to small trials of short duration.

2. Bipolar Disorders: AAPs are used as adjunctive therapy to mood stabilizers in treating mania and mixed episodes. Six AAPs are FDA-approved for use in bipolar disorders (aripiprazole, asenapine, olanzapine, quetiapine, ziprasidone, and risperidone). Recommendations from the 2010 VA/DoD Clinical Practice Guideline (CPG) for bipolar disorder conclude olanzapine and quetiapine have more positive evidence than the other AAPs.
3. Major Depressive Disorder (MDD): For treatment-resistant MDD, AAPs are superior to placebo in augmenting antidepressant therapy. Three AAPs are FDA-approved for the treatment of MDD: aripiprazole, olanzapine/fluoxetine, and quetiapine ER. Data from systematic reviews suggests more positive evidence exists with quetiapine and aripiprazole for this indication. Risperidone also shows benefit in treating MDD, but is not FDA-approved.
4. Post-Traumatic Stress Disorder (PTSD): The available evidence from the 2010 VA/DoD CPG for PTSD and the American Psychiatric Association supports some benefit for the AAPs when used as adjunctive therapy to cognitive behavioral therapy (CBT) and selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors (SNRIs). The results of one meta-analysis show olanzapine and risperidone were more efficacious than placebo. None of the AAPs are FDA-approved for treating PTSD.
5. Dementia: There is evidence from systematic reviews that dementia symptoms of aggression and agitation are improved with AAPs (risperidone and olanzapine) but there is no benefit conferred in terms of cognition and functionality. Use of AAPs for psychiatric symptoms and behavioral disturbances in dementia patients is not approved by the FDA and is associated with significant risks of adverse events, including development of heart failure, cerebrovascular accident, and sudden cardiac death.
6. Insomnia: None of the AAPs are FDA-approved for treating insomnia. USCENTCOM MOD-10, military guidance for deployment, currently allows for the use of low-dose quetiapine (25 mg) for sleep with no waivers required. In the absence of other psychiatric comorbidities, the use of low-dose AAPs for primary insomnia should be discouraged due to the lack of supportive evidence, risk of adverse events (metabolic and cardiac), and lack of monitoring (e.g., EKG) for adverse events in-theatre. Other drug options to treat insomnia are available on the CENTCOM formulary, which have a lower risk of adverse events than the AAPs.

- The P&T Committee strongly recommends education of providers regarding the lack of evidence to support use of AAPs for primary insomnia and revision of current theater guidance (MOD-10).

7. With regards to safety, a black box warning applies to the entire class precluding use in elderly patients with behavioral and psychological symptoms of dementia due to increased mortality risk.
8. AAPs have different tolerability profiles as noted below:
   - Extrapyramidal symptoms are most likely to occur with risperidone (higher doses), paliperidone, and asenapine; and are least likely to occur with quetiapine, ziprasidone, aripiprazole, iloperidone and olanzapine.
   - Diabetes and weight gain are most commonly associated with clozapine and olanzapine. These effects are less common with aripiprazole, lurasidone, and ziprasidone.
   - Hyperprolactinemia has been most commonly associated with risperidone and paliperidone. Aripiprazole, iloperidone, and quetiapine have the lowest risk of this adverse event.
   - QTc interval prolongation is a concern with ziprasidone and iloperidone, but is least likely to occur with aripiprazole and lurasidone.
9. Adverse events are usually dose dependent and can be potentiated by patient characteristics such as age and comorbid conditions. AAP receptor binding affinities are associated with individual adverse events. Overall, the benefits conferred by AAPs are offset by limiting adverse effects.
10. For the pediatric population, the AAPs differ in their FDA-approved indications and ages. Aripiprazole, olanzapine, risperidone, paliperidone, and quetiapine are approved for use in pediatrics.
11. In a request for provider opinion, most respondents wanted 4 or more AAPs on their local formulary. In addition to risperidone, most respondents requested aripiprazole and quetiapine for inclusion on the BCF.
12. The clinician's choice for selecting an AAP should be influenced by the relationship between the efficacy and tolerability profile of the drug as well as individual patient characteristics.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of the AAP Drug Class. Although there are differences within the drug class regarding safety and tolerability profiles, CMA and budget impact analyses (BIA) were conducted, since clinically relevant differences in efficacy for schizophrenia are not apparent Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA and BIA were used to assess the potential impact of cost scenarios where selected AAPs—aripiprazole (Abilify, Abilify Discmelt), asenapine (Saphris), clozapine (Clozaril, generics; Fazaclo), iloperidone (Fanapt), lurasidone (Latuda), olanzapine (Zyprexa, Zyprexa Zydis), olanzapine/fluoxetine (Symbyax), paliperidone (Invega), quetiapine IR and ER (Seroquel IR, Seroquel XR), risperidone (Risperdal, Risperdal ODT), and ziprasidone (Geodon)—were designated with formulary or NF status on the UF. Cost scenarios evaluating the impact of designating selected agents on the BCF were also considered.

Relative Cost Effectiveness Conclusion—Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) BIA results for the AAP agents showed that all investigated scenarios resulted in lower cost estimates compared to current MHS expenditures. Overall cost analyses indicated the most cost-effective scenario and operationally-appropriate choice placed clozapine (Clozaril, generics; Fazaclo), risperidone (Risperdal, Risperdal ODT, generics), aripiprazole (Abilify, Abilify Discmelt), olanzapine (Zyprexa, Zyprexa Zydis), olanzapine/fluoxetine (Symbyax), paliperidone (Invega), quetiapine (Seroquel; Seroquel XR), and ziprasidone (Geodon) on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATIONS***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (9 for, 6 against, 2 abstained, 0 absent) clozapine (Clozaril, generics; Fazlaco), risperidone (Risperdal, Risperdal ODT, generics), aripiprazole (Abilify, Abilify Discmelt), olanzapine (Zyprexa, Zyprexa Zydis), olanzapine/fluoxetine (Symbyax), paliperidone (Invega), quetiapine (Seroquel; Seroquel XR), and ziprasidone (Geodon) remain formulary on the UF. The P&T Committee recommended iloperidone (Fanapt), asenapine (Saphris), and lurasidone (Latuda) be designated NF on the UF.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: BCF RECOMMENDATIONS***—Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (16 for, 0 against, 1 abstained, 0 absent) to maintain risperidone (Risperdal, Risperdal ODT, generics), quetiapine IR (Seroquel), and quetiapine XR (Seroquel XR) on the BCF.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—Based on the clinical evaluation of iloperidone (Fanapt), asenapine (Saphris), lurasidone (Latuda), and the conditions for establishing MN for NF medications, the P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) MN criteria for iloperidone (Fanapt), asenapine (Saphris), and lurasidone (Latuda). (See Appendix B for full MN criteria.)

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 against, 2 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60 days implementation period in all points of service, and 2) TMA send a letter to beneficiaries affected by this UF decision. Based on the Committee's recommendation the effective date is October 5, 2011.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Nasal Allergy Drugs (NADs)

Relative Clinical Effectiveness—The P&T Committee evaluated the clinical effectiveness of the NADs. The nasal corticosteroids were previously reviewed in November 2005, August 2007, and November 2008. The class is comprised of three subclasses as listed below.

- *Nasal Corticosteroids*: beclomethasone (Beconase AQ), budesonide (Rhinocort AQ), ciclesonide (Omnaris), flunisolide (generics), fluticasone furoate (Veramyst), fluticasone propionate (Flonase, generics), mometasone furoate (Nasonex), and triamcinolone (Nasacort AQ)
- *Nasal Antihistamines*: azelastine 0.1% (Astelin, generic), azelastine 0.15% with sucralose and sorbitol (Astepro), and olopatadine (Patanase)
- *Nasal Anticholinergics*: ipratropium (Atrovent, generics)

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

In terms of numbers of prescriptions dispensed, fluticasone propionate (Flonase, generics) is the highest utilized nasal allergy drug in the MTFs, followed by mometasone (Nasonex), and azelastine 0.1% (Astelin). This utilization pattern is also seen in the Retail Network. The current BCF drug for the NAD Drug Class is azelastine 0.1%; fluticasone propionate was removed from the BCF in May 2010 due to supply issues.

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

Nasal Corticosteroids:

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

- FDA-approved indications—The P&T Committee recognized that there were minor differences among the drugs with regard to FDA-approved uses for seasonal allergic rhinitis (SAR), perennial allergic rhinitis (PAR), prophylaxis of allergic rhinitis (AR) symptoms, nonallergic rhinitis, and nasal polyps. Additionally, the pediatric FDA-approved age ranges differ between the products.
- Clinical Practice Guidelines—Evidence-based guidelines from the 2008 American Academy of Allergy, Asthma and Immunology (AAAAI) and 2010 Allergic Rhinitis and its Impact on Asthma (ARIA) consider the nasal corticosteroids as the most effective drug class at reducing allergic rhinitis symptoms of sneezing, rhinorrhea, nasal congestion, and itching.

- Pharmacodynamic/pharmacokinetic properties—The AAAAI guidelines concluded that despite differences in topical potency, lipid solubility, receptor binding affinity, and systemic bioavailability, the overall clinical response does not appear to vary significantly between drugs.
- Efficacy for SAR/PAR—There was no compelling new data to change the conclusion from the 2008 P&T Committee Meeting review, which established there is no evidence of clinically relevant differences between the agents at relieving nasal or ocular symptoms of AR. However, ciclesonide lacks published evidence for reducing ocular symptoms.
- Nasal polyps—Mometasone and beclomethasone are FDA-approved for nasal polyps.
- There was no compelling new evidence to change previous conclusions.

With regards to regards to safety and tolerability, the following conclusions were made:

- Local effects—Nasal irritation, epistaxis, and rhinorrhea are the most common local adverse effects and are equally likely to occur with any of the nasal corticosteroids.
- Systemic effects—For systemic effects of hypothalamic pituitary adrenal-axis suppression, growth suppression, and ocular adverse events (cataracts/glaucoma), there is insufficient evidence to determine whether one nasal corticosteroid is more likely to cause these effects than another. When given in recommended doses, the nasal corticosteroids are not generally associated with clinically significant systemic adverse effects.
- Tolerability and patient preferences—Patient preferences may play a role in differentiating between the nasal corticosteroids. However, the available clinical data is poor, and no nasal corticosteroid has proven superior to the others in patient preference trials. Nevertheless, flunisolide is poorly tolerated and must be dosed three or four times daily while the others are dosed once or twice daily. Budesonide (Rhinocort AQ) is the only nasal corticosteroid with a pregnancy category B rating by the FDA. All the nasal corticosteroids have a class labeling that these drugs should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nasal Antihistamines:

With regards to efficacy/clinical effectiveness of the nasal antihistamines, the following conclusions were made:

- FDA-approved indications—The P&T Committee recognized that there were minor differences between olopatadine (Patanase), azelastine 0.1% (Astelin, generic), and azelastine 0.15% (Astepro) with regard to FDA-approved uses for SAR and nonallergic rhinitis [e.g., vasomotor rhinitis (VMR)], and pediatric approval.
- Clinical Practice Guidelines—The 2010 ARIA guidelines suggest use of non-sedating oral antihistamines preferentially to nasal antihistamines. The 2008 AAAAI guidelines state that nasal antihistamines are generally less effective than nasal corticosteroids for treating AR, but may be considered for use as first-line treatment for AR and nonallergic rhinitis. Nasal antihistamines are associated with a clinically significant effect on reducing nasal congestion.
- Efficacy for SAR—Azelastine and olopatadine are superior to placebo in relieving symptoms of SAR. There is no new compelling clinical data to suggest one product is more efficacious than the others.
- Head-to-head study—One head-to-head trial comparing the use of olopatadine with azelastine found no difference in relief of nasal symptoms, but suggests that olopatadine may be better tolerated by patients, as shown by a lower incidence of bitter taste.

With regards to safety and tolerability of the nasal antihistamines, the following conclusions were made:

- Local adverse effects—Somnolence is considered a class effect (AAAAI guidelines). Bitter taste has a higher incidence with azelastine, while epistaxis occurred with roughly equal frequency between olopatadine and azelastine.
- Patient preferences and tolerability—The available clinical data is sparse and is limited to manufacturer-sponsored studies, but tends to favor olopatadine. However, there is insufficient evidence to definitively conclude that clinically relevant differences exist between the nasal antihistamines.

Nasal Anticholinergics:

With regards to efficacy/clinical effectiveness, safety, tolerability, and other factors, of the ipratropium nasal spray (Atrovent, generics), the following conclusions were made:

- FDA-approved indications—Ipratropium is solely indicated for the relief of SAR in adults and children 12 years of age and older.
- Clinical Practice Guidelines—2010 AAAAI guidelines state that nasal anticholinergics may effectively reduce rhinorrhea, but have no effect

on other nasal symptoms. Although adverse events are minimal, dryness of the nasal membranes may occur.

- Efficacy and Safety—No new efficacy or safety data have been published since the prior review. Ipratropium is rated Pregnancy Category B by the FDA.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of the NADs. CMAs and BIAs were performed based on findings that there were no clinically relevant differences in efficacy, safety, tolerability, and other factors among the NADs. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

CMA and BIA were used to assess the potential impact of cost scenarios where selected nasal allergy agents were designated as formulary or nonformulary on the UF. Cost scenarios evaluating the impact of designating selected agents on the BCF were also considered.

Relative Cost-Effectiveness Conclusion—Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

BIA results for the NADs showed that six out of seven investigated scenarios resulted in lower cost estimates than current MHS expenditures. Scenarios where generic fluticasone propionate was selected as a BCF agent, with branded agents olopatadine (Patanase) and mometasone (Nasonex) on the UF were the most cost-effective scenarios overall. Sensitivity analysis results supported the above conclusion unless generic fluticasone propionate becomes unavailable for an extended period of time.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the NADs, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (16 for, 0 opposed, 1 abstained, and 0 absent) to recommend that:
    a) Fluticasone propionate (Flonase, generics), flunisolide (generics), mometasone (Nasonex), azelastine 0.1% (Astelin, generic), olopatadine (Patanase), and ipratropium (Atrovent, generics) be classified as formulary on the UF.
    b) Azelastine 0.15% (Astepro), beclomethasone (Beconase AQ), budesonide (Rhinocort Aqua), ciclesonide (Omnaris), fluticasone furoate (Veramyst), and triamcinolone (Nasacort AQ) remain designated as nonformulary under the UF.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee considered the BCF status of the NADs. Based on the results of the clinical and cost evaluations presented, the P&T Committee voted (16 for, 0 opposed, 1 abstained, and 0 absent) to recommend that fluticasone propionate (Flonase, generics) be designated with BCF status. As a result of this action, azelastine 0.1% (Astelin, generics) is no longer designated with BCF status. Implementation would occur immediately on signing of the May 2011 P&T Committee minutes by the Director, TMA.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UTILIZATION MANAGEMENT

A. Sumatriptan (Alsuma)—QUANTITY LIMITS (QLs): A new sumatriptan autoinjection (Alsuma) is now marketed. Alsuma will be reviewed as a new FDA-approved drug in the triptan drug class at an upcoming P&T Committee meeting. QLs are currently in place for both oral and other injectable formulations of sumatriptan (Imitrex, generics; Sumavel) and the other oral triptans, which are consistent with their product labeling.

COMMITTEE ACTION: QL—The P&T Committee voted (16 for, 0 against, 1 abstain, 0 absent) to recommend QLs of 24 units/90 days in the mail order pharmacy and 8 units/30 days in the retail network, which is consistent with the recommended dosing from the product labeling and avoids breaking apart packages for dispensing.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Buprenorphine Transdermal System (Butrans)—QL: A transdermal formulation of buprenorphine is now available. Buprenorphine transdermal system (Butrans) is FDA-approved for management of moderate-to-severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. The manufacturer's dosing recommendation mandates one transdermal system for seven days. Butrans will be reviewed as a new FDA-approved drug in the narcotic analgesics drug class at an upcoming P&T Committee meeting.

1. ***COMMITTEE ACTION: QL***—The P&T Committee voted (16 for, 0 against, 1 abstain, 0 absent) to recommend QLs for transdermal buprenorphine of 12 patches/84 days in the mail order pharmacy and 4 patches/28 days in the retail network, which is consistent with the recommended dosing from the product labeling and will decrease the risk of inadvertent misuse of the product.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. ITEMS FOR INFORMATION

A. Dabigatran (Pradaxa)—Potential Prior Authorization: Dabigatran is the first oral anticoagulant to reach the market since warfarin (Coumadin). It is currently limited to use in patients with non-vavular atrial fibrillation to reduce the risk of stroke and systemic embolism. The P&T Committee reviewed the existing clinical data for dabigatran and its advantages and disadvantages versus warfarin. The P&T Committee also discussed whether prior authorization was required to ensure prescribing is consistent with the current FDA-approved indications. The P&T Committee agreed that Prior Authorization was not needed at this time. Dabigatran will be reviewed with the other anticoagulants at a future meeting.

B. PORT—The PORT updated the P&T Committee on their mission, and reviewed ongoing initiatives and studies.

C. Over-the-counter Fexofenadine (Allegra OTC)—Allegra is now available over-the-counter and does not require a prescription. Therefore, it is not covered under the TRICARE benefit. Fexofenadine (generic Allegra) is a covered benefit by prescription. However, raw material is not being supplied to the generic manufacturers. Therefore,

the supply of fexofenadine is diminishing. Once fexofenadine supplies are depleted, it is unlikely the medication will be available in the future.

VII. FUTURE CLASS OVERVIEWS

An overview of the antidepressants/pain drug class was presented to the P&T Committee. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important to use in completing the clinical effectiveness reviews and developing appropriate cost-effectiveness models. The clinical and economic analyses of this drug class will be presented at an upcoming meeting.

VIII. ADJOURNMENT

The meeting adjourned at 1615 hours on May 11, 2011, and at 1140 hours on May 12, 2011. The next meeting will be in August 2011.

Appendix A—Attendance

Appendix B—Table of Medical Necessity Criteria for Newly-Approved Drugs

Appendix C—Table of Implementation Status of UF Recommendations/Decisions

Appendix D—Table of Abbreviations

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

5 August 2011
(Date)

Appendix A—Attendance

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
LTC Stacia Spridgen, MSC	Director, DoD Pharmacoeconomic Center (Recorder)
Col George Jones, BSC	Deputy Chief, Pharmaceutical Operations Directorate
LTC Travis Watson, MSC for COL Carole Labadie, MSC	Army, Pharmacy Officer
Col Mike Spilker, BSC	Air Force, Pharmacy Officer
CAPT Vernon Lew	Coast Guard, Pharmacy Officer
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician
LCDR Tim Thompson	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
COL Ted Cieslak, MC	Army, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Major Jeremy King, MC	Air Force, OB/GYN Physician
LTC Amy Young, MC for LTC Bruce Lovins, MC	Army, Family Practice Physician
CAPT Walter Downs, MC	Navy, Internal Medicine Physician
CDR Eileen Hoke, MC	Navy, Pediatrics
Lt Col Sam Munro, MC	Air Force, Physician at Large
Mr. Joe Canzolino	Department of Veterans Affairs
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
CDR Michele Hupp, MSC	Defense Medical Standardization Board
Maj Achilles Hamilothoris	Defense Logistics Agency Troop Support

Appendix A—Attendance (continued)

Guests	
CAPT Nita Sood	Chief of Staff, TRICARE Management Activity/Pharmaceutical Operations Directorate
LCDR Jodi Sparkman	United States Public Health Service/Indian Health Service
Francine Goodman	VA PBM
MAJ Sandra Shelmerdine	Brooke Army Medical Center, Attending Psychiatrist
Capt Arnaldo Figueroa	Air Force Pharmacy Resident
Others Present	
COL Cynthia Clagett	DoD Pharmacoeconomic Center
CDR Joe Lawrence	DoD Pharmacoeconomic Center
Lt Col Rey Morales	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
Lt Col Cynthia Lee, BSC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez	DoD Pharmacoeconomic Center
LCDR Ola Ojo	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe	DoD Pharmacoeconomic Center
Dr. Joshua Devine	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacoeconomic Center
Dr. Amy Lugo	DoD Pharmacoeconomic Center
Dr. Libby Hearin	DoD Pharmacoeconomic Center
Dr. Dean Valibhai	DoD Pharmacoeconomic Center
Dr. Stephen Yarger	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor

Appendix B—Table of Medical Necessity Criteria for Newly-Approved Drugs

Drug / Drug Class	Medical Necessity Criteria
Asenapine (Saphris) Iloperidone (Fanapt) Lurasidone (Latuda) **Atypical Antipsychotics (AAPs)**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • Patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk
Beclomethasone (Beconase AQ) Budesonide (Rhinocort Aqua) Ciclesonide (Omnaris) Fluticasone furoate (Veramyst) Triamcinolone (Nasacort AQ) **Nasal Allergy Drugs (NADs)**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives.
Azelastine 0.15% with sorbitol and sucralose (Astepro) **Nasal Allergy Drugs (NADs)**	• Use of formulary alternatives is contraindicated

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

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 2011	**Atypical Antipsychotics**	UF Review	▪ Risperidone (Risperdal, Risperdal ODT, generics) ▪ Quetiapine (Seroquel, Seroquel XR)	▪ Aripiprazole (Abilify), Abilify discmelt ▪ Clozapine (Clozaril, Fazaclo, generics) ▪ Olanzapine (Zyprexa, Zydis) ▪ Paliperidone ER (Invega) ▪ Olanzapine/fluoxetine (Symbyax) ▪ Ziprasidone (Geodon)	▪ Asenapine (Saphris) ▪ Iloperidone (Fanapt) ▪ Lurasidone (Latuda)	Pending signing of minutes/ 60 days	None	Risperidone (all oral formulations including ODT) remains on the BCF along with quetiapine IR and ER
May 2011	**Nasal Allergy Drugs**	UF Review	▪ Fluticasone propionate (Flonase, generics)	*Nasal Corticosteroids* ▪ Flunisolide (generics) ▪ Mometasone (Nasonex) *Nasal Antihistamines* ▪ Azelastine 0.1% (Astelin, generic) ▪ Olopatadine (Patanase) *Anticholinergic* ▪ Ipratropium (Atrovent, generics)	*Nasal Corticosteroids* ▪ Beclomethasone dipropionate (Beconase AQ) ▪ Budesonide (Rhinocort Aqua), ▪ Ciclesonide (Omnaris) ▪ Fluticasone furoate (Veramyst) ▪ Triamcinolone acetonide (Nasacort AQ) *Anticholinergic* ▪ Azelastine 0.15% (Astepro)	Pending signing of minutes	No change to previous QLs	▪ Azelastine 0.1% (Astelin, generics) no longer BCF ▪ Olopatadine (Patanase) now UF
May 2011	**Benign Prostatic Hypertrophy (BPH) Alpha 1-Blockers (A1Bs)**	New Drug in Already Reviewed Class	*May 2010* ▪ Alfuzosin (Uroxatral) ▪ Tamsulosin (Flomax, generics) ▪ Terazosin (Hytrin; generics)	*May 2011* ▪ Tamsulosin/dutasteride (Jalyn) *May 2010* ▪ Doxazosin IR (Cardura; generics)	▪ Silodosin (Rapaflo) ▪ Doxazosin ER (Cardura XL)	Pending signing of minutes/ 60 days	See comments	Step Therapy (automated PA) with tamsulosin or alfuzosin as the preferred agents ▪ (Note: Step Therapy does not apply to terazosin, doxazosin, or doxazosin ER.)

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 2011	**Ophthalmic-1 Agents**	New Drug in Already Reviewed Class	*August 2010* ▪ Olopatadine 0.1% (Patanol) ▪ Ketorolac 0.5% (Acular, generics)	***May 2011*** ▪ **Bromfenac QD (Bromday)** ***August 2010*** ▪ **Emedastine** (Emadine) ▪ Pemirolast (Alamast) ▪ Nedocromil (Alocril) ▪ Cromolyn (Crolom/Opticrom, generics) ▪ Lodoxamide (Alomide) ▪ Ketotifen (Zaditor, OTC) ▪ Bepotstine (Bepreve) ▪ Olopatadine 0.2% (Pataday) ▪ Azelastine (Optivar, generics) ▪ Epinastine (Elestat) ▪ Bromfenac BID (Xibrom) ▪ Ketorolac 0.4% (Acular LS, generics) ▪ Ketorolac 0.45% (Acuvail) ▪ Diclofenac (Voltaren, generics) ▪ Flurbiprofen (Ocufen, generics) ▪ Nepafenac (Nevanac)	▪ Not applicable (Bromday recommended for UF)	Pending signing of minutes	Not applicable	▪ Bromday QD formulation of bromefenac designated UF
Nov 2010	**Non-Insulin Diabetes Drugs** DPP-4 Inhibitors	New Drug in Already Reviewed Class	*Nov 2010* ▪ Sitagliptin (Januvia) ▪ Sitagliptin/Metformin IR (Janumet)	***May 2011*** ▪ **Saxagliptin/metformin ER (Kombiglyze XR)** *Nov 2010* ▪ Saxagliptin (Onglyza)	▪ Not applicable (Kombiglyze XR recommended for UF)	Pending signing of minutes/ 60 days	See comments	Step Therapy (automated PA) with metformin and sulfonylureas as step-preferred drugs

Appendix D—Table of Abbreviations

5-ARI	5-Alpha Reductase Inhibitor drug class
A1B	Alpha 1 Blocker drug class
AAAAI	American Academy of Allergy, Asthma, and Immunology
AAP	Atypical Antipsychotics drug class
AR	allergic rhinitis
ARIA	Allergic Rhinitis in Asthma
AUR	acute urinary retention
BCF	Basic Core Formulary
BPH	benign prostatic hypertrophy
BIA	budget impact analysis
CATIE	Clinical Antipsychotic Trials of Intervention Effectiveness
CBT	cognitive behavioral therapy
CFR	Code of Federal Regulations
CMA	cost minimization analysis
CombAT	Combination of Avodart and Tamsulosin clinical trial
CPG	Clinical Practice Guidelines
DoD	Department of Defense
DHP	Dihydropyridine
DPP-4	dipeptidyl-peptidase-4
ECF	Extended Core Formulary
ER	extended release
FDA	U.S. Food and Drug Administration
FDC	fixed dose combination
HbA1C	Hemoglobin A1C
IR	immediate release
MDD	major depressive disorder
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NAD	Nasal Allergy Drug Class
NSAIDs	Non-steroidal Anti-inflammatory Drug Class
ODT	orally dissolving tablets
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAR	perennial allergic rhinitis
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
PTSD	post traumatic stress disorder
QL	quantity limit
Rxs	prescriptions
SAR	seasonal allergic rhinitis
SU	sulfonylurea
VA	Veterans Affairs
VMR	vasomotor rhinitis