DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
June 2008

1) CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 1300 hours on 12 Jun 2008, and at 0800 hours on 13 Jun 2008 at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

2) ATTENDANCE

The attendance roster is found in Appendix A.

3) REVIEW MINUTES OF LAST MEETING

A. **Corrections to the minutes** – February 2008 DoD P&T Committee meeting minutes were approved as written, with no corrections noted.

B. **Approval of February minutes** – Dr. Samuel Ward Casscells, III., M.D., approved the minutes of the February 2008 DoD P&T Committee meeting on 30 Apr 2008.

4) REVIEW OF RECENTLY APPROVED AGENTS

A. Antilipidemic-II (LIP-2) – Fenofibrate meltdose (Fenoglide)

Relative Clinical Effectiveness – Fenofibrate meltdose (Fenoglide) is a new formulation of fenofibrate that is FDA-approved for treating hyperlipidemia and mixed dyslipidemia. To review the full clinical effectiveness evaluation, see the Fenoglide New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library; note that rxnet is restricted to those with a ".mil" e-mail address).

Relative Clinical Effectiveness Conclusion – The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that 1) there is no evidence to suggest that there are clinically relevant differences in the efficacy, safety and clinical outcomes of fenofibrate meltdose compared to other fenofibrate formulations, as they all contain the same active ingredient. 2) In terms of packaging and storage requirements, fenofibrate meltdose has advantages over fenofibrate insoluble drug delivery microparticle (IDD-P; Triglide) in that it is available in 90 count bottles and does not require dispensing in moisture-proof containers.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of fenofibrate meltdose in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the class. Information considered by the P&T Committee included, but was not limited to sources of information listed in 32 CFR 199.21 (e)(2).

A cost minimization analysis (CMA) was employed to evaluate the cost effectiveness of fenofibrate meltdose (Fenoglide). The cost effectiveness of Fenoglide was evaluated relative to the following agents: Triglide (currently the most cost effective UF fenofibrate) and Tricor. The results of the CMA showed that the projected

weighted average daily cost of Fenoglide was significantly lower than the weighted average daily cost of Triglide or Tricor.

Relative Cost Effectiveness Conclusion – The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that fenofibrate meltdose is cost effective relative to the evaluated agents in the LIP-2 class. The weighted average cost of Fenoglide is more cost effective relative to Triglide or Tricor.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 1 abstained, 1 absent) that: 1) fenofibrate meltdose (Fenoglide) be classified as formulary on the UF; and 2) the normal brand cost-share of $9.00 for fenofibrate meltdose (Fenoglide) be lowered to the generic formulary cost share of $3.00 in the retail and mail order points of service.

   The authority for the last recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate." The objective is to maximize use of fenofibrate meltdose in the retail network and mail order, given its significantly lower cost relative to other fenofibrate products. Lowering the cost-share for brand name fenofibrate meltdose will provide a greater incentive for beneficiaries to use the most cost effective fenofibrate formulation in the purchased care arena.

Fenofibrate meltdose (Fenoglide) was covered by the UF VARR submission at or below the FCP.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2) ***COMMITTEE ACTION: BCF RECOMMENDATION*** – Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 0 opposed, 1 abstained, and 1 absent) to recommend that 1) fenofibrate meltdose (Fenoglide) be added to the BCF; and 2) that gemfibrozil (Lopid, generics) be maintained on the BCF. As a result of the above actions, fenofibrate IDD-P (Triglide) would no longer be designated as BCF, but maintained as formulary on the UF.

   Director, TMA, Decision: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** – The P&T Committee voted (13 for, 0 opposed, 1 abstained, 1 absent) to recommend: 1) for

immediate implementation of the addition of fenofibrate meltdose (Fenoglide) to the BCF and the $3.00 co-pay reduction upon signing of the June 2008 DoD P&T Committee minutes by the Director, TMA; 2) that the special $3.00 co-pay that applied to fenofibrate IDD-P (Triglide) be terminated the first Wednesday following a 90-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Network Pharmacy (TRRx) programs; and 3) that TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following the approval by the Director, TRICARE Management Activity (TMA).

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Adrenergic Blocking Agents (ABAs) – Nebivolol (Bystolic)

Relative Clinical Effectiveness–Nebivolol is an Adrenergic Blocking Agent that is FDA-approved for treatment of hypertension. To review the full clinical effectiveness evaluation, see the Nebivolol New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion – The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that nebivolol (Bystolic) does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other ABA agents currently included on the UF.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of nebivolol in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the class, particularly to the following ABA medications: atenolol (Tenormin, generics), carvedilol extended release (Coreg CR) and metoprolol succinate extended release (Toprol XL, generics). Information considered by the P&T Committee included, but was not limited to sources of information listed in 32 CFR 199.21 (e)(2). A CMA was employed to determine the cost effectiveness of nebivolol (Bystolic) relative to atenolol, Coreg CR and metoprolol succinate ER. Results of the CMA showed that the projected weighted average daily cost of nebivolol was significantly higher than its ABA comparators.

Relative Cost Effectiveness Conclusion – P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 0 abstained, 0 absent) that the weighted average daily cost of nebivolol (Bystolic) was significantly higher than the weighted average daily cost of atenolol, carvedilol extended release (Coreg CR), or metoprolol succinate extended release (Toprol XL, generics)

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness of nebivolol, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend that nebivolol (Bystolic) be designated as non-formulary on the UF. This recommendation was based on the clinical

effectiveness conclusion, and the determination that atenolol, carvedilol extended release and metoprolol succinate extended release remain the most cost effective ABA agents on the UF compared to nebivolol.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2) ***COMMITTEE ACTION: MN CRITERIA*** – Based on the clinical evaluation of nebivolol and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) MN criteria for nebivolol (Bystolic). (See Appendix B for full MN criteria).

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. Newer Antihistamines (NAs)– Levocetirizine (Xyzal)

Relative Clinical Effectiveness – Levocetirizine is a Newer Antihistamine that is the R-enantiomer of cetirizine. It is FDA-approved in adults and in children as young as six years of age for the treatment of seasonal and perennial allergic rhinitis, and chronic idiopathic urticaria. To review the full clinical effectiveness evaluation, see the Levocetirizine New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that levocetirizine (Xyzal) did not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome over other NAs included on the UF.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of levocetirizine (Xyzal) in relation to efficacy, safety, tolerability, and clinical outcomes of other agents in the class. A CMA was employed to determine the cost effectiveness of levocetirizine relative to other NAs: loratadine (OTC Claritin, generics), cetirizine (OTC Zyrtec, generics), fexofenadine (Allegra,

generics), and desloratadine (Clarinex). The results of the CMA revealed that the weighted average cost per day of levocetirizine is significantly higher than loratadine, cetirizine, and fexofenadine, but is significantly lower than the non-formulary NA desloratadine (Clarinex).

Relative Cost Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that levocetirizine (Xyzal) is not cost effective relative to the other UF NAs.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of levocetirizine (Xyzal) and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 2 absent) to recommend that levocetirizine be designated as non-formulary under the UF.

   Director, TMA, Decision: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

2) ***COMMITTEE ACTION: MN CRITERIA*** – Based on the clinical evaluation of levocetirizine and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) MN criteria for levocetirizine (Xyzal). (See Appendix B for full MN criteria).

   Director, TMA, Decision: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** – The P&T Committee voted (13 for, 0 opposed, 0 abstained, 2 absent): 1) an effective date of the first Wednesday following a 60-day implementation period in the TMOP and TRRx, and no later than a 60-day implementation period at MTFs; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by Director, TMA.

   Director, TMA, Decision: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

D. Leukotriene Modifier (LM) – Zileuton extended release (Zyflo CR)

Relative Clinical Effectiveness– Zileuton extended release (Zyflo CR) is a new formulation of zileuton immediate release (Zyflo) that is dosed twice daily, rather than four times daily. It is FDA-approved for the treatment of asthma in adults and in children as young as 12 years of age. To review the full clinical effectiveness evaluation, see the Zileuton extended release New Drug in Previously Reviewed

Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that zileuton extended release (Zyflo CR) did not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome over other LMs included on the UF.

Relative Cost Effectiveness – The Committee evaluated the relative cost effectiveness of zileuton extended release (Zyflo CR) in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the LM class. A CMA was employed to evaluate the cost effectiveness of zileuton extended release relative to montelukast (Singulair), zafirlukast (Accolate), and zileuton immediate release (Zyflo). The results of the CMA demonstrated that the projected weighted average daily cost of zileuton extended release was significantly higher than the weighted average daily cost of the comparators within the LM class.

Relative Cost Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that zileuton extended release (Zyflo CR) is not cost effective relative to the other agents in the LM class. The weighted average cost of montelukast (Singulair), zafirlukast (Accolate) and zileuton immediate release (Zyflo) is more cost effective relative to zileuton extended release.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of zileuton extended release (Zyflo CR) and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 2 absent) to recommend that zileuton extended release be designated as non-formulary under the UF.

   Director, TMA, Decision: ☒ Approved ☐ Disapproved

   Approved, but modified as follows:

2) ***COMMITTEE ACTION: MN CRITERIA*** – Based on the clinical evaluation of zileuton extended release and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) MN criteria for zileuton extended release (Zyflo CR). (See Appendix B for full MN criteria).

   Director, TMA, Decision: ☒ Approved ☐ Disapproved

   Approved, but modified as follows:

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** – The P&T Committee voted (13 for, 0 opposed, 0 abstained, 2 absent): 1) an effective date of the first Wednesday following a 60-day implementation period in the TMOP and TRRx, and no later than a 60-day implementation period at MTFs; and 2) TMA send a letter to beneficiaries affected by this UF decision. The

implementation period will begin immediately following approval by Director, TMA.

Director, TMA, Decision: ☑ Approved ☐ Disapproved
Approved, but modified as follows:

E. Antilipidemic – I (Lip-1) – Simvastatin/niacin extended release (Simcor)

Relative Clinical Effectiveness – Simcor is the combination of 40 mg simvastatin (Zocor, generics) with 500-, 750- or 1000- mg of niacin extended release (Niaspan). It is approved by the FDA for patients with hyperlipidemia to raise HDL concentrations, and to lower LDL, triglyceride, non-HDL, and total cholesterol concentrations, when monotherapy is inadequate. To review the full clinical effectiveness evaluation, see the Simcor New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that there is insufficient evidence to suggest if there are clinically relevant differences between simvastatin/niacin extended release (ER; Simcor) and the other statins and niacin in terms of efficacy, and that in terms of safety and tolerability, Simcor appears comparable to giving the simvastatin and niacin components separately.

Relative Cost Effectiveness - The P&T Committee evaluated the relative cost effectiveness of simvastatin/niacin ER (Simcor) in relation to efficacy, safety, tolerability, and clinical outcomes of other agents in the LIP-1 class. A CMA was employed to evaluate the cost effectiveness of simvastatin/niacin ER relative to simvastatin (Zocor, generics), niacin ER (Niaspan), lovastatin/niacin ER (Advicor) and the combination of the individual components of Simcor (simvastatin plus Niaspan). The results of the CMA showed that the projected weighted average daily cost of Simcor was significantly less than the weighted average daily cost of its comparators.

Relative Cost Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that simvastatin/niacin ER (Simcor) is cost effective relative to the evaluated agents in the LIP-1 class.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of simvastatin/niacin ER (Simcor) and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 2 absent) to recommend that simvastatin/niacin ER be classified as formulary on the UF.

Simvastatin/niacin ER was covered by a UF VARR submission at or below the FCP

Director, TMA, Decision: ☑ Approved ☐ Disapproved
Approved, but modified as follows:

F. Glaucoma Agents – Brimonidine 0.02% / timolol maleate 0.05% (Combigan)

Relative Clinical Effectiveness – Combigan is a combination ophthalmic product that contains the alpha-2 adrenergic agonist brimonidine 0.02% (Alphagan, generics) with the beta blocker timolol maleate 0.05% (Timoptic, generics). Combigan is approved for twice daily use for the reduction of elevated intraocular pressure in patients with ocular hypertension or glaucoma who require adjunctive or replacement therapy. To review the full clinical effectiveness evaluation, see the Combigan New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that while brimonidine/timolol (Combigan) offers a convenience to the patient in terms of ease of administration, there is currently insufficient evidence to suggest if there are clinically relevant differences between Combigan and the other Glaucoma Agents in terms of efficacy. In terms of safety and tolerability, Combigan appears comparable to administering brimonidine and timolol as separate products dosed twice daily.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of brimonidine/timolol ophthalmic solution (Combigan) in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the class. A CMA was employed to evaluate the cost effectiveness of Combigan relative to timolol maleate (Timoptic, generics), brimonidine (Alphagan, generics), dorzolamide/timolol (Cosopt), and the single ingredient agents of Combigan (timolol maleate and brimonidine). The results of the CMA showed that the projected weighted average daily cost of Combigan was significantly lower than its comparators.

Relative Cost Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that the projected weighted average daily cost of Combigan was significantly lower than the weighted average daily cost of dorzolamide/timolol (Cosopt), or the pairings of the individual brimonidine and timolol components.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of brimonidine/timolol maleate (Combigan) and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 2 absent) to recommend that brimonidine/timolol maleate be classified as formulary under the UF.

Brimonidine/timolol maleate was covered by the UF VARR submission at or below the FCP.

Director, TMA, Decision: ☑ Approved ☐ Disapproved
Approved, but modified as follows:

G. Renin Angiotensin Antihypertensives (RAAs) – Olmesartan / amlodipine (Azor)

Relative Clinical Effectiveness – Azor is the combination of the angiotensin receptor blocker (ARB) olmesartan with the dihydropyridine calcium channel blocker (DHP CCB) amlodipine. It is FDA-approved for treating hypertension. To review the full clinical effectiveness evaluation, see the Azor New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library). .

Relative Clinical Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that while olmesartan/amlodipine (Azor) offers a convenience to the patient in terms of decreased tablet burden and simplified medication regimen, it does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome over other renin angiotensin antihypertensives included on the UF.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of olmesartan/amlodipine (Azor) in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the RAA class, particularly the ARBs. A CMA was employed to evaluate the cost effectiveness of olmesartan/amlodipine relative to telmisartan (Micardis), the BCF ARB; generic amlodipine (Norvasc), a BCF DHP-CCB; valsartan/amlodipine (Exforge); and to the combination of the individual components of telmisartan plus generic amlodipine. The results of the CMA demonstrated that the projected weighted average daily cost of Azor was significantly higher than the weighted average daily cost of combined individual agents (telmisartan plus generic amlodipine).

Relative Cost Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that olmesartan/ amlodipine is not cost effective relative to the other UF agents in the RAA class. The weighted average cost of combined individual agents (the BCF ARB telmisartan and BCF generic DHP CCB amlodipine) is more cost effective relative to Azor.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of olmesartan/amlodipine (Azor) and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 2 absent) to recommend that olmesartan/amlodipine be designated as non-formulary under the UF.

   Director, TMA, Decision: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

2) ***COMMITTEE ACTION: MN CRITERIA*** – Based on the clinical evaluation of olmesartan/amlodipine and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee

recommended (13 for, 0 opposed, 0 abstained, 2 absent) MN criteria for olmesartan/amlodipine (Azor). (See Appendix B for full MN criteria).

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** – The P&T Committee voted (13 for, 0 opposed, 0 abstained, 2 absent): 1) an effective date of the first Wednesday following a 60-day implementation period in the TMOP and TRRx, and no later than a 60-day implementation period at MTFs; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by Director, TMA.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

H. Renin Angiotensin Antihypertensives (RAAs) – Aliskiren / hydrochlorothiazide (Tekturna HCT)

Background – Tekturna HCT contains the renin inhibitor aliskiren with the diuretic hydrochlorothiazide (HCTZ). It is FDA-approved for treating hypertension. Preliminary results of clinical outcomes trials with aliskiren evaluating benefits in addition to blood pressure reduction have been positive. To review the full clinical effectiveness evaluation, see the Tekturna HCT New Drug in Previously Reviewed Classes monograph found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that while aliskiren/HCTZ offers a convenience to the patient in terms of decreased tablet burden and simplified medication regimen, there is insufficient evidence to suggest that the blood pressure lowering effect of aliskiren/HCTZ would be significantly greater than that achieved with other antihypertensive fixed-dose combinations. In terms of safety and tolerability, Tekturna HCT appears comparable to administering the aliskiren and HCTZ components separately.

Relative Cost Effectiveness - The P&T Committee evaluated the relative cost effectiveness of aliskiren/HCTZ (Tekturna HCT) in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the RAA class, particularly the ARBs. A CMA was employed to evaluate the cost effectiveness of aliskiren/HCTZ relative to the renin inhibitor aliskiren (Tekturna) and the ARBs, which were evaluated at the May and August 2007 DoD P&T Committee meetings. The results of the CMA showed that the projected weighted average daily cost of aliskiren/HCTZ was higher than the weighted average daily cost of the ARBs designated as formulary on the UF, but similar to the UF agent aliskiren (Tekturna).

Relative Cost Effectiveness Conclusion – The Committee voted (13 for, 0 opposed, 0 abstained, 2 absent) that the projected weighted average daily cost of aliskiren/HCTZ (Tekturna HCT) was comparable to the renin inhibitor aliskiren, and higher than the weighted average daily cost of ARBs designated as formulary within the RAA class on the UF.

1) ***COMMITTEE ACTION: UF RECOMMENDATION*** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of aliskiren/HCTZ (Tekturna HCT) and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 2 absent) that although aliskiren/HCTZ was somewhat more costly relative to the ARBs designated as formulary in the RAA class, Tekturna HCT was recommended to be classified as formulary on the UF, due to the novel mechanism of action of the aliskiren component and preliminary positive outcomes data.

Aliskiren/hydrochlorothiazide was covered by the UF VARR submission at or below the FCP.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

5) DRUG CLASS REVIEW – 5-HYDROXYTRYPTAMINE AGONISTS (TRIPTANS)

Relative Clinical Effectiveness: The P&T Committee evaluated the relative clinical effectiveness of the eight marketed 5-hydroxytryptamine agonists (triptans) in the US, almotriptan (Axert), eletriptan (Relpax), frovatriptan (Frova), naratriptan (Amerge), sumatriptan (Imitrex), sumatriptan/naproxen (Treximet), rizatriptan (Maxalt), and zolmitriptan (Zomig). None of the triptans are available in generic formulations, although generic formulations of sumatriptan are expected in early 2009.

MHS expenditures for the triptans were approximately $70 million for the time period of May 2007 to April 2008. In terms of total quantity dispensed between May 2007 and April 2008, sumatriptan is the highest utilized triptan in the MHS (~150,000 tablets dispensed/month), followed by zolmitriptan (~60,000 tablets/month), and rizatriptan (~45,000 tablets/month). To review the full clinical effectiveness evaluation, see the Triptan DoD Drug Class Review found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion: The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the following clinical effectiveness conclusion:

a) With regards to efficacy at providing pain relief at 2 hours,1) rizatriptan 10 mg (Maxalt) appears superior to the other triptans; 2) almotriptan (Axert), eletriptan (Relpax), sumatriptan (Imitrex) and zolmitriptan (Zomig) have comparable relative effectiveness; 3) frovatriptan (Frova) appears inferior to the other triptans, although these results are based on limited data; 4) naratriptan (Amerge) appears inferior to the other triptans; and 5) sumatriptan/naproxen (Treximet) appears superior to sumatriptan 85 mg, but there is insufficient evidence to suggest clinically relevant differences between Treximet and the other triptans.

b) With regards to other efficacy endpoints, 1) rizatriptan 10 mg (Maxalt) and almotriptan 12.5 mg (Axert) are superior to the other triptans for pain free response at 24 hours; and 2) rizatriptan 10 mg is superior to the other triptans for pain-free response at 2 hours.

c) With regards to safety and tolerability, almotriptan (Axert) and naratriptan (Amerge) had the most favorable adverse event profiles compared to the other triptans. There is only limited data for frovatriptan from the product labeling.

Relative Cost Effectiveness: In considering the relative cost-effectiveness of pharmaceutical agents in this class, the P&T Committee evaluated the costs of the agents in relation to the efficacy, safety, tolerability, and clinical outcomes of the other agents in the class. Information considered by the P&T Committee included but was not limited to sources of information listed in 32 CFR 199.21(e)(2).

Relative Cost Effectiveness Conclusion: The cost effectiveness of the triptan agents was evaluated by CMA, cost effectiveness analysis (CEA), and by budget impact analysis (BIA). Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) the following:

a) Results from the triptan CMA revealed that sumatriptan/naproxen (Treximet) was the most cost effective agent overall. However, sumatriptan (Imitrex) is expected to become the most cost-effective triptan when generic formulations reach the market in early 2009.

b) Results from the 2 hour pain response CEA revealed that 1) sumatriptan/naproxen (Treximet), eletriptan (Relpax) and rizatriptan (Maxalt) formed the efficiency frontier and are the most cost-effective agents; and 2) when the price for generic formulations of sumatriptan (Imitrex) drops below 70% of the current price, sumatriptan and rizatriptan will become the most cost-effective agents.

c) Results from the 2 hour pain-free response CEA yielded results similar to the 2 hour pain response.

d) The BIA evaluated the potential impact of scenarios with selected triptans designated formulary or non-formulary on the UF. Results from the BIA revealed that the scenario that designated almotriptan (Axert), frovatriptan (Frova), and naratriptan (Amerge) as non-formulary under the UF was more favorable to the MHS.

A. COMMITTEE ACTION: UF RECOMMENDATION – In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the triptans, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 1 abstained, and 1 absent) to recommend that:

1) Sumatriptan (Imitrex), sumatriptan/naproxen (Treximet), eletriptan (Relpax), rizatriptan (Maxalt), and zolmitriptan (Zomig) be classified as formulary on the UF.

2) Almotriptan (Axert), frovatriptan (Frova), and naratriptan (Amerge) be designated as non-formulary under the UF, based on cost effectiveness.

All triptan drugs recommended for inclusion on the UF were covered by Uniform Formulary Voluntary Agreement for Retail Refunds (UF VARR) submissions at or below the Federal Ceiling Price (FCP). (One of the triptan drugs recommended for non-formulary status was also covered by a UF-VARR at or below the FCP, but was not considered cost-effective.)

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. ***COMMITTEE ACTION: MN CRITERIA*** – Based on the clinical evaluation for almotriptan (Axert), frovatriptan (Frova), and naratriptan (Amerge), and the conditions for establishing medical necessity for a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) MN criteria for almotriptan, frovatriptan, and naratriptan. (See Appendix B for full MN criteria).

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD*** –The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday following a 90-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 90-day implementation period. 2) That TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following the approval by the Director, TMA.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

D. ***COMMITTEE ACTION: BCF RECOMMENDATION*** – The P&T Committee considered the BCF status of the triptan agents. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (12 for, 1 opposed, 1 abstained, and 1 absent) to recommend that 1) rizatriptan (Maxalt) be designated as BCF immediately upon signing of the June 2008 DoD P&T Committee minutes by the Director, TMA; 2) sumatriptan (Imitrex oral tablets and one injectable sumatriptan formulation be designated as BCF when multi-source generic formulations that are cost effective reach the marketplace. As a result of the above actions, zolmitriptan (Zomig) would no longer be designated as BCF, but maintained as formulary on the UF.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

E. COMMITTEE ACTION: QUANTITY LIMIT (QL) RECOMMENDATIONS – The P&T Committee voted (13 for, 0 opposed, 1 abstained, 1 absent) to 1) to recommend QLs for sumatriptan 85 mg/naproxen 500 mg (Treximet) of 9 tablets per 30 days and 27 tablets per 90 days; 2) to recommend QLs for sumatriptan (Imitrex) 4 mg injection of 9 syringes per 30 days and 24 syringes per 90 days; and 3) to maintain the existing QLs for the other triptans.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

6) 6) DRUG CLASS REVIEW – OSTEOPOROSIS AGENTS

Relative Clinical Effectiveness: The P&T Committee evaluated the relative clinical effectiveness of the osteoporosis agents currently marketed in the US. The individual drugs included in the class are listed below:

- *Bisphosphonates*: alendronate (Fosamax), alendronate/vitamin D (Fosamax plus D), ibandronate (Boniva), risedronate (Actonel), and risedronate/calcium (Actonel with calcium). Intravenous (IV) zoledronic acid (Reclast) and IV ibandronate (Boniva) were not part of the UF review, as they are not included as a TRICARE pharmacy benefit.

  Selective estrogen receptor modulators (SERMs): raloxifene (Evista)

- *Parathyroid hormone(PTH) 1-34 amino acids:* teriparatide (Forteo)

- *Calcitonin nasal sprays:* calcitonin-salmon (Miacalcin) and recombinant calcitonin (Fortical)

Generic formulations of alendronate 2800 IU (Fosamax) became commercially available in 2008. There are no generic formulations of any of the other osteoporosis agents. All the agents are approved for treating osteoporosis; raloxifene (Evista) is also approved for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis or those at high risk of invasive breast cancer.

MHS expenditures from May 2007 to April 2008 exceeded $200 million, of which over $151 million was attributed to the bisphosphonates alone. In terms of 30-day equivalent prescriptions dispensed, alendronate is the highest utilized osteoporosis agent (approximately 120,000/month), followed by risedronate (approximately 40,000/month) and raloxifene (less than 40,000/month). To review the full clinical effectiveness evaluation, see the Osteoporosis DoD Drug Class Review found at https://rxnet.army.mil/ (Forum: File Library; Folder: DoD P&T library).

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that:

a) With regard to changes in bone mineral density (BMD), all the drugs in the bisphosphonates, SERMs, PTH derivative, and calcitonin subclasses increase

BMD, but superiority of one drug over another cannot be determined by BMD changes alone.

b) With regard to fracture risk reduction, 1) the supporting evidence for the bisphosphonates is stronger than that available for raloxifene (Evista), teriparatide (Forteo) and the calcitonin nasal sprays (Fortical and Miacalcin); and 2) there is insufficient evidence to determine if there are clinically relevant differences between the drugs in each osteoporosis subclass.

c) With regard to the orally administered bisphosphonates, 1) the bisphosphonates reduce the risk of vertebral fractures to a similar degree, but the data is limited to daily dosing and there is insufficient evidence to determine if there are clinically relevant differences in fracture risk reduction with extended interval dosing regimens; 2) risedronate (Actonel) and IV zoledronic acid have evidence from adequately powered clinical trials that they reduce the risk of non-vertebral and hip fractures compared to the other bisphosphonates; and 3) there is insufficient evidence to suggest clinically relevant differences between the orally administered bisphosphonates in preventing fractures.

d) With regard to the SERM raloxifene (Evista) and the calcitonin nasal sprays, 1) both subclasses reduce the risk of vertebral fractures, but the data is more limited than that available with the bisphosphonates; and 2) there is no data to suggest clinically relevant efficacy differences between calcitonin-salmon (Miacalcin) and recombinant calcitonin (Fortical).

e) With regard to the PTH derivative teriparatide (Forteo), 1) there is evidence from one clinical trial supporting vertebral and non-vertebral fracture risk reduction; and 2) teriparatide is potentially beneficial in reducing fracture risk in patients experiencing fractures despite bisphosphonate therapy.

f) With regard to safety of the oral bisphosphonates, 1) there is no evidence to suggest that there are clinically relevant differences between alendronate (Fosamax), risedronate (Actonel) and ibandronate (Boniva) in the incidence of gastrointestinal complaints; 2) the overall incidence of osteonecrosis of the jaw with the oral agents is low; and 3) long-term safety data extending out to 10 years is available with alendronate (Fosamax).

g) With regard to tolerability of the oral bisphosphonates, a retrospective observational cohort analysis of 23,044 DoD beneficiaries performed by the Pharmacy Operations Outcomes Team (PORT) compared medication persistence between weekly vs. monthly dosing regimens, based on prescription claims during the year following the initial prescription. The study included all DoD beneficiaries filling initial prescriptions for bisphosphonates at the retail and mail order points of service from 1 Aug 06 to 31 Jan 07. Results of the multivariate logistic regression model were adjusted for age, gender, point of service, TRICARE region, and number of concomitant maintenance medications. The odds of a patient being persistent with treatment (≥80% of days covered based on cumulative days supply) were 18% higher among monthly users compared to weekly users of bisphosphonates (OR 1.18; 95% CI 1.12-1.25). Improved persistence on bisphosphonate therapy has been shown to be associated with a

reduced risk of fracture based on observational data, although data from randomized controlled trials supporting a causal relationship are not yet available.

h) With regard to safety and tolerability of the other osteoporosis subclasses, each subclass (SERM, calcitonin and PTH derivative) has unique adverse event profiles.

i) With regard to other factors of the calcitonin nasal sprays, there are no clinically relevant differences between calcitonin-salmon (Miacalcin) and recombinant calcitonin (Fortical), with the exception of differences in the preservative and ease of administration.

Relative Cost Effectiveness: In considering the relative cost-effectiveness of pharmaceutical agents in this class, the P&T Committee evaluated the costs of the agents in relation to the efficacy, safety, tolerability, and clinical outcomes of the other agents in the class. Information considered by the P&T Committee included but was not limited to sources of information listed in 32 CFR 199.21(e)(2).

The relative clinical effectiveness evaluation concluded that: 1) the bisphosphonates are highly clinically interchangeable with each other for the treatment of osteoporosis; 2) there is evidence that the extended dosing interval (monthly) bisphosphonates may yield greater rates of persistence than the weekly formulations; 3) the two calcitonin products are formulated with identical molecules and are highly clinically interchangeable for their osteoporosis indications; and 4) teriparatide and raloxifene occupy treatment niches for selected patients. As a result, CMAs were conducted for the bisphosphonate and calcitonin subclasses to compare the relative cost effectiveness of these agents. Additionally a CEA was performed to evaluate the extended dosing interval bisphosphonates. The SERM and parathyroid agents were compared to the other subclasses in a further cost analysis.

Relative Cost Effectiveness Conclusion: The P&T Committee concluded (14 for, 1 opposed, 0 abstained, 0 absent) the following:

a) Results from the bisphosphonate CMA revealed that ibandronate (Boniva) was the most cost effective agent overall. However, generic formulations of alendronate (Fosamax) have recently become available, and alendronate is expected to become the most cost effective oral bisphosphonate when the generic exclusivity period ends in the third quarter, 2008.

b) Results from the nasal calcitonin CMA revealed that recombinant calcitonin (Fortical) is significantly more cost effective than salmon-calcitonin (Miacalcin).

c) Results from the extended dosing interval bisphosphonate CEA revealed: 1) based on available published literature, improved persistence with extended cycle bisphosphonates would likely result in a small decrease in the risk of fractures; 2) the incremental annual cost per patient using extended dosing interval bisphosphonates is modest; and 3) while extended dosing interval products are slightly more costly, these agents remain cost effective for the treatment of osteoporosis.

d) The cost comparison of teriparatide (Forteo) and raloxifene (Evista) to the other osteoporosis subclasses concluded that 1) raloxifene is slightly more costly than

the bisphosphonates and calcitonin; and 2) teriparatide is significantly more costly than bisphosphonates and calcitonin.

e) The BIA evaluated the potential impact of scenarios with selected bisphosphonates, teriparatide (Forteo), and calcitonin products designated formulary or non-formulary on the UF. The BIA results showed that the scenario that designated the salmon-calcitonin (Miacalcin) as non-formulary on the UF was more favorable to the MHS.

*A. **COMMITTEE ACTION: UF RECOMMENDATION*** – In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the osteoporosis agents, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (12 for, 1 opposed, 2 abstained, and 0 absent) to recommend that: 1) alendronate (Fosamax), alendronate/vitamin D (Fosamax plus D), risedronate (Actonel), risedronate with calcium (Actonel with calcium), ibandronate (Boniva), raloxifene (Evista), teriparatide (Forteo), and recombinant calcitonin (Fortical) be maintained as formulary on the UF and that 2) salmon-calcitonin (Miacalcin) be designated as non-formulary on the UF. The Committee member casting the dissenting vote felt that an additional agent, teriparatide, should also be classified as NF, due to existing low MHS utilization (less than 5,000 patients); that its clinical niche would allow for unique MN criteria specific to this agent; and that NF placement would allow for additional cost avoidance.

Despite the higher cost of raloxifene (Evista) and teriparatide (Forteo) compared to the other osteoporosis agents, the Committee recommended designating these agents as formulary on the UF, due their clinical niche (reduction in risk of invasive breast cancer; and non-oral administration route and approval for severe osteoporosis, respectively), and the expectation that several SERMs and PTH hormone derivatives currently under investigation will reach the marketplace in 2009-2010.

All osteoporosis drugs recommended for inclusion on the UF were covered by Uniform Formulary Voluntary Agreement for Retail Refunds (UF VARR) submissions at or below the Federal Ceiling Price (FCP), with the exception of raloxifene, teriparatide, and recombinant calcitonin. These three osteoporosis agents were recommended for inclusion on the UF without UF VARR quotes, due to their unique indications and place in therapy.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

*B. **COMMITTEE ACTION: MN CRITERIA*** – Based on the clinical evaluation for salmon-calcitonin (Miacalcin) and the conditions for establishing medical necessity for a non-formulary medication provided for in the UF rule, the P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Miacalcin. (See Appendix B for full MN criteria).

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

*C. **COMMITTEE ACTION: IMPLEMENTATION PERIOD*** –The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday following a 90-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 90-day implementation period. 2) That TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following the approval by the Director, TMA.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

*D. **COMMITTEE ACTION: BCF RECOMMENDATION*** – The P&T Committee considered the BCF status of the osteoporosis agents. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (9 for, 4 opposed, 2 abstained, and 0 absent) to recommend that alendronate (Fosamax) and ibandronate (Boniva) be designated as BCF. As a result of the above actions, raloxifene (Evista) would no longer be designated as BCF, but maintained as formulary on the UF.

Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

7) UTILIZATION MANAGEMENT - PRIOR AUTHORIZATIONS (PA)/ QL / MEDICAL NECESSITY (MN)

A. Targeted Immunomodulatory Biologics (TIBs)

Adalimumab (Humira) Juvenile Idiopathic Arthritis (JIA) new indication - Administrative Action – Adalimumab received an additional indication from the FDA for children aged 4 to 17 years to reduce the signs and symptoms of moderate to severely active polyarticular JIA. Adalimumab may be used with or without methotrexate for this indication. The FDA-approved JIA indication will be added to the PA for Humira.

B. Phosphodiesterase type 5 inhibitors (PDE5s)

Tadalafil (Cialis) QL – Administrative Action – Tadalafil was recently approved in 2.5 mg and 5 mg dosages for daily use for erectile dysfunction (ED). Health Affairs Policy 98-04 was rescinded in Nov 2003 to state that prior authorization was no longer required for PDE-5 inhibitors in the treatment of ED for males older than 50 years of age. The HA policy still maintains QLs collectively for all strengths of sildenafil, tadalafil and vardenafil of no more than 18 tablets of any combination of these medications per 90-day supply in the TMOP, and no more than 6 tablets of any

combination of these medications per 30-day supply in the Retail Network. The existing QLs for tadalafil will apply to the new 2.5 mg and 5 mg dosages.

C. **LIP-2s – Colesevelam (Welchol) MN Criteria** – The Committee discussed the MN criteria for colesevelam with regard to a new FDA-approved indication for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus (T2DM). The LIP-2 drug class was previously reviewed for UF placement in May 2007; at the time of the meeting, colesevelam was solely approved for lowering elevated LDL concentrations in primary hyperlipidemia. The clinical trial used to gain FDA-approval of colesevelam for T2DM evaluated the drug as adjunctive therapy to other glucose-lowering drugs, and did not evaluate colesevelam use as monotherapy. The Committee agreed that there were other treatments for T2DM with greater efficacy than colesevelam.

COMMITTEE ACTION: The P&T Committee voted (14 for, 0 opposed, 0 abstained, 1 absent) to maintain the current MN criteria for colesevelam.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

D. **Aprepitant (Emend) – QL** – Aprepitant was approved by the FDA in a new 40 mg strength solely indicated for prevention of post-operative nausea and vomiting. Currently, QLs apply to the aprepitant formulation approved for prevention of chemotherapy-induced nausea and vomiting; QLs also apply to other antiemetics.

COMMITTEE ACTION: The P&T Committee voted (14 for, 0 opposed, 0 abstained, 1 absent) to approve the QLs for aprepitant 40 mg of 1 capsule/prescription fill at the retail and mail order points of service.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

8) ITEMS FOR INFORMATION

A. Outcomes Research Reports

1) *Step Therapy* – To support the P&T Committee's consideration of a potential step therapy requirement in the triptan drug class, the PORT reported results of an analysis of changes in medication usage attributable to step therapy/prior authorization requirements for newer sedative hypnotics (effective date 1 Aug 07) and proton pump inhibitors (effective date 24 Oct 07). The step therapy / prior authorization program, which requires new users of non-preferred medications to try a preferred agent before receiving a non-preferred agent, appears highly effective at promoting use of preferred agents. However, the Committee agreed that more information is needed concerning the effect of the program on beneficiaries. A study of outcomes associated with step therapy interventions is

under development and is currently being considered by the MHS Scientific Advisory Panel.

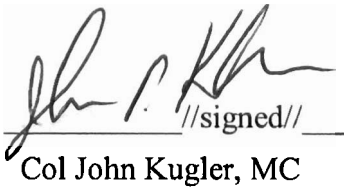
2) *Fentanyl Patch Safety Program* – The PORT notified the P&T Committee of implementation issues detected during data collection for a study of the Fentanyl Patch Safety Program. These issues were corrected, bringing the program into line with requirements previously set by the P&T Committee. Preliminary results of the analysis are scheduled for the next P&T meeting.

9) ADJOURNMENT

The second day of the meeting adjourned at 1400 hours on 13 Jun 2008. The next meeting will be 12-13 Aug 2008.

Appendix A – Attendance
Appendix B – Table of Medical Necessity Criteria
Appendix C – Implementation Status of UF Recommendations/Decisions
Appendix D – Table of Abbreviations

SUBMITTED BY:

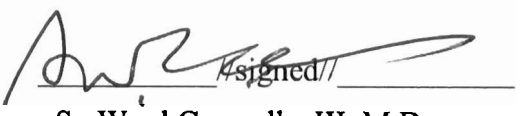


//signed//

Col John Kugler, MC
DoD P&T Committee Chair
25 Aug 08

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.



//signed//

S. Ward Casscells, III, M.D.
27 Aug 08

Appendix A – Attendance

Voting Members Present	
Col John Kugler, MC, USA	DoD P&T Committee Chair
LTC Brett Kelly, MSC, USA	DoD P&T Committee Recorder
Major Jeremy King, MC	Air Force, OB/GYN Physician
Major William Hannah, MC	Air Force, Internal Medicine Physician
Lt Col Brian Crownover, MC	Air Force, Physician at Large
Col Everett McAllister, BSC	Air Force, Pharmacy Officer
LCDR Scott Akins, MC	Navy, Pediatrics Physician
CAPT Stephanie Simon, MSC	Navy, Pharmacy Officer
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician
Col Karl R. Kerchief, MC *for* Major Roger Brockbank, MC	Army, Family Practice Physician
COL Ted Cieslak, MC	Army, Physician at Large
LTC (P) Peter Bulatao, MSC *for* COL Isiah Harper, MSC	Army, Pharmacy Officer
CAPT Vernon Lew, USPHS	Coast Guard, Pharmacy Officer
Lt Col Thom Bacon *for* CAPT William Blanche, MSC, USN	DoD Pharmacy Operations Directorate, TMA
Mr. Joe Canzolino, RPh.	Department of Veterans Affairs
Voting Members Absent	
CDR David Tanen, MC	Navy, Physician at Large
LCDR Michelle Perelló, MC	Navy, Internal Medicine Physician
Non-Voting Members Present	
COL Kent Maneval, MSC, USA	Defense Medical Standardization Board
Lt Col Paul Hoerner, BSC, USAF	Deputy Director, DoD Patient Safety Center
CDR Kim Lefebvre, MSC	Defense Supply Center Philadelphia
Ms. Carol Cooper	Deputy General Counsel, TMA
LCDR Thomas Jenkins, MSC, USN	TMA Aurora
Non-Voting Members Absent	
Martha Taft	Health Plan Operations, TMA

Appendix A – Attendance – (continued)

Others Present	
CDR James Ellzy, MC, USN	Vice DoD P&T Committee Chair
CDR Matthew Carlberg, MC, USN	DoD PEC
Lt Col James McCrary, MC, USAF	DoD PEC
LTC Chris Conrad, MC, USA	DoD PEC
Maj Josh Devine, BSC, USAF	DoD PEC
CPT Josh Napier, MC, USA	DoD PEC
Angela Allerman, Pharm.D.	DoD PEC
David Meade, Pharm.D.	DoD PEC
Harsha Mistry, Pharm.D.	DoD PEC
Eugene Moore, Pharm.D.	DoD PEC
Shana Trice, Pharm.D.	DoD PEC
Dean Valibhai, Pharm.D.	DoD PEC – Pharmacy Operations Center
Jeremy Briggs, Pharm.D.	DoD PEC – Pharmacy Operations Center
Major Mike Lee, BSC	Air Force, Alternate Pharmacist Officer
LCDR Timothy Thompson	Navy, Pharmacy Officer Alternate
CAPT Travis Watts	USPHS/HIS
Lisa McNair	DoD Pharmacy Operations Directorate – TMA

Appendix B – Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Levocetirizine (Xyzal) **Newer Antihistamines**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives. • Formulary agents have resulted in therapeutic failure.
Nebivolol (Bystolic) **Adrenergic Blocking Agent**	• Use of formulary alternatives is contraindicated • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.
Olmesartan / amlodipine (Azor)	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives.
Calcitonin-salmon nasal spray (Miacalcin) **Osteoporosis Agents**	• Use of formulary alternatives is contraindicated • The patient has experienced or is likely to experience significant adverse effects from formulary alternatives. • Formulary agents have resulted or are likely to result in therapeutic failure. • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.
Almotriptan (Axert), Frovatriptan (Frova), Naratriptan (Amerge) **Triptans**	• Use of formulary alternatives is contraindicated • The patient has experienced or is likely to experience significant adverse effects from formulary alternatives. • Formulary agents have resulted or are likely to result in therapeutic failure. • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.
Zileuton extended release (Zyflo CR) **Leukotriene Modifiers**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives. • Formulary agents have resulted in therapeutic failure. • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.

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

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) ▪ (Note: raloxifene (Evista) removed from BCF, but still UF)	Pending approval	Pending approval
Jun 08	Triptans	▪ almotriptan (Axert) ▪ frovatriptan (Frova) ▪ naratriptan (Amerge)	BCF	▪ rizatriptan (Maxalt), immediate upon signing of the minutes ▪ sumatriptan oral and one injectable formulation, when multi-source generics are available	Pending approval	Pending approval
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II		BCF	**Recommended for addition to BCF Nov 07** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide)	Pending approval	Pending approval
		To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)		Currently BCF ▪ gemfibrozil ▪ (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	24 July 07	21 Nov 07 (120 days)
Jun 08 (update; reviewed Nov 07)	Adrenergic Blocking Agents	**Recommended for non-formulary status Jun 08** ▪ nebivolol (Bystolic)	BCF		Pending approval	Pending approval
				Currently BCF ▪ atenolol tablets ▪ metoprolol tartrate IR tablets ▪ carvedilol IR tablets ▪ metoprolol succinate ER tablets	13 Feb 08	-
Jun 08 (update; reviewed Aug 07	Newer Antihistamines	**Recommended for non-formulary status Jun 08** ▪ levocetirizine (Xyzal)	BCF		Pending approval	Pending approval
		To remain NF ▪ desloratadine (Clarinex) ▪ desloratadine/pseudoephedrine (Clarinex D)		▪ MTFs required to carry at least one single ingredient agent from the newer antihistamine class (loratadine, cetirizine, or fexofenadine) on their local formulary, including at least one dosage form suitable for pediatric use	17 Oct 07	16 Jan 08 (90 days)
Jun 08 (update; reviewed Aug 07)	Leukotriene Modifiers	**Recommended for non-formulary status Jun 08** ▪ Zileuton ER (Zyflo CR)	BCF		Pending approval	Pending approval

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
		To remain NF ▪ zileuton (Zyflo)		Currently BCF ▪ montelukast (Singulair)	17 Oct 07	16 Jan 08 (90 days)
Jun 08 (update) Original reviews ▪ ACE inhibitors: Aug 05 ▪ Miscellaneous antihypertensives, including ACE/CCB combos. Feb 06 ▪ ARBs: May 07 ▪ Renin inhibitors. Aug 07 ▪ CCB/ARB combos Nov 07 update	Renin Angiotensin Antihypertensives	**Recommended for non-formulary status Jun 08** ▪ olmesartan/amlodipine (Azor)	BCF	-		
		To remain NF ▪ valsartan amlodipine (Exforge)			13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ **moexipril (Univasc),** ▪ **moexipril / HCTZ (Uniretic** ▪ **perindopril (Aceon)** ▪ **quinapril (Accupril)** ▪ **quinapril / HCTZ (Accuretic)** ▪ **ramipril (Altace)** ACE/CCB combos ▪ **felodipine/enalapril (Lexxel)** ▪ **verapamil/trandolapril (Tarka)** ARBs ▪ **eprosa tan (Teveten)** ▪ **eprosa tan HCTZ (Teveten HCT)** ▪ **irbesar an (Avapro)** ▪ **irbesar an HCTZ (Avalide)** ▪ **olmesa tan (Benicar)** ▪ **olmesa tan HCTZ (Benicar HCT)** ▪ **valsart n (Diovan)** ▪ **valsart n HCTZ (Diovan HCT)**		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel) ARBs ▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	ACE inhibitors ▪ 13 Oct 05 ACE/CCB combos ▪ 26 Apr 06 ARBs ▪ 24 July 07	ACE inhibitors ▪ **15 Feb 06** ACE/CCB combos ▪ **26 Jul 06** ARBs ▪ **21 Nov 07**
Nov 07	Targeted Immunomodulatory Biologics	▪ etanercept (Enbrel) ▪ anakinra (Kineret)	ECF	adalimumab (Humira) injection	13 Feb 08	18 Jun 08 (120 days)
Nov 07 re-review (Aug 05 original)	BPH Alpha Blockers	▪ tamsulosin (Flomax) Automated PA requiring trial of alfuzosin (Uro tral) applies to new users of tamsulosin (no use of uroselective alpha blockers in last 180 days)	BCF	▪ terazosin tablets or capsules ▪ alfuzosin tablets (Uroxatral)	13 Feb 08	16 Apr 08 (60 days)
Nov 07 (update, original review Aug 05)	Calcium Channel Blockers	**Currently non-formulary, recommended for UF status Nov 07** ▪ amlodipine (Norvasc generic)	BCF	**Recommended for addition to BCF Nov 07** ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
		To Remain Non-Formulary ▪ isradipine IR (Dynacirc) ▪ isradipine ER (Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER for bedtime dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently on the BCF ▪ nifedipine ER (Adalat CC) ▪ verapamil SR ▪ diltiazem ER (Tiazac)	13 Oct 05	15 Mar 06 (150 days)
Nov 07 (update, original review Nov 06)	ADHD / Narcolepsy Agents	**Recommended for non-formulary status Nov 07** ▪ lisdexamfetamine (Vyvanse)	BCF		13 Feb 08	16 Apr 08 (60 days)
		To remain NF ▪ dexmethylphenidate IR (Focalin) ▪ dexmethylphenidate SODAS (Focalin XR) ▪ methylphenidate transdermal system (Daytrana)		Currently on the BCF ▪ methylphenidate OROS (Concerta) ▪ **mixed amphetamine salts ER (Adderall XR)** ▪ methylphenidate IR (Ritalin)	17 Jan 07	18 Apr 07
Nov 07 (update, original review May 06)	Contraceptives	**Recommended for non-formulary status Nov 07** ▪ EE 20 mcg/levonorgestrel 0.09 mg in special packaging for continuous use (Lybrel)	BCF		13 Feb 08	16 Apr 08 (60 days)
		To remain NF ▪ **EE 30 mcg** / levonorgestrel 0.15 mg in special packaging for extended use (Seasonale) EE 25 mcg / norethindrone 0.4 mg (Ovcon 35) ▪ EE 50 mcg / norethindrone 1 mg (Ovcon 50) ▪ EE 20/30/35 mcg / norethindrone 1 mg (Estrostep Fe)		Currently on the BCF ▪ EE 20 mcg / 3 mg drospirenone (Yaz) ▪ EE 20 mcg / 0.1 mg levonorgestrel (Lutera, Sronyx, or equivalent) ▪ EE 30 mcg / 3 mg drospirenone (Yasmin) ▪ EE 30 mcg / 0.15 mg levonorgestrel (Nordette or equivalent / excludes Seasonale) ▪ EE 35 mcg / 1 mg norethindrone (Ortho-Novum 1/35 or equivalent) ▪ EE 35 mcg / 0.25 mg norgestimate (Ortho-Cyclen or equivalent) ▪ EE 25 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo) ▪ EE 35 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen or equivalent) ▪ 0.35 mg norethindrone (Nor-QD, Ortho Micronor, or equivalent)	26 Jul 06	24 Jan 07
		▪ EE 30/10 mcg / 0.15 mg levonorgestrel in special packaging for extended use (Seasonique) ▪ EE 20 mcg / 1 mg norethindrone (Loestrin 24 Fe)			17 Jan 07	18 Mar 07

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Aug 07	Leukotriene Modifiers	▪ zileuton (Zyflo)	BCF	▪ montelukast (Singulair)	17 Oct 07	16 Jan 08 (90 days)
Aug 07	Growth Stimulating Agents	▪ somatropin (Genotropin, Genotropin Miniquick) ▪ somatropin (Humatrope) ▪ somatropin (Omnitrope) ▪ somatropin (Saizen)	ECF	▪ somatropin (Norditropin)	17 Oct 07	19 Dec 07 (60 days)
Aug 07 (new drug update, original review Nov 05)	Nasal Corticosteroids	▪ beclomethasone dipropionate (Beconase AQ, Vancenase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ fluticasone propionate (Flonase)	19 Jan 06	19 Apr 06 (90 days)
		Recommended for non-formulary status Aug 07 ▪ fluticasone furoate (Veramyst)			17 Oct 07	19 Dec 07 (60 days)
May 07 re-review (Feb 05 original)	PPIs	▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate (Zegerid) ▪ pantoprazole (Protonix) ▪ rabeprazole (Aciphex) Automated PA requiring trial of omeprazole OR esomeprazole (Nexium) applies to new users of non-formulary PPIs (no use of PPIs in last 180 days)	BCF	▪ generic omeprazole 10 mg and 20 mg (excludes Prilosec 40 mg) ▪ esomeprazole (Nexium)	24 July 07	24 Oct 07 (90 days)
May 07 re-review (Feb 05 original)	ARBs	▪ eprosartan (Teveten) ▪ eprosartan HCTZ (Teveten HCT) ▪ irbesartan (Avapro) ▪ irbesartan HCTZ (Avalide) ▪ olmesartan (Benicar) ▪ olmesartan HCTZ (Benicar HCT) ▪ valsartan (Diovan) ▪ valsartan HCTZ (Diovan HCT)	BCF	▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	24 July 07	21 Nov 07 (120 days)
May 07	5-Alpha Reductase Inhibitors	▪ dutasteride (Avodart)	BCF	▪ finasteride	24 July 07	24 Oct 07 (90 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Feb 07	Newer Sedative Hypnotics	▪ zolpidem ER (Ambien CR) ▪ zaleplon (Sonata) ▪ ramelteon (Rozerem) Automated PA requiring trial of zolpidem IR applies to new users of eszopiclone (Lunesta), ramelteon (Rozerem), zaleplon (Sonata), or zolpidem ER (Ambien CR) (new users = no use of newer sedative hypnotics in last 180 days)	BCF	▪ zolpidem IR (Ambien)	02 May 07	01 Aug 07 (90 days)
Feb 07	Narcotic Analgesics	▪ tramadol ER (Ultram ER)	BCF	▪ morphine sulfate IR 15 mg, 30 mg ▪ morphine sulfate 12-hour ER (MS Contin or equivalent) 15, 30, 60 mg ▪ oxycodone/APAP 5/325 mg ▪ hydrocodone/APAP 5/500 mg ▪ codeine/APAP 30/300 mg ▪ codeine/APAP elixir 12/120 mg/5 mL ▪ tramadol IR	02 May 07	01 Aug 07 (90 days)
Feb 07	Ophthalmic Glaucoma Agents	▪ travoprost (Travatan, Travatan Z) ▪ timolol maleate for once daily dosing (Istalol) ▪ timolol hemihydrate (Betimol) ▪ brinzolamide (Azopt)	BCF	▪ latanoprost (Xalatan) ▪ brimonidine (Alphagan P); excludes 0.1% ▪ timolol maleate ▪ timolol maleate gel-forming solution ▪ pilocarpine	02 May 07	01 Aug 07 (90 days)
Nov 06	Older Sedative Hypnotics		BCF	▪ temazepam 15 and 30 mg	17 Jan 07	
Aug 06	TZDs		BCF	▪ rosiglitazone (Avandia) ▪ rosiglitazone / metformin (Avandamet)	23 Oct 06	
Aug 06	H2 Antagonists / GI protectants		BCF	▪ ranitidine (Zantac) – excludes gelcaps and effervescent tablets	23 Oct 06	
Aug 06	Antilipidemic Agents I	▪ rosuvastatin (Crestor) ▪ atorvastatin / amlodipine (Caduet)	BCF	▪ simvastatin (Zocor) ▪ pravastatin ▪ simvastatin / ezetimibe (Vytorin) ▪ niacin extended release (Niaspan)	23 Oct 06	1 Feb 07 (90 days)
May 06	Antiemetics	▪ dolasetron (Anzemet)	BCF	▪ promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Feb 06	OABs	▪ tolterodine IR (Detrol) ▪ oxybutynin patch (Oxytrol) ▪ trospium (Sanctura)	BCF	▪ oxybutynin IR (Ditropan tabs/soln) ▪ tolterodine SR (Detrol LA)	26 Apr 06	26 Jul 06 (90 days)
Feb 06	Misc Antihypertensive Agents	▪ felodipine/enalapril (Lexxel) ▪ verapamil/trandolapril (Tarka)	BCF	▪ amlodipine/benazepril (Lotrel) ▪ hydralazine ▪ clonidine tablets	26 Apr 06	26 Jul 06 (90 days)
Feb 06	GABA-analogs	▪ pregabalin (Lyrica)	BCF	▪ gabapentin	26 Apr 06	28 Jun 06 (60 days)
Nov 05	Alzheimer's Drugs	▪ tacrine (Cognex)	ECF	▪ donepezil (Aricept)	19 Jan 06	19 Apr 06 (90 days)
Nov 05	Macrolide/ Ketolide Antibiotics	▪ azithromycin 2 gm (Zmax) ▪ telithromycin (Ketek)	BCF	▪ azithromycin (Z-Pak) ▪ erythromycin salts and bases	19 Jan 06	22 Mar 06 (60 days)
Nov 05	Antidepressants I	▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg for weekly administration (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL)	BCF	▪ citalopram ▪ fluoxetine (excluding weekly regimen and special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	19 Jan 06	19 Jul 06 (180 days)
Aug 05	ACE Inhibitors & ACE Inhibitor / HCTZ Combinations	▪ moexipril (Univasc), ▪ moexipril / HCTZ (Uniretic) ▪ perindopril (Aceon) ▪ quinapril (Accupril) ▪ quinapril / HCTZ (Accuretic) ▪ ramipril (Altace)	BCF	▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ	13 Oct 05	15 Feb 06 (120 days)
May 05	PDE5 Inhibitors	▪ sildenafil (Viagra) ▪ tadalafil (Cialis)	ECF	▪ vardenafil (Levitra)	14 Jul 05	12 Oct 05 (90 days)
May 05 (updated Nov 06)	Topical Antifungals*	▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm)	BCF	▪ nystatin ▪ clotrimazole	14 Jul 05	17 Aug 05 (30 days)
		Recommended for non-formulary status Nov 06: ▪ 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)			17 Jan 07	18 Mar 07 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	**Decision Date** (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	**Effective Date for Non-Formulary Medications** (Implementation period)
May 05	MS-DMDs		ECF	▪ interferon beta-1a intramuscular injection (Avonex)	14 Jul 05	

BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary
ER = extended release; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle
ADHD = Attention Deficit Hyperactivity Disorder; ARBs = Angiotensin Receptor Blockers; ACE Inhibitors = Angiotensin Converting Enzyme Inhibitors; BPH = Benign Prostatic Hyperplasia; CCBs = Calcium Channel Blockers; EE = ethinyl estradiol; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HCTZ = hydrochlorothiazide; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; OABs = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; TZDs= Thiazolidinediones
*The topical antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])

Appendix D – Table of Abbreviations

ABA	Adrenergic Beta Antagonist drug class
AE	adverse event
ARB	angiotensin receptor blocker
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BMD	bone mineral density
BP	blood pressure
CCB	calcium channel blocker
CEA	cost effectiveness analysis
CFR	Code of Federal Regulations
CI	confidence interval
CMA	cost minimization analysis
CR	controlled release (extended release)
DHP	dihydropyridine
DoD	Department of Defense
CI	confidence interval
ED	erectile dysfunction
FCP	Federal Ceiling Price
FDA	Food and Drug Administration
FY	fiscal year
GA	Glaucoma Agent drug class
HA	Health Affairs
HCTZ	hydrochlorothiazide
HDL	high density lipoprotein cholesterol
IDD-P	Insoluble drug delivery microparticle
IR	immediate release
IU	international unit
JIA	juvenile idiopathic arthritis
LDL	low density lipoprotein cholesterol
LIP-1s	Antilipidemic -1 drug class
LIP-2s	Antilipidemic -2 drug class
LM	Leukotriene Modifier drug class
MHS	Military Health System
MN	medical necessity
MTF	military treatment facility
OR	odds ratio
P&T	Pharmacy and Therapeutics
PA	prior authorization
PDE5	phosphodiesterase type 5
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
PTH	parathyroid hormone
QD	once daily
QL	quantity limit
SERM	selective estrogen receptor modulator
TC	total cholesterol
T2DM	Type 2 diabetes mellitus
TMA	TRICARE Management Activity
UF VARR	Uniform Formulary Voluntary Agreement for Retail Refund