DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
November 2009

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on 5 November 2009 and 6 November 2009 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 August minutes** — Ellen P. Embrey, Acting Director, approved the minutes of the August 2009 DoD P&T Committee meeting on 21 October 2009.

III. REVIEW OF RECENTLY APPROVED FDA AGENTS

A. Multiple Sclerosis - Disease-Modulating Drugs (MS-DMDs) — Interferon Beta-1b Injection (Extavia)

Relative Clinical Effectiveness — Interferon beta-1b injection (Extavia) is an immunomodulator classified as a multiple sclerosis disease-modulating drugs (MS-DMDs). The MS-DMDs were last reviewed for Uniform Formulary (UF) placement in August 2005; no products are currently designated non-formulary.

Extavia is a new branded version of interferon beta-1b, and is the same product as that found under the proprietary name Betaseron. The two manufacturers have agreed to this arrangement. FDA approval for Extavia was based on the same registration trials as the approval for Betaseron, but a separate Biologic License Agreement (BLA) was filed by the manufacturer of Extavia. Availability of generic formulations of biologic agents, including the MS-DMDs, is unknown at this time. Extavia is supplied with a larger needle size (27 gauge vs. 30 gauge) and different packaging than Betaseron (30-day supply vs. 28-day supply). The FDA-approved indications for Extavia are the same as Betaseron.

The interferon beta-1b clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no head-to-head trials comparing interferon beta-1b (Extavia) to interferon-beta-1b (Betaseron) and there is no conclusive data to support superiority of one drug over the other. After review of the clinical literature, interferon beta-1b (Extavia) does not have compelling clinical advantages over existing MS-DMDs on the UF.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) there is currently insufficient data to conclude interferon beta-1b (Extavia) offers improved efficacy, safety, or tolerability compared to the UF product interferon beta-1b (Betaseron).

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the other currently available MS-DMDs. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of interferon beta-1b (Extavia). Results from the CMA showed the projected weighted average cost per day for interferon beta-1b (Extavia) is higher than the other formulary MS-DMDs, including interferon beta-1a (Avonex), interferon beta-1a (Rebif), interferon beta-1b (Betaseron), and glatiramer acetate (Copaxone).

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 0 abstained, 1 absent) interferon beta-1b (Extavia) was not cost effective relative to the other UF agents in the MS-DMDs drug 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, 0 abstained, 1 absent) interferon beta-1b (Extavia) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —Based on the clinical evaluation of interferon beta-1b (Extavia) and the conditions for establishing medical necessity (MN) of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) that no MN criteria are applicable for Extavia.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Pharmacy Benefits Program (TPHARM), and at Military Treatment Facilities (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Antidepressant-1s (AD-1s) — Bupropion Hydrobromide Extended Release (Bupropion HBr ER) Tablets (Aplenzin)

Relative Clinical Effectiveness — Bupropion HBr (Aplenzin) is a norepinephrine and dopamine reuptake inhibitor (NDRI) approved for the treatment of major depressive disorder (MDD) in adults. The antidepressants in the AD-1 drug class were last reviewed for UF placement in November 2005 and are comprised of the selective serotonin reuptake inhibitors (SSRIs), NDRIs, serotonin-norepinephrine reuptake inhibitors (SNRIs), and the serotonin antagonist/reuptake inhibitors. Bupropion HBr ER (Aplenzin) was approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic (FDC) Act after demonstrating bioequivalence to bupropion hydrochloride (HCl) ER tablets (Wellbutrin XL). The other NDRIs on the UF are bupropion HCl immediate release (IR) (Wellbutrin IR, generics) and bupropion HCl sustained release (SR) (Wellbutrin SR, generics), with the latter designated as BCF. Bupropion HBr ER tablets are dosed daily, whereas the IR and SR formulations of bupropion HCl are dosed three times and two times daily, respectively. Inclusion of the HBr salt in Aplenzin, rather than the HCl salt included in Wellbutrin products, allows the maximum bupropion dose to be contained in one tablet.

The bupropion HBr ER (Aplenzin) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no direct comparative clinical trials between bupropion HBr ER tablets and the other NDRIs, and no trials are available that evaluate outcomes. The clinical trials used to obtain FDA approval were pharmacokinetic studies demonstrating bioequivalence to bupropion HCl

ER (Wellbutrin XL). The safety profile of bupropion HBr is based on data collected for Wellbutrin SR (bupropion hydrochloride sustained release), thus it is identical to other bupropion products.

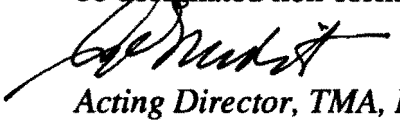
Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) bupropion HBr ER tablets (Aplenzin) do not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other NDRIs currently included on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the cost of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the other NDRIs in the AD-1 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).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of bupropion HBr ER tablets (Aplenzin) relative to other UF NDRIs. Results from the CMA showed the projected weighted average cost per day for bupropion HBr ER (Aplenzin) is higher than the bupropion HCl formulations (Wellbutrin IR, SR, and XL). The CMA also revealed the projected weighted average cost per day for bupropion HBr ER tablets (Aplenzin) is higher than the formulary NDRI, bupropion HCl 12-hour formulation (Wellbutrin SR) and the non-formulary 24-hour formulation (Wellbutrin XL).

Relative Cost-Effectiveness Conclusion —The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 1 abstained, 0 absent) that bupropion HBr ER tablets (Aplenzin) are not cost effective relative to other AD-1 NDRIs included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness, relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (14 for, 0 opposed, 2 abstained, 0 absent) that bupropion HBr ER tablets (Aplenzin) be designated non-formulary on the UF.



Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —

Based on the clinical evaluation of bupropion HBr ER tablets (Aplenzin) and the conditions for establishing MN of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) that no MN criteria are applicable for Aplenzin.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TPHARM, 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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. Antidepressant-1s (AD-1s) — Milnacipran Tablets (Savella)

Relative Clinical Effectiveness — Milnacipran (Savella) is an SNRI approved for the treatment of fibromyalgia in adults. The agents in the AD-1 drug class were last reviewed for UF placement in November 2005. The other SNRIs on the Uniform Formulary are venlafaxine immediate-release tablets (Effexor, generics), venlafaxine extended release capsules (Effexor XR), and venlafaxine extended-release tablets (no brand name). The UF also includes other drugs medically accepted to treat fibromyalgia, including several selective serotonin reuptake inhibitors (SSRIs), the tricyclic antidepressant (TCA) amitriptyline (Elavil, generics) and cyclobenzaprine (Flexeril, generics). Milnacipran is approved for depression outside of the US, but the manufacturer will not seek FDA approval for depression.

The milnacipran (Savella) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). In clinical trials, milnacipran significantly improved a composite of fibromyalgia symptoms when compared to placebo. There are no direct comparative clinical trials between milnacipran and the other medications FDA-approved or used off-label for the management of fibromyalgia. Meta-analyses have shown efficacy for use of the antidepressants (SSRIs and TCAs) and cyclobenzaprine in treating fibromyalgia. After review of the clinical literature, milnacipran (Savella) does not have compelling clinical advantages over existing fibromyalgia therapies on the UF. There is currently insufficient data to conclude that milnacipran (Savella) offers improved efficacy, safety, or tolerability compared to other SNRIs or other drugs medically accepted for the treatment of fibromyalgia.

Other Factors — The Pharmacy Outcomes Research Team (PORT) reported results of an analysis comparing the relative frequency of ICD-9 diagnosis codes indicative of fibromyalgia; nerve disorders including phantom limb syndrome, carpal tunnel, peripheral neuropathy, diabetes with neurological symptoms, and postherpetic neuralgia (neuropathic pain); depression; or seizure disorder, among patients receiving SNRIs (duloxetine or venlafaxine), GABA analogs (pregabalin or gabapentin), or the SSRI citalopram.

Study patients (n=20,271) comprised a 10% random sample of all patients who received a prescription for any of these medications at any DoD pharmacy point of service in March 2009. All ICD-9 diagnosis codes were collected for these patients over a 21-month period (1 Oct 07 – 30 Jun 09) from purchased and direct care medical claims data (inpatient and outpatient) in the MHS Data Mart (M2). A second, separate analysis using the same methods examined ICD-9 coding among a 10% sample of patients who received a tricyclic antidepressant (TCA) or cyclobenzaprine in March 2009 (n=10,866).

Pertinent results included:

- The percentage of patients with a ICD-9 diagnosis code for fibromyalgia (729.1) was highest among patients with prescriptions for the two agents with FDA-approved indications for fibromyalgia, pregabalin (30%) and duloxetine (26%), followed by 15% with gabapentin, 11% with venlafaxine, and 7% with citalopram. A total of 14% of patients with prescriptions for a TCA or cyclobenzaprine had ICD-9 codes for fibromyalgia.
- ICD-9 codes consistent with neuropathic pain occurred most commonly among patients with prescriptions for pregabalin (50%) or gabapentin (44%), followed by 29%, 15%, and 13% of patients with prescriptions for duloxetine, venlafaxine, or citalopram, respectively.
- A diagnosis of depression was noted in more than half of patients with prescriptions for duloxetine (54%) or venlafaxine (52%), followed by citalopram (47%), pregabalin (28%), and gabapentin (24%).

- A high percentage of patients with ICD-9 codes for fibromyalgia also had ICD-9 codes for depression, ranging from 71% of patients with prescriptions for citalopram to about 40% with gabapentin or pregabalin. A smaller but still substantial percentage of patients with ICD-9 codes for neuropathic pain also had ICD-9 codes for depression (25 to 60%).
- ICD-9 codes for seizure disorder ranged between 2-3% for any study medication.

While this analysis had clear limitations (including the inability to link diagnosis codes with the actual reason for use), the Committee agreed that it was unlikely that fibromyalgia represents the most common use for any study medication. Taken together with milnacipran's regulatory approval and use for depression outside the U.S. and multiple uses for other agents with a fibromyalgia indication, the Committee did not feel that the results supported consideration of a separate drug class for fibromyalgia, even given milnacipran's lack of any other FDA-approved indication. Several Committee members commented that logically such a grouping of agents should also contain the TCAs (particularly amitriptyline) and cyclobenzaprine, which have a substantial body of evidence supporting first-line use for fibromyalgia.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) that despite its FDA-approved status, milnacipran is one of many available treatments for fibromyalgia. Milnacipran (Savella) does not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other SNRIs and medically-accepted drugs used for fibromyalgia currently included on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the cost of milnacipran (Savella) in relation to the efficacy, safety, tolerability, and clinical outcomes of the other SNRIs in the AD-1 class, as well as other medically-accepted treatments for fibromyalgia. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of milnacipran (Savella) relative to other UF SNRIs and medically-accepted treatments for fibromyalgia. Results from the CMA showed the projected weighted average cost per day for milnacipran (Savella) is higher than the UF alternatives commonly used to treat fibromyalgia, including the tricyclic antidepressant amitriptyline (Elavil, generics) and cyclobenzaprine (Flexeril, generics).

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 1 abstained, 0 absent) that

milnacipran (Savella) is not cost effective relative to other medically-accepted drugs for the management of fibromyalgia included on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness, 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, 0 absent) that milnacipran (Savella) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —Based on the clinical evaluation of milnacipran (Savella) and the conditions for establishing MN of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria. (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TPHARM, 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.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Overactive Bladder Drugs (OABs) — Oxybutynin Topical Gel (Gelnique)

Relative Clinical Effectiveness — Oxybutynin chloride 10% topical gel (Gelnique) is an antimuscarinic agent classified as an overactive bladder (OAB) drug. It is the second topical oxybutynin product to reach the market, following the transdermal patch (Oxytrol). Like the other OAB drugs, Gelnique is FDA-approved for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and frequency. Gelnique is a clear and colorless hydroalcoholic gel available in a 1 gram sachet (1.14 mL) unit dose that contains 100 mg oxybutynin chloride, which is estimated to deliver approximately 4 mg of oxybutynin chloride per day. The OAB drug class was previously reviewed for UF placement in August 2008 and February 2006. Other oxybutynin products are included on the UF (oxybutynin immediate release (IR) and sustained release (SR) tablets [Ditropan, Ditropan SR, generics] and the Oxytrol patch).

The oxybutynin 10% gel (Gelnique) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no comparative clinical trials between Gelnique and the other OAB drugs, and no published trials evaluating outcomes other than changes in signs and symptoms of OAB. The clinical trials used to obtain FDA approval reported Gelnique was effective at reducing the number of incontinence episodes per day, number of urinary frequency episodes per day, and increasing the urinary volume per void in patients with OAB, comparable to the other OAB agents. The safety profile of Gelnique appears to be comparable to other OAB agents.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that oxybutynin 10% gel (Gelnique) did not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other OAB agents included on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the cost of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the anticholinergic agents in the overactive bladder (OAB) 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).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of oxybutynin 10% gel (Gelnique) relative to other UF anticholinergic OAB agents. Results from the CMA showed the projected weighted average cost per day for oxybutynin 10% gel (Gelnique) is higher than the other formulary OAB anticholinergic agents, including extended-release oral agents (oxybutynin ER [Ditropan XL] and tolterodine ER [Detrol LA]), and the UF transdermal patch formulation (Oxytrol).

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 0 abstained, 1 absent) that oxybutynin 10% gel (Gelnique) is not cost effective relative to the other UF anticholinergic agents in the OAB 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 (14 for, 1 opposed, 0 abstained, 1 absent) oxybutynin 10% gel (Gelnique) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** — Based on the clinical evaluation for oxybutynin 10% gel (Gelnique) 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, 0 abstained, 2 absent) MN criteria for oxybutynin 10% gel (Gelnique). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TPHARM, 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.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

E. Narcotic Analgesics — Tapentadol Tablets (Nucynta)

Relative Clinical Effectiveness — Tapentadol (Nucynta) is an oral, centrally acting, synthetic opioid analgesic, indicated for the relief of moderate to severe acute pain in adults. It is a Schedule II controlled substance and classified as an immediate release, single component high potency agent in the narcotic analgesic drug class, which was last reviewed for UF in February 2007. Tapentadol's exact mechanism of action is unknown, but analgesia is potentially conferred by mu-agonist activity and inhibition of norepinephrine reuptake. It has no pharmacologically active metabolites and requires multiple daily dosing.

The clinical evaluation for tapentadol included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). The pivotal trials used to obtain FDA approval reported that tapentadol was superior to placebo, and non-inferior at specific doses to oxycodone immediate release (IR) in relieving pain in patients with end-stage joint disease or following bunionectomy. There are no published direct comparative trials between tapentadol and other narcotic analgesics. The safety profile of tapentadol reflects that of other narcotic analgesics on the UF, with the exception of a lower incidence of constipation observed in clinical trials compared to immediate-release oxycodone.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) that although tapentadol may result in less gastrointestinal adverse events compared to oxycodone IR, this was an irrelevant benefit given its current indication for short-term therapy in the treatment of acute pain. There is insufficient evidence to suggest a clinically meaningful therapeutic advantage in patient outcomes, in terms of efficacy and safety, compared to the other narcotic analgesics already on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the cost of tapentadol in relation to the efficacy, safety, tolerability, and clinical outcomes of the other immediate release, single component high potency agents in the narcotic analgesic drug 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).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of tapentadol (Nucynta) relative to other UF scheduled and non-scheduled agents in the narcotic analgesic class. Results from the CMA showed the projected weighted average

cost per day for tapentadol (Nucynta) is higher than the other formulary immediate release, single component high potency agent in the narcotic analgesic drug class, including morphine sulfate IR oral, oxycodone hydrochloride IR, and tramadol hydrochloride IR formulations.

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (16 for, 0 opposed, 0 abstained, 0 absent) that tapentadol (Nucynta) is not cost effective relative to the other immediate release, single component high potency agents in the narcotic analgesic drug 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, 0 absent) tapentadol (Nucynta) be designated non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the determination that morphine sulfate (MS-IR/generic; MS-Contin/generic) remains the most cost-effective narcotic analgesic on the UF compared to tapentadol (Nucynta).

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —Based on the clinical evaluation of tapentadol (Nucynta) and the conditions for establishing medical necessity (MN) of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for tapentadol (Nucynta). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** —
The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TPHARM, 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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

F. Narcotic Analgesics — Tramadol Extended Release (ER) Tablets (Ryzolt)

Relative Clinical Effectiveness — Tramadol extended-release (ER), (Ryzolt) is an oral centrally acting analgesic, and is classified as an extended release, single component, low-potency agent in the narcotic analgesic drug class; it is not a controlled drug. Ryzolt has the same active ingredient as Ultram IR and Ultram ER, but with a differing mode of delivery, and was approved under section 505(b)(2) of the FDC. Ryzolt exhibits immediate-release and extended-release properties, due to its dual-matrix delivery system.

Tramadol ER is indicated for the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time. The postulated mechanism for analgesic efficacy of tramadol is a combination of mu-agonist activity and weak inhibition of serotonin and norepinephrine reuptake. The clinical evaluation for Ryzolt included, but was not limited to the requirements stated in the UF rule, 32 CFR 199.21(e)(1).

In three out of four pivotal trials, Ryzolt was unable to demonstrate superiority over a comparator. The study on which approval was based showed questionable efficacy over placebo. No direct comparative trials have been conducted between Ryzolt and other tramadol products available in the US or other narcotic analgesics. The safety profile of Ryzolt reflects that of other tramadol products on the UF.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that although Ryzolt offered a novel delivery mechanism, there was insufficient evidence to suggest a clinically meaningful

therapeutic advantage in terms of efficacy and safety, compared to the other tramadol products available on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the cost of the tramadol ER in relation to the efficacy, safety, tolerability, and clinical outcomes of the other extended release, single component low-potency agents in the narcotic analgesic drug 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).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of tramadol ER (Ryzolt) relative to the other UF chemically identical chronic pain agents. Results from the CMA showed the projected weighted average cost per day for tramadol ER (Ryzolt) is higher than the non-formulary low-potency single analgesic agent, tramadol extended-release (Ultram ER) and significantly higher than the formulary product tramadol immediate-release (Ultram/generics) Results from the CMA showed the projected weighted average cost per day for tramadol ER (Ryzolt) is higher than the non-formulary low-potency single analgesic agent, tramadol extended release (Ultram ER) and significantly higher than the formulary product tramadol immediate release (Ultram/generics).

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (15 for, 0 opposed, 0 abstained, 1 absent) that tramadol ER (Ryzolt) is not cost effective relative to tramadol extended-release (Ultram ER).

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, 0 abstained, 1 absent) tramadol ER tablets (Ryzolt) be designated non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the determination that Ultram (tramadol IR) remains the most cost effective low-potency single narcotic agent on the UF compared to Ryzolt (tramadol ER).

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —Based on the clinical evaluation of Ryzolt (tramadol ER) and the conditions for establishing medical necessity (MN) of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Ryzolt (tramadol ER). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TPHARM, 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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

G. Renin Angiotensin Aldosterone Antihypertensive Agents (RAAs) — Valsartan/Amlodipine/Hydrochlorothiazide (HCTZ) Tablets (Exforge HCT)

Relative Clinical Effectiveness — Exforge HCT is a fixed-dose combination product containing valsartan (Diovan), amlodipine (Norvasc, generics), and hydrochlorothiazide (HCTZ, generics). It is the first three-drug combination product approved for hypertension and contains an angiotensin receptor blocker (ARB; Diovan), a dihydropyridine calcium channel blocker (DHP CCB; amlodipine), and a diuretic (HCTZ). Valsartan/amlodipine/hydrochlorothiazide is solely indicated for treating hypertension. Valsartan (Diovan) and the combination product valsartan/amlodipine (Exforge) are currently designated as non-formulary on the UF; amlodipine (Norvasc, generics) and HCTZ are BCF products. Exforge HCT is included in the renin-angiotensin antihypertensive agents (RAAs) UF drug class, which is comprised of several sub-classes (ARBs, angiotensin converting enzyme (ACE) inhibitors, direct

renin inhibitors and their combinations with CCBs or HCTZ).

Treatment with Exforge HCT has been shown in one randomized trial to produce additive BP lowering and superior BP control compared to combinations of the individual components administered as pairs.

The adverse event profile of valsartan/amlodipine/HCTZ is similar to that of the individual ARB, DHP CCB, and diuretic components. In the clinical trial, the incidence of dizziness (7%) was higher among patients taking the three-drug combination than with any of two-drug combinations, resulting in a 0.7% study drop-out rate, which is less than that seen in a typical ACE inhibitor trial. Hypokalemia was less frequent among participants who took a combination that included the ARB and diuretic than among those who took a combination that included a diuretic without an ARB. Peripheral edema was less common among participants who took a combination that included an ARB and a DHP CCB than among those who took a combination that included a DHP CCB without an ARB.

Studies specifically evaluating patient compliance (adherence and persistence) using Exforge HCT have not been conducted. Nevertheless, there is significant evidence that adherence (short-term compliance) and persistence (long-term compliance) are improved 10–15% for each tablet reduced. That is, both measures of compliance improve 15% when reducing from three tablets to two, and improve 10% when reducing two tablets to one. No study has been conducted addressing reduction of three tablets to one.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that, while valsartan/amlodipine/HCTZ (Exforge HCT) does not have a significant, clinically meaningful therapeutic advantage in terms of safety or efficacy over other antihypertensive combinations/agents included on the UF, the benefits it offers in terms of improved compliance, via decreased tablet burden and simplified medication regimen, are clinically significant.

Relative Cost-Effectiveness — The P&T Committee evaluated the cost of valsartan/amlodipine/HCTZ (Exforge HCT) in relation to the efficacy, safety, tolerability, and clinical outcomes of the antihypertensive agents in the RAAs UF drug class as single ingredient agents and combination formulations. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of Exforge HCT relative to other UF RAAs. Results from the CMA showed the projected weighted average cost per day for amlodipine/valsartan/HCTZ (Exforge HCT) is higher than multi-tablet combinations of the other formulary RAAs, including

amlodipine tablets with lisinopril/HCTZ (Prinzide, generics), telmisartan/HCTZ (Micardis HCT), aliskiren/HCTZ (Tekturna HCT) and losartan/HCTZ (Hyzaar).

Relative Cost-Effectiveness Conclusion — The P&T Committee voted (14 for, 0 opposed, 1 abstained, 1 absent) that amlodipine/valsartan/HCTZ (Exforge HCT) is cost effective relative to the other single ingredient or combination agents in the RAAs drug class. After extensive discussion, the P&T Committee determined that the minimal extra daily cost for the amlodipine/valsartan/HCTZ (Exforge HCT) single tablet formulation was offset by the added patient convenience, and may clinically improve patient compliance.

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, voted (4 for, 11 opposed, 0 abstained, 1 absent) against recommending that valsartan/ amlodipine/HCTZ (Exforge HCT) be designated as non-formulary on the UF, thus Exforge HCT will retain uniform formulary status.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: BCF RECOMMENDATION*** — The P&T Committee considered the BCF status of valsartan/amlodipine/HCTZ (Exforge HCT). Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (15 for, 0 opposed, 0 abstained, and 1 absent) to recommend Exforge HCT not be added to the BCF.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IV. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. Phosphodiesterase-5 (PDE5) Inhibitors for Pulmonary Arterial Hypertension (PAH)

Relative Clinical Effectiveness — The P&T Committee evaluated the clinical effectiveness of the Phosphodiesterase Type-5 (PDE-5) inhibitors for the treatment of pulmonary arterial hypertension (PAH). Sildenafil (Revatio) was previously reviewed for UF placement in August 2005. Tadalafil (Adcirca) is the second PDE-5 inhibitor FDA-approved for PAH, and was recently launched in August 2009. Sildenafil and tadalafil are FDA-approved for treating erectile dysfunction (ED), under the trade names of Viagra and Cialis, respectively. Information regarding the safety, effectiveness, and clinical outcomes of the PAH subclass of the PDE-5 inhibitors was considered. The clinical review included, but was not limited to, the requirements stated in the UF Rule, 32 CFR 199.21(e)(1).

Military Health System (MHS) expenditures for the PDE-5 inhibitors for PAH exceeded $400,000 per month at the retail, mail order and MTFs points of service from September 2007 to September 2009. In the MHS, sildenafil (Revatio) is the highest utilized PDE-5 inhibitor for PAH, with approximately 500 prescriptions dispensed monthly. There have been less than 60 unique utilizers of Adcirca, since its market launch in August 2009.

Relative Clinical Effectiveness Conclusion — The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following clinical effectiveness conclusions regarding PDE-5 inhibitors for PAH:

1. With regard to efficacy, the following conclusions were made:
    a) Sildenafil (Revatio) and tadalafil (Adcirca) are FDA-approved to improve exercise ability in patients with PAH. Sildenafil has an additional indication specifically to delay clinical worsening in patients with PAH when used in combination with background intravenous epoprostenol (Flolan).
    b) There are no head-to-head trials comparing the two PDE-5 inhibitors for PAH. However, sildenafil and tadalafil show similar improvements in 6-minute walking distance (6MWD) when indirect comparisons of clinical trial results that incorporated the FDA-approved dosing regimens are made.
    c) Sildenafil and tadalafil delay the time to clinical worsening of disease, which is defined variously as a composite of death, transplantation, hospitalization for PAH, initiation of new therapy, or worsening functional class.
        (1) A clinically significant delay in the time to clinical worsening with sildenafil was shown in one trial that used doses four times higher than the FDA-approved dose, and used adjunctive IV epoprostenol treatment in all the patients.

(2) Tadalafil was shown to delay the time to clinical worsening of PAH in one trial that used FDA-approved dosing and used adjunctive bosentan (Tracleer) therapy in 55% of the patients.

d) There is insufficient evidence to conclude that there are clinically relevant differences in clinical effectiveness of PDE-5 inhibitors for PAH.

2. With regards to safety and tolerability, the P&T Committee agreed that there is insufficient evidence to conclude there are clinically relevant differences in safety between PDE-5 inhibitors for PAH. The product labeling for the two drugs is similar with regard to contraindications, precautions, and warnings, and reflects the safety section found in the package inserts for the ED products Viagra and Cialis. The sildenafil and tadalafil doses used for PAH treatment are associated with an increased incidence of adverse events (headache, flushing, myalgia), than occurs with the doses used in ED. Headache is the most frequently reported adverse event with Revatio and Adcirca.
3. With regards to other factors, generic availability of sildenafil (Viagra and Revatio trade names) is expected in 2012, compared to 2020 for tadalafil (Cialis and Adcirca). Additionally, the P&T Committee recognized the convenience to the patient with the once daily dosing required with Adcirca, in contrast to the 3-times daily dosing needed with Revatio. Sildenafil and tadalafil require Prior Authorization when used for PAH (*see* August 2009 DoD P&T Committee meeting minutes for full PA criteria for the PDE-5 inhibitors).

Relative Cost-Effectiveness —The P&T Committee evaluated the costs of sildenafil (Revatio) and tadalafil (Adcirca) in relation to the efficacy, safety, tolerability, and clinical outcomes of the PDE-5 inhibitors for PAH. 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 Budget Impact Analysis (BIA) were used to evaluate the cost effectiveness of the PDE-5 inhibitors for PAH.

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (16 for, 0 opposed, 0 abstained, 0 absent) that:

1. Results from the CMA of PDE-5 inhibitors for PAH agents revealed that sildenafil (Revatio) is the most cost effective PDE-5 inhibitor for PAH agent based on an analysis of the cost per day of treatment. Cost per day of therapy was calculated using average daily consumption rates for sildenafil (Revatio) and tadalafil (Adcirca).
2. Budget impact analysis (BIA) was used to evaluate the potential impact of scenarios with selected PDE-5 inhibitor agents designated formulary or non-formulary on the UF. Results from the BIA of PDE-5 inhibitors for PAH

revealed that placing sildenafil citrate (Revatio) on the UF was the most cost effective scenario overall.

3. The results of the BIA showed that tadalafil (Adcirca) is more costly than sildenafil (Revatio) in all scenarios evaluated.

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, voted (14 for, 0 opposed, 1 abstained, 1 absent):

   a) Sildenafil (Revatio 20 mg) remain classified as formulary on the UF.

   b) Tadalafil (Adcirca 20 mg) be designated as non-formulary under the UF, based on cost effectiveness.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** —

   Based on the clinical evaluation of tadalafil (Adcirca) and the conditions for establishing medical necessity (MN) of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for tadalafil (Adcirca). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TPHARM, 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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

IV. UTILIZATION MANAGEMENT — UF/BCF ADDITIONS/DELETIONS

A. Status of Bupropion HCl ER Tablets (Wellbutrin XL) on the UF

On an ongoing basis, the DoD PEC monitors changes in the clinical information, current costs, and utilization trends to determine whether the UF status of agents designated as non-formulary needs to be readdressed. The P&T Committee reevaluated the UF status of bupropion ER (Wellbutrin XL, generics) in light of recent price reductions in the generic 150 mg and 300 mg formulations across all three points of service.

Clinical Effectiveness Conclusion — The AD-1 agents were evaluated for UF status at the November 2005 meeting. At that meeting, the P&T Committee concluded bupropion appears similar in efficacy to SSRIs; its major advantage is a lower incidence of sexual adverse effects than the other AD-1 agents. The major disadvantages are the risk of seizures at high doses and its tendency to produce activation/agitation. The putative advantage of the once-daily ER formulation (Wellbutrin XL) is increased compliance, although clinical trial data assessing compliance is not available.

Cost Effectiveness Conclusion — The P&T Committee agreed that the generic bupropion ER (Wellbutrin XL) formulations were now cost effective at all three points of service.

1. ***COMMITTEE ACTION: UF DECISION*** — 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, voted (15 for, 0 opposed, 1 abstained, and 0 absent) that bupropion ER (Wellbutrin XL, generic) be immediately reclassified as generic on the UF. Wellbutrin XL was included on the "list of non-formulary drugs for re-evaluation of UF status" presented to the Beneficiary Advisory Panel in January 2008 and approved by the Director, TMA on 13 February 2008. No further approval is needed.

VI. BASIC CORE FORMULARY ISSUES

A. Levonorgestrel — BCF Addition

The Committee received a request to reconsider BCF addition of levonorgestrel (Plan B, generics). Levonorgestrel is currently designated as formulary on the UF; it was originally reviewed for UF status as part of the contraceptive drug class in May 2006. Since the original UF class review, levonorgestrel is now available in a generic product under the trade name Next Choice, which contains two 0.75 mg tablets, taken 12 hours apart for emergency contraception. The Plan B product has been voluntarily discontinued by the manufacturer as of June 2009. A new product, Plan B One Step, is marketed that contains one 1.5 mg tablet, taken in a single dose. Studies evaluating the two tablets vs. one tablet products reported no clinically relevant differences between the regimens in the pharmacokinetic profiles, number of resulting pregnancies, or incidence of nausea and vomiting. The American College of Obstetrics and Gynecology recommends a single dose of 1.5 mg levonorgestrel as one option, or two doses of levonorgestrel 0.75 mg taken 12–24 hours as another option for emergency contraception.

Plan B, Next Choice, and Plan B One Step do not require a prescription for patients 17 years of age and older, thus they are not available from the TPHARM, since they are over-the-counter products for this age group. A prescription is required for patients younger than 17 years; the products are available from the TPHARM if a prescription is supplied. A quantity limit of one fill per prescription, with no refills applies at the TPHARM. Each of the three military services has a policy supporting availability of emergency contraception at the MTFs. A cost analysis between Next Choice and Plan B One Step found Next Choice as the more cost effective product. After reviewing the clinical and cost effectiveness of the product, the P&T Committee agreed that levonorgestrel should be placed on the BCF.

1. ***COMMITTEE ACTION: BCF ADDITION*** — The Committee voted (13 for, 2 opposed, 0 abstained, 1 absent) to recommend adding levonorgestrel 0.75 mg (Next Choice; generic Plan B) to the BCF immediately upon signing of the November 2009 meeting minutes. Plan B One Step would remain designated as formulary under the UF. The current quantity limits of one fill per prescription, with no refills, remains.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Hydrocodone/Acetaminophen 5 mg/500 mg — BCF Deletion

The P&T Committee received a request from the field to re-examine the BCF status of hydrocodone/acetaminophen (Vicodin, generics). Recent FDA communications

outline the potential for accidental ingestion of excessive acetaminophen (Tylenol, generics) doses and a proposed black box warning for prescription products that combine acetaminophen with another drug. Several prescription and OTC products contain acetaminophen, which increases the risk of inadvertent ingestion of higher than maximally recommended dose, and the potential for resulting hepatic injury. Administering hydrocodone/acetaminophen 5mg/500 mg at the highest recommended dose and dosing interval results in an acetaminophen dose that exceeds the maximal FDA-approved dose.

1. ***COMMITTEE ACTION: BCF DELETION*** — The Committee voted (11 for, 3 opposed, 0 abstained, 2 absent) to delete hydrocodone/acetaminophen 5mg/500 mg from the BCF immediately upon signing of the November 2009 meeting minutes; it will remain formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. Telmisartan +/- HCTZ (Micardis, Micardis HCT) — BCF Deletion

The ARBs and ARB combinations with HCTZ were last reviewed for UF placement in May 2007. Since the last review, the ARB +/- HCTZ combinations have been categorized into a larger class, the Renin-Angiotensin Antihypertensives (RAAs), which is comprised of the angiotensin converting enzyme inhibitors (ACEs +/- HCTZ), the ARB combinations with CCBs, the direct renin inhibitors +/- HCTZ, and the ARB/CCB/HCTZ combinations. The existing preferential pricing for the current BCF ARB, telmisartan +/- HCTZ (Micardis, Micardis HCT) has been terminated by the manufacturer, effective Jan 2010. Additionally in 2010, generic competition in the class is expected, and updated hypertension treatment guidelines from the Joint National Commission will be released. The RAAs drug class will be reviewed for UF status at an upcoming meeting. Due to the aforementioned developments, the Committee recommended deleting telmisartan +/- HCTZ from the BCF.

1. ***COMMITTEE ACTION: BCF DELETION*** — The Committee voted (15 for, 0 opposed, 0 abstained, 1 absent) to delete telmisartan +/- HCTZ (Micardis, Micardis HCT) from the BCF immediately upon signing of the November 2009 DoD P&T Committee minutes; it will remain formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VII. NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) SECTION 703 — INCLUSION OF TRICARE RETAIL PHARMACY PROGRAM IN FEDERAL PROCUREMENT OF PHARMACEUTICALS UPDATE

A. Medical Necessity for August 09 Section 703 Recommendations —

The committee reviewed medical necessity criteria for drugs that were not included on a Department of Defense Retail Refund Pricing Agreement at the August 2009 meeting. These drugs are not compliant with FY2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated non-formulary under the Uniform Formulary and will require a pre-authorization prior to use in the retail point of service (POS) and medical necessity in military treatment facilities. These non-formulary drugs will remain available in the mail order POS without pre-authorization. Pre-authorization was determined at the November 2009 DoD P&T Committee meeting. Drugs with and without pricing agreements were systematically classified based along therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification. See Appendix C for the full list of affected medications.

1. ***COMMITTEE ACTION — DRUGS GENERICALLY AVAILABLE REQUIRING PRIORI-AUTHORIZATION:*** The P&T Committee voted (15 for, 0 against, 0 abstained, 1 absent) to recommend the drugs listed in Appendix C, Section A follow the standard TRICARE rules for brand-generic prior-authorization criteria.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION — MEDICAL NECESSITY CRITERIA:*** The P&T Committee voted (13 for, 0 against, 0 abstained, 3 absent) to recommend medical necessity criteria for the drugs listed in Appendix C, Section B.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION — IMPLEMENTATION DATE FOR MEDICAL NECESSITY:*** The P&T Committee voted (13 for, 0 against, 0 abstained, 3 absent) to recommend the implementation date will not be prior to 1 April 2010 and not later than 180 days after the minutes of this meeting are signed.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

4. ***COMMITTEE ACTION — TRANSITION DATE AT THE MTF POS:*** The P&T Committee voted (13 for, 0 against, 0 abstained, 3 absent) to recommend a transition period at the MTF POS as ending no later than 1 January 2011.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Drug Non-compliant with NDAA Section 703 The P&T Committee reviewed drugs that were not included on a DoD Retail Refund Pricing Agreement. These drugs are not compliant with FY08 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated non-formulary on the UF and will require a pre-authorization prior to use in the retail point of service (POS) and medical necessity in MTFs. These non-formulary drugs will remain available in the mail order POS without pre-authorization. Pre-authorization will be determined at the February 2010 DoD P&T Committee meeting. Drugs with and without pricing agreements were systematically classified based along therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification. See Appendix D for the full list of affected medications.

1. ***COMMITTEE ACTION — DRUGS RETAINING UF STATUS:*** The P&T Committee voted (12 for, 0 against, 0 abstained, 4 absent) to recommend the drugs listed in Appendix E, Section A to retain formulary status on the Uniform Formulary.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

2. ***COMMITTEE ACTION — DRUGS RETAININ OR DESIGNATED AS NON-FORMULARY:*** The P&T Committee voted (12 for, 0 against, 0 abstained, 4 absent) to recommend the drugs listed in Appendix E, Section B to retain non-formulary status or be designated non-formulary on the Uniform Formulary.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3. ***COMMITTEE ACTION — IMPLEMENTATION DATE FOR PRE-AUTHORIZATION:*** The P&T Committee voted (12 for, 0 against, 0 abstained, 4 absent) to recommend the implementation date will not be prior to 1 April 2010 and not later than 180 days after the minutes of this meeting are signed. Formulary status of a drug in these lists will revert back to previous formulary status if Price Agreements are received prior to 1 February, 2010.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

4. ***COMMITTEE ACTION — TRANSITION DATE AT THE MTF POS:*** The P&T Committee voted (12 for, 0 against, 0 abstained, 4 absent) to recommend a transition period at the MTF POS as ending no later than 1 January 2011.

Acting Director, TMA, Decision: ☑Approved ☐ Disapproved

Approved, but modified as follows:

VIII. CLASS OVERVIEWS

Class overviews for the Basal Insulins and the RAAs were presented to the P&T Committee. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important for the PEC to use in completing the clinical effectiveness reviews and developing the appropriate cost effectiveness models. The clinical and economic analyses of these classes will be completed at an upcoming meeting.

IX. ADJOURNMENT

The meeting adjourned at 1700 hours on 5 November 2009 and at 1100 hours on 6 November 2009. The next meeting will be in February 2010.

Appendix A — Attendance

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

Appendix C — Table of Medical Necessity for August 09 Section 703 Recommendations

Appendix D — National Defense Authorization Act (NDAA)-Section 703 Affected Medications

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

Appendix F — Table of Abbreviations

SUBMITTED BY:

CDR James Ellzy, MC, USN
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Allen W. Middleton
Acting Director

3 Feb 2010
(Date)

Appendix A — Attendance

Voting Members Present	
CDR James Ellzy, MC	DoD P&T Committee Chair
LTC Stacia Spridgen, MSC	Director, DoD Pharmacoeconomic Center, (Recorder)
Lt Col Thom Bacon *for Col Everett McAllister, MSC*	Chief, Pharmaceutical Operations Directorate
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Major Jeremy King, MC	Air Force, OB/GYN Physician
Capt Walter Downs, MC	Navy, Internal Medicine Physician
CAPT David Tanen, MC	Navy, Physician at Large
Lt Col Mike Spilker, BSC	Consultant to the AF/SG
Lt Col Brian Crownover, MC	Air Force, Physician at Large
CDR Phil Blaine *for CAPT Stephanie Simon, MSC*	Navy, Pharmacy Officer
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician, Alternate
LTC Bruce Lovins, MC	Army, Family Practice Physician, Alternate
LTC Douglas Louggee for COL Ted Cieslak, MC	Army, Physician at Large
COL Peter Bulatao *for COL Carole Labadie, MSC*	Army, Pharmacy Officer, Alternate
CAPT Vernon Lew	Coast Guard, Pharmacy Officer
Mr. Joe Canzolino	Department of Veterans Affairs
Voting Members Absent	
COL Carole Labadie, MSC	Army, Pharmacy Officer
CAPT Stephanie Simon, MSC	Navy Pharmacy Officer
COL Ted Cieslak, MC	Army, Physician at Large
Col Everett McAllister BSC	Chief, Pharmaceutical Operations Directorate
Nonvoting Members Present	
Mr. David Hurt	Assistant General Counsel, TMA
Nonvoting Members Absent	
COL Kent Maneval, MS	Defense Medical Standardization Board
Mr. William Davies	TRRx/TMOP COR
Guests	
CDR Michael Lee	Indian Health Service
Dr. Lisa Longo	VA PBM
Ms. Melanie Richardson	DoD Pharmacy Operations Directorate

Appendix A — Attendance (continued)

Others Present	
Lt Col James McCrary, MC	DoD Pharmacoeconomic Center
Lt Col Cynthia Lee, BSC	DoD Pharmacoeconomic Center
LCDR Bob Selvester, MC	DoD Pharmacoeconomic Center
CAPT Brian Haney, MC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez	DoD Pharmacoeconomic Center
HM2 Trishonya McMihelk	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. Jeremy Briggs	DoD Pharmacoeconomic Center
Mr. 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
Dr. Roger Potyk	DoD Pharmacy Outcomes Research Team contractor
Dr. Dean Valibhai	DoD Pharmacy Operations Center contractor

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

Drug / Drug Class	Medical Necessity Criteria
Tadalafil tablets (Adcirca) **Phosphodiesterase-5 (PDE-5) Inhibitors for Pulmonary Arterial Hypertension (PAH)**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives. • Formulary agents have resulted in therapeutic failure
Interferon Beta 1-b injection (Extavia) **Multiple Sclerosis - Disease Modulating Drugs (MS-DMDs)**	• None of the medical necessity criteria apply; interferon Beta 1-b injection (Betaseron brand name) is on the UF
Milnacipran tablets (Savella) **Antidepressant -1s (AD-1s)**	• 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
Bupropion hydrobromide extended release tablets (Aplenzin) **Antidepressant -1s (AD-1s)**	• None of the medical necessity criteria apply; Bupropion HCl ER (Wellbutrin XL generic) is now recommended for UF status
Oxybutynin topical gel (Gelnique) **Overactive Bladder (OAB)**	• The patient has experienced significant adverse effects from formulary alternatives.
Tapendatol tablets (Nucynta) Tramadol ER (Ryzolt) **Narcotic Analgesics**	• Use of formulary alternatives is contraindicated

Appendix C — Table of Medical Necessity and Branded Drugs with Formulary Equivalents for August 09 Section 703 Recommendations

Brand Name	Generic Name
Aclovate	aclomethasone diproprionate
Altace	ramipril
Carnitor, Carnitor SF	levocarnitine tablets, solution
Cutivate	fluticasone propionate
Cytoxan	cyclophosphamide
Depakene	valproic acid
Kaon-CL	potassium chloride
Mobic	meloxicam
Omnicef	cedinir capsules, suspension
Persantine	dipyridamole
Pletal	cilostazol
Septra;Septra DS	trimethoprim/sulfamethoxazole
Silvadene	silver sulfadiazine
Tapazole	methimazole
Temovate	clobetasol
Viroptic	trifluridine
Zonegram	zonisamide

Appendix C — Table of Medical Necessity and Branded Drugs with Formulary Equivalents for August 09 Section 703 (continued)

Drug	Generic Alternative	Brand Alternative	Applicable MN Rules
APTIVUS			1,2,3,4,5
ATROVENT HFA		Spiriva Inhaler	1,2,3,4
CORGARD	Atenolol, Metoprolol		1,2,4
CYTOMEL	Levothroid, Levothyroxine tables	Armour Thyroid	1,2,3,4,5
ELESTRIN	Estradiol Patch	Estrogel Gel, Divigel Gel, Evamist Spray, Menostar Patch, Vivelle Dot Patch	1,2,4
ELIGARD	Leuprolide Acetate Kit		1,2,3,4,5
ENDOMETRIN		First-Progesterone Vaginal Suppositories, Crinone Gel	1,2,3,4
LITHOSTAT			1,2,3,4,5
MIRAPEX	Bromocriptine	Requip XL, Ropinirole	1,2,3,4
NIRAVAM	Alprazolam Tabs Generic		1,2,3
OXISTAT	Clotrimazole Cream, Ketoconazole Cream, Shampoo	Lamisil, Mentax, Halotin, Xolegel Gel	1,3
PAMINE	Methscopolamine Bromide tablets		1,2,3
PAMINE FORTE	Methscopolamine Bromide tablets		1,2,3
PAMINE FQ	Methscopolamine Bromide tablets		1,2,3
PHOSLO	Calcium Acetate Tabs	Eliphos Tabs, Renagel Tabs, Renvela Tabs	1,2,3,4
RHEUMATREX	Methotrexate dosepack		1,2,3
SALAGEN	Pilocarpine HCl Tab	Evoxac Caps	1,2,3
THALITONE	Chlorthalidone Tabs	Diuril Oral Susp	1,2,3,4
TINDAMAX			1,2,3,4,5
TRANSDERM-SCOP			1,2,3,4,5
ULTRAVATE PAC	Halobetasol cream, ointment, gel		1,
VIRAMUNE			1,2,3,4,5

1) Use of formulary alternatives is contraindicated; 2) Patient has experienced significant adverse effects from the formulary alternative; 3) The formulary agents have resulted in therapeutic failure; 4) The patient previously responded to non-formulary agent, and changing to the formulary agent would incur unacceptable risk; 5) There is no formulary alternative

Appendix D — National Defense Authorization Act (NDAA) Section 703 Affected Medications

Product Name	Category	Manufacturer	Number of Affected Patients
ARICEPT	Alzheimers medications	EISAI INC.	85107
ARICEPT ODT	Alzheimers medications	EISAI INC.	229
DILANTIN	Anticonvulsants / antimania medications	PFIZER US PHARM	512
EPIPEN	Misc respiratory medications	DEY LABS.	13232
EPIPEN JR	Misc respiratory medications	DEY LABS.	3216
FARESTON	Oral oncological agents	GTX INC.	49
HEXALEN	Oral oncological agents	EISAI INC.	18
MENOPUR	FSH/LH fertility agents	FERRING PH INC	850
MESNEX	Oral oncological agents	BAXTER HEALTHCA	6
QUALAQUIN	Antimalarials	AR SCIENTIFIC	10967
TARGRETIN	Topical antineoplastic & premalignant lesion medic	EISAI INC.	39
VANCOCIN HCL	Misc anti-infectives	VIROPHARMA INCO	3534

Product Name	Category	Manufacturer	Number of Affected Patients
ADOXA	Tetracyclines	PHARMADERM	4
ALLEGRA	2nd gen antihistamines & combos	AVENTIS PHARM	6661
ALOCRIL	Ophthalmics for allergic conjunctivitis	ALLERGAN INC.	572
AMICAR	Misc hematological agents	XANODYNE PHARM	28
ANTABUSE	Alcohol deterrants, narcotic antagonists	DURAMED/BARR	448
ARMOUR THYROID	Thyroid and antithyroid medications	FOREST PHARM	14766
AVAGE	Psoriasis medications	ALLERGAN INC.	3
AZASAN	Immunosuppressives	SALIX PHARMACEU	70
AZELEX	Acne meds	ALLERGAN INC.	3034
BANZEL	Anticonvulsants / antimania medications	EISAI INC.	125
BETAGAN	Ophthalmics for glaucoma	ALLERGAN INC.	133
BIAXIN XL	Macrolides/ketolides	ABBOTT LABS.	430
BLEPHAMIDE	Ophthalmic antibiotics & combos	ALLERGAN INC.	3106

Product Name	Subclass	Manufacturer	Number of Utilizers
BLEPHAMIDE S.O.P.	Ophthalmic antibiotics & combos	ALLERGAN INC.	1375
BRAVELLE	FSH/LH fertility agents	FERRING PH INC	130
BREVOXYL-4	Keratolytics	STIEFEL LABS.	29
BREVOXYL-8	Keratolytics	STIEFEL LABS.	20
CAFCIT	Pulmonary II agents	BEDFORD LABS	1
CAPITAL W-CODEINE	Narcotic analgesics & combos	VALEANT	229
CARDENE SR	CCBs	EKR THERAPEUTIC	80
CITRANATAL 90 DH	Prenatal vitamins	MISSION PHARM.	524
CITRANATAL DHA	Prenatal vitamins	MISSION PHARM.	893
CITRANATAL RX	Prenatal vitamins	MISSION PHARM.	111
CLARIFOAM EF	Misc topical anti-infectives	ONSET THERAPEUT	175
CLINDESSE	Vaginal anti-infectives/antiseptics	THER-RX	3672
CORZIDE	Beta blockers & HCTZ combos	KING PHARM	59
CYCLOGYL	Ophthalmics, mydriatics	ALCON LABS.	103
CYCLOSPORINE	Immunosuppressives	IVAX PHARMACEUT	12
DARVOCET A500	Narcotic analgesics & combos	XANODYNE PHARM	8
DARVOCET-N 100	Narcotic analgesics & combos	XANODYNE PHARM	140
DARVOCET-N 50	Narcotic analgesics & combos	XANODYNE PHARM	2
DARVON	Narcotic analgesics & combos	XANODYNE PHARM	5
DARVON-N	Narcotic analgesics & combos	XANODYNE PHARM	442
DENAVIR	Misc topical anti-infectives	NOVARTIS CONSUM	6954
DILANTIN	Anticonvulsants / antimania medications	PFIZER US PHARM	857
DILTZAC ER	CCBs	APOTEX CORP	59
DORAL	Sedative/hypnotics II	QUESTCOR	40
DUET STUARTNATAL	Prenatal vitamins	XANODYNE PHARM	85
E.E.S. 200	Macrolides/ketolides	ABBOTT LABS.	109
E.E.S. 400	Macrolides/ketolides	ABBOTT LABS.	38
ELDOPAQUE FORTE	Misc topical agents	VALEANT	5
ELDOQUIN FORTE	Misc topical agents	VALEANT	2
ELESTAT	Ophthalmics for allergic conjunctivitis	ALLERGAN INC.	7821
ELIMITE	Misc topical anti-infectives	ALLERGAN INC.	8931

Product Name	Category	Manufacturer	Number of Affected Patients
EMLA	Topical local anesthetics	APP PHARMACEUTI	2
EPIFOAM	Topical local anesthetics	ALAVEN PHARMACE	14
ERGOLOID MESYLATES	Misc cardiovascular medications	MUTUAL PHARM CO	62
ERYPED 200	Macrolides/ketolides	ABBOTT LABS.	278
ERYPED 400	Macrolides/ketolides	ABBOTT LABS.	192
ERY-TAB	Macrolides/ketolides	ABBOTT LABS.	3208
ERYTHROCIN STEARATE	Macrolides/ketolides	ABBOTT LABS.	2002
ERYTHROMYCIN	Macrolides/ketolides	ABBOTT LABS.	3457
ESGIC	Analgesic combos	FOREST PHARM	1
ESGIC-PLUS	Analgesic combos	FOREST PHARM	33
FML	Ophthalmic anti-inflammatories	ALLERGAN INC.	7446
FML FORTE	Ophthalmic anti-inflammatories	ALLERGAN INC.	362
FML S.O.P.	Ophthalmic anti-inflammatories	ALLERGAN INC.	2830
FRAGMIN	Anticoagulants	EISAI INC.	1754
GENGRAF	Immunosuppressives	ABBOTT LABS.	4
GLUCAGEN	Binders/chelators/antidotes/overdose agents	BEDFORD LABS	194
GRANULEX	Misc topical agents	UDL	190
HYCET	Narcotic analgesics & combos	XANODYNE PHARM	157
INDERAL LA	Beta blockers & HCTZ combos	AKRIMAX PHARMAC	55
KERAFOAM	Keratolytics	ONSET THERAPEUT	109
LAMICTAL ODT	Anticonvulsants / antimania medications	GLAXOSMITHKLINE	30
LAMICTAL ODT (BLUE)	Anticonvulsants / antimania medications	GLAXOSMITHKLINE	1
LAMICTAL ODT (GREEN)	Anticonvulsants / antimania medications	GLAXOSMITHKLINE	1
LAMICTAL ODT (ORANGE)	Anticonvulsants / antimania medications	GLAXOSMITHKLINE	10
LAMICTAL XR	Anticonvulsants / antimania medications	GLAXOSMITHKLINE	43
LINDANE	Misc topical anti-infectives	MORTON GROVE PH	620
LO-OVRAL-28	Contraceptives	AKRIMAX PHARMAC	16760
LORCET 10-650	Narcotic analgesics & combos	FOREST PHARM	113
LORCET PLUS	Narcotic analgesics & combos	FOREST PHARM	18
LORTAB	Narcotic analgesics & combos	UCB PHARMA	170

Product Name	Subclass	Manufacturer	Number of Months Paneled
MAGNACET	Narcotic analgesics & combos	MALLINCKRODT BR	102
MAVIK	Renin-Angiotensin Antihypertensives (RAAs)	ABBOTT LABS.	6
MAXIDONE	Narcotic analgesics & combos	WATSON PHARMA	1
MEBARAL	Anticonvulsants / antimania medications	OVATION PHARM	40
METHYLIN ER	ADHD / narcolepsy agents	MALLINKRT PHARM	170
MIMYX	Emollients	STIEFEL LABS.	880
MONONESSA	Contraceptives	WATSON LABS	1281
NATAFORT	Prenatal vitamins	WC PROF PRODS	1
NORCO	Narcotic analgesics & combos	WATSON PHARMA	556
OCUFEN	Ophthalmic anti-inflammatories	ALLERGAN INC.	146
OCUFLOX	Ophthalmic antibiotics & combos	ALLERGAN INC.	2814
OGEN	Estrogens & estrogen/androgen combos	PHARMACIA/UPJHN	49
OPTASE	Misc topical agents	ONSET THERAPEUT	8
PACERONE	Antiarrhythmics	UPSHER SMITH	141
PERANEX HC	Topical corticosteroids/immune modulators	KENWOOD LAB.	19
PERPHENAZINE	Typical antipsychotics	SANDOZ	709
PHRENILIN FORTE	Analgesic combos	VALEANT	126
POLY-PRED	Ophthalmic antibiotics & combos	ALLERGAN INC.	16
POLYTRIM	Ophthalmic antibiotics & combos	ALLERGAN INC.	15645
PRED MILD	Ophthalmic anti-inflammatories	ALLERGAN INC.	874
PRED-G	Ophthalmic antibiotics & combos	ALLERGAN INC.	82
PRIMSOL	Sulfonamides/folate antagonists	FSC LABS	104
PROCTOCORT	Topical corticosteroids/immune modulators	SALIX PHARMACEU	17
PROCTOFOAM-HC	Topical corticosteroids/immune modulators	ALAVEN PHARMACE	601
PROGLYCEM	Binders/chelators/antidotes/overdose agents	IVAX PHARMACEUT	28
PYRIDIUM	Misc urinary agents	WC PROF PRODS	3
REPRONEX	FSH/LH fertility agents	FERRING PH INC	92
RIMSO-50	Misc urinary agents	BIONICHE PHARMA	65
ROCALTROL	Fat soluble vitamins, replacement	VALIDUS PHARMAC	7
ROSAC	Misc topical anti-infectives	STIEFEL LABS.	189
SALAGEN	Misc neurological agents	EISAI INC.	539

Product Name	Subclass	Manufacturer	Number of Months Billed
SALKERA	Keratolytics	ONSET THERAPEUT	2
STIMATE	Misc endocrine agents	CSL BEHRING LLC	223
SYNTHROID	Thyroid and antithyroid medications	ABBOTT LABS.	7516
THEO-24	Pulmonary II agents	UCB PHARMA	910
TRINESSA	Contraceptives	WATSON LABS	8405
TUSSICAPS	Cough-cold medications	MALLINCKRODT BR	1997
ULTRASE	Gastric and pancreatic enzymes	AXCAN PHARMA US	52
ULTRASE MT 12	Gastric and pancreatic enzymes	AXCAN PHARMA US	111
ULTRASE MT 18	Gastric and pancreatic enzymes	AXCAN PHARMA US	36
ULTRASE MT 20	Gastric and pancreatic enzymes	AXCAN PHARMA US	326
VICODIN ES	Narcotic analgesics & combos	ABBOTT LABS.	40
VICOPROFEN	Narcotic analgesics & combos	ABBOTT LABS.	5
VIMPAT	Anticonvulsants / antimania medications	SCHWARZ PHARMA	384
VIOKASE	Gastric and pancreatic enzymes	AXCAN PHARMA US	518
VIVACTIL	TCAs & combos	DURAMED/BARR	76
XENADERM	Misc topical agents	HEALTHPOINT MED	388
ZARONTIN	Anticonvulsants / antimania medications	PFIZER US PHARM	2
UROCIT-K*	Urinary Agent	MISSION	4

***Added to list by electronic vote Nov 16-18, 2009**

Product Name	Subclass	Manufacturer	Number of Claims Paid
CLOUD ENHANCER	Inhaler spacers	DEY LABS.	20
ADVATE	Factor VIII	BAXTER BIOSCIEN	16
ADVATE H	Factor VIII	BAXTER BIOSCIEN	29
ADVATE L	Factor VIII	BAXTER BIOSCIEN	31
ADVATE M	Factor VIII	BAXTER BIOSCIEN	40
ADVATE SH	Factor VIII	BAXTER BIOSCIEN	13
ADVATE UH	Factor VIII	BAXTER BIOSCIEN	18
BEBULIN VH IMMUNO	Factor IX preparation	BAXTER BIOSCIEN	2
EASIVENT	Inhaler spacers	DEY LABS.	1155
FEIBA VH IMMUNO	Multiple Factors	BAXTER BIOSCIEN	17
FLUOROPLEX	Topical antineoplastic & premalignant lesion medic	ALLERGAN INC.	393
HEMOFIL M	Factor VIII	BAXTER BIOSCIEN	3
HUMATE-P	Factor VII + VWF	CSL BEHRING LLC	21
HUMATE-P	Factor VII + VWF	CSL BEHRING LLC	25
PANRETIN	Topical antineoplastic & premalignant lesion medic	EISAI INC.	2
RECOMBINATE	Factor VIII	BAXTER BIOSCIEN	59
RESTASIS	Misc ophthalmic agents	ALLERGAN INC.	38760
SUBOXONE	Narcotic analgesics & combos	RECKITT BENCKIS	590
SUBUTEX	Narcotic analgesics & combos	RECKITT BENCKIS	80
TARCEVA	Antineoplastic systemic enzyme inhibitors	GENENTECH, INC.	2068
TARGRETIN	Oral oncological agents	EISAI INC.	49
TAZORAC	Psoriasis medications	ALLERGAN INC.	9690
THIOLA	Misc urinary agents	MISSION PHARM.	25
PAREMYD*	Ophthalmic	AKORN	0

***Added to list by electronic vote Nov 16-18, 2009**

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

[illegible]	[illegible] Class	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Nov 09	Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension subclass	**Recommended for non-formulary status Nov 09** ▪ tadalafil (Adcirca)	Now BCF for ED	**N/A** ▪ vardenafil (Levitra) is BCF for erectile dysfunction (ED)	pending approval	pending approval
Aug 09 (update; original review May 05)	Phosphodiesterase Type-5 Inhibitors	**No change to non-formulary status from May 05** Automated PA requiring trial of vardenafil (Levitra) applies to new users of non-formulary PDE5s (no use of PDE5s in last 180 days)			21 Oct 09	28 Dec 09 (60 days)
Nov 09 (update; original review May 05)	MS-DMDs	**Recommended for non-formulary status Nov 09** ▪ Beta interferon 1-b injection (Extavia)	ECF	**No changes to ECF recommended Nov 09** ▪ interferon beta-1a intramuscular injection (Avonex)	pending approval (original decision 14 Jul 05)	pending approval (60 days)
Nov 09 (update; original review Nov 05; updated Nov 08 & Aug 08)	Antidepressants I	**Recommended for non-formulary status Nov 09** ▪ bupropion HBr (Aplenzin) ▪ milnacipran (Savella) **Recommended to move from non-formulary status to UF Nov 09** ▪ bupropion extended release (Wellbutrin XL)	BCF	**No changes to BCF recommended Nov 09**	pending approval	pending approval
		▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg weekly admin. (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ desvenlafaxine (Pristiq)		Currently BCF ▪ citalopram ▪ fluoxetine (excluding weekly regimen & special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	10 Feb 09; original signing date 24 Oct 08 (Pristiq) 19 Jan 06 (original review)	7 Jan 09 (Pristiq) 19 Jul 06 (180 days)
Nov 09 (update; original review Feb 07)	Narcotic Analgesics	**Recommended for non-formulary status Nov 09** ▪ tramadol ER (Ryzolt) ▪ tapendatol (Nucynta)	BCF	**No changes to BCF recommended Nov 09**	pending approval	pending approval

Meeting	Drug Class	Non-Formulary Medications	[illegible]	[illegible]	Decision Date [illegible]	Effective Date [illegible]
		▪ tramadol ER (Ultram ER)		▪ 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)
May 09 update; reviewed Aug 08; Feb 06 original review)	Overactive Bladder Drugs	**Recommended for non-formulary status Nov 09;** ▪ oxybutynin topical gel Gelnique)	BCF	**No changes to BCF recommended Nov 09**	pending approval	pending approval
		▪ fesoterodine (Toviaz) (recommended for NF status May 09) ▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)		▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	17 Aug 09 (fesoterodine) 24 Oct 08 (original review)	28 Oct 09(fesoterodine) 4 Feb 09 (original review)
Nov 09	ARB – Renin Angiotensin Antihypertensives	**No changes to NF recommended Nov 09**	BCF	**BCF change recommended Nov 09** ▪ **Delete telmisartan +/- HCTZ (Micardis, Micardis HCT) from BCF**	pending approval	pending approval
Nov 09	ARB/CCB/diuretic Renin Angiotensin Antihypertensives	**No changes to NF recommended Nov 09**		**No changes to BCF recommended Nov 09; valsartan/amlodipine/HCTZ (Exforge HCT) recommended for UF**	pending approval	pending approval

Meeting	Class Class	Non-Formulary Recommendation	BCF ECF	Formulary Recommendation	Implementation Date for Non-Formulary Recommendation	Implementation Date for Formulary Recommendation
Jun 08 (update) Original reviews ▪ ACE inhibitors: Aug 05 ▪ Misc. anti-hypertensives, including ACE/CCB combos. Feb 06 ▪ ARBs: May 07 ▪ Renin inhibitors. Aug 07 ▪ CCB/ARB combos Nov 07 update	Renin Angiotensin Antihypertensives	To remain NF ARB/CCB combos ▪ olmesartan/amlodipine (Azor) – rec NF Jun 08 ▪ valsartan amlodipine (Exforge) ACE inhibitors ▪ Moexipril +/- HCTZ (Univasc; Uniretic) ▪ perindopril (Aceon) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) (D/C'd from market) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan+/- HCTZ (Avapro, Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- (Diovan; Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) ARBs ▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	ARB/CCB combos ▪27 Aug 08 (Azor) ▪13 Feb 08 (Exforge) ▪ACE inhibitors ▪10 Feb 09 (Ramipril removed from NF and moved to UF at Nov 08 mtg) ▪13 Oct 05 ACE/CCB combos ▪26 Apr 06 ▪ARBs ▪24 July 07	ARB/CCB combos Revised implementation date: 26 Nov 08 Azor (60 days) ACE inhibitors ▪ 15 Feb 06 ACE/CCB combos ▪ 26 Jul 06 ARBs ▪ 21 Nov 07 ▪ 16 Apr 08
Aug 09 (update; original review Nov 2007)	Targeted Immunomodulatory Biologics	Recommended for non-formulary status Aug 09; no change to non-formulary status from Nov 07 ▪ golimumab injection (Simponi) ▪ certolizumab injection (Cimzia)	ECF	No changes to ECF recommendation Nov 07	21 Oct 09	28 Dec 09 (60 days)
		▪ etanercept injection (Enbrel) ▪ anakinra injection (Kineret)	ECF	▪ adalimumab injection (Humira)	13 Feb 08	18 Jun 08 (120 days)
Aug 09 (update; updated Nov 07; original review Aug 05)	Alpha Blockers for BPH	Recommended for non-formulary status Aug 09; no change to non-formulary status from Nov 07 or Aug 05 ▪ silodosin (Rapaflo)	BCF	No changes to BCF recommendation Nov 07	21 Oct 09	28 Dec 09 (60 days)
		▪ tamsulosin (Flomax) Automated PA requiring trial of alfuzosin (Uroxatral) 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)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Aug 09 (update; updated Nov 07; original review Nov 06)	ADHD / Narcolepsy Agents	No change to non-formulary status from Aug 05 or Nov 07	BCF	No changes to BCF recommendation from Aug 05	21 Oct 09	28 Dec 09
		Recommended for non-formulary status Nov 07 ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	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
May 09 (update; reviewed Jun 08; original review May 07)	Antilipidemic Agents-II	Recommended for non-formulary status May 09; no change to non-formulary status in Jun 08 ▪ fenofibrate acid (Trilipix)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		No changes to NF recommended Jun 08	BCF	Recommended for addition to BCF Jun 08 ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	24 July 07	21 Nov 07 (120 days)
May 09 (update; reviewed Nov 08) update to include nasal	Nasal Allergy Drugs	Recommended for non-formulary status May 09; no change to non-formulary status in Nov 08 ▪ azelastine with sucralose (Astepro)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09

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antihistamines ; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst)		• olopatadine (Patanase) • ciclesonide (Omnaris) • fluticasone furoate (Veramyst) • beclomethasone (Beconase AQ) • budesonide (Rhinocort Aqua) • triamcinolone (Nasacort AQ)	BCF	• Fluticasone propionate (generic Flonase) • Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
May 09 (update; reviewed May 07& Feb 05)	Proton Pump Inhibitors	Recommended for non-formulary status May 09 no change to non-formulary status in May 07 • Dexlansoprazole (Kapidex)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		• 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 09 (update; reviewed May 06)	Antiemetics	Recommended for non-formulary status May 09; no change to non-formulary status • granisetron transdermal system (Sancuso)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		• dolasetron (Anzemet)	BCF	• promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)
Feb 09	Inhaled Corticosteroids	• Beclomethasone HFA MDI (Qvar) • Budesonide MFA MDI (Pulmicort Flexhaler) • Ciclesonide HFA MDI (Alvesco) • Flunisolide CFC MDI (Aerobid, Aerobid M) • Triamcinolone CFC MDI (Azmacort)	BCF	• Fluticasone DPI (Flovent Diskus) • Fluticasone HFA MDA (Flovent HFA) • Mometasone DPI (Asmanex Twisthaler)	12 May 2009	16 Sep 09 (120 days)
Feb 09	Long-Acting Beta Agonists	• formoterol inhalation solution (Perforomist)	BCF	• Salmeterol DPI (Serevent Diskus)	12 May 2009	16 Sep 09 (120 days)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(No ICS/LABA combinations recommended for NF placement Feb 09)	BCF	• Fluticasone/salmeterol DPI (Advair Diskus) • Fluticasone/salmeterol HFA MDI (Advair HFA)	12 May 2009	16 Sep 09 (120 days)
Nov 08	Short-Acting Beta Agonists	• albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured) • metaproterenol (Alupent) CFC MDI (no longer marketed) • metaproterenol inhalation solution • pirbuterol (Maxair) MDI	BCF	• Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI • Albuterol inhalation solution; Note – does not include the following: Accuneb 0.021% [0.63 mg/mL] Accuneb 0.042% [1.25 mg/3mL] Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial]	10 Feb 09	8 Apr 09 (60 days)
Oct 08 (interim teleconference meeting) & 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	24 Oct 08;; original signing date: 27 Aug 08	26 Nov 08 (90 days)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	• OneTouch Ultra 2 strips (for OneTouch Ultra 2, Ultra Mini, and Ultra Smart meters) • TrueTrack strips (for TrueTrack meter) • Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) • Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) • Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check • Plus all other store/private label brand strips not included on the UF (see BCF/ECF column)	BCF	**Basic Core Formulary SMBGS test strips** • Precision Xtra strips (for Precision Xtra meter) **Uniform Formulary SMBGS test strips** • Accu-chek Aviva (for Accu-chek Aviva meter) • Ascensia Contour (for Ascensia Contour meter) • Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters)	24 Oct 08	17 Mar 09 (120 days)

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	Recommended for non-formulary status Aug 08 ▪ nisoldipine geomatrix (Sular geomatrix)	BCF	No changes to BCF recommended Aug 08	24 Oct 08	7 Jan 09 (60 days)
		Previously non-formulary, recommended for UF status Nov 07 ▪ amlodipine besylate (Norvasc generic)		Recommended for addition to BCF Nov 07 ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08
		To Remain Non-Formulary ▪ isradipine IR, ER (Dynacirc; Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER HS dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently BCF ▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting) ▪ nifedipine ER (Adalat CC, generics) ▪ verapamil SR ▪ diltiazem ER (Tiazac, generics)	13 Oct 05	15 Mar 06 (150 days)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (90 days)
Jun 08 (update; reviewed Nov 07)	Adrenergic Blocking Agents	Recommended for non-formulary status Jun 08 ▪ nebivolol (Bystolic)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)

		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	No changes to BCF rec Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF • zileuton (Zyflo)		Currently BCF • montelukast (Singulair)	17 Oct 07	16 Jan 08 (90 days)
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	No change to BCF recommended Nov 07	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 / noreth. 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
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)

[illegible]	Drug Class	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
May 07	5-Alpha Reductase Inhibitors	• dutasteride (Avodart)	BCF	• finasteride	24 July 07	24 Oct 07 (90 days)
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	Monoamine Oxidase Inhibitors	• selegiline transdermal patch (Emsam)	ECF	• phenelzine (Nardil)	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	-
Nov 06 (update; reviewed Nov 06)	Dermatologic Topical Antifungals*	Recommended for non-formulary status Nov 06: 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)	BCF	No change to BCF recommended Nov 06	14 Jul 05	17 Aug 05 (30 days)
		• econazole • ciclopirox • oxiconazole (Oxistat) • sertaconazole (Ertaczo) • sulconazole (Exelderm)		• nystatin • clotrimazole	17 Jan 07	18 Mar 07 (60 days)

[illegible]	[illegible] Class	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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)
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)

BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary
CFC = chlorofluorocarbon; ER = extended release; HFA = hydrofluoroalkane; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle;
AD-1s: Antidepressant-1 Drugs; ADHD = Attention Deficit Hyperactivity Disorder; ARBs = Angiotensin Receptor Blockers; ACE Inhibitors = Angiotensin Converting Enzyme Inhibitors; BPH = Benign Prostatic Hyperplasia; CCBs = Calcium Channel Blockers; ED = erectile dysfunction; EE = ethinyl estradiol; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HBr = hydrobromide; HCTZ = hydrochlorothiazide; LIP-1 = Antihyperlipidemic-1 Drugs; LIP-2 = Antihyperlipidemic-2 Drugs; MDIs = metered dose inhalers; MOAIs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NADs = Nasal Allergy Drugs; OABs = Overactive Bladder Medications; PAH = pulmonary arterial hypertension; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAs = Renin Angiotensin Antihypertensives Drugs; SABAs = Short-Acting Beta Agonists; SMBGS: Self-Monitoring Blood Glucose Systems; TIBs = Targeted Immunomodulatory Biologics; TZDs= Thiazolidinediones
*The Dermatologic Topical Antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])

Appendix F — Table of Abbreviations

6MWD	6-minute walking distance
ACE	angiotensin converting enzyme
AD-1	antidepressant-1 drug class
ARB	angiotensin receptor blocker
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
CCB	calcium channel blocker
CEA	Cost-effectiveness analysis
CFR	Code of Federal Regulations
CMA	cost minimization analysis
DHP	dihydropyridine CCB
DoD	Department of Defense
ECF	Extended Core Formulary
ED	erectile dysfunction
ER	extended release
ESI	Express Scripts, Inc
FCP	Federal Ceiling Price
FDA	Food and Drug Administration
FSS	Federal Supply Schedule Price
FY	fiscal year
HA	Health Affairs
HBr	hydrobromide
HCl	hydrochloride
HCTZ	hydrochlorothiazide
IR	immediate release
M2	MHS Data mart
MHS	Military Health System
MN	medical necessity
MS-DMDs	multiple sclerosis disease modulating drugs class
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
OAB	overactive bladder drug class
OMB	Office of Management and Budget
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAH	pulmonary arterial hypertension
PDE-5	phosphodiesterase-type 5 inhibitor drug class
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
POS	point of service
QL	quantity limit
RAAs	renin-angiotensin antihypertensive drug class
SNRI	serotonin norepinephrine reuptake inhibitor
SSRI	selective serotonin reuptake inhibitor
SR	sustained release
TCA	tricyclic antidepressant
TMA	TRICARE Management Activity
TMOP	TRICARE Mail Order Pharmacy
TPHARM	TRICARE Pharmacy Benefit Program
TRRx	TRICARE Retail Pharmacy Network
UF VARR	Uniform Formulary Voluntary Agreement for Retail Refunds

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
August 2009

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 12, 2009 and August 13, 2009 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. Revisions to the minutes — Revisions to the May 2009 minutes will be reviewed at the November 2009 DoD P&T Committee meeting.
2. Approval of May minutes — The minutes from the DoD P&T Committee meeting held May 13, 2009 are still undergoing review.

III. REVIEW OF RECENTLY FDA-APPROVED AGENTS

A. Targeted Immunomodulatory Biologics (TIBs) — Golimumab injection (Simponi)

Relative Clinical Effectiveness — Golimumab injection (Simponi) is a humanized monoclonal antibody that inhibits biological activity of tumor necrosis factor alpha (TNFα). Golimumab injection is classified in the Targeted Immunomodulatory Biologic (TIB) drug class, which was reviewed for Uniform Formulary (UF) placement in November 2007.

1. *Background* — The clinical evaluation for golimumab included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). Golimumab is administered subcutaneously (SQ) once a month. It is FDA-approved for the treatment of moderate to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX), moderate to severely active psoriatic arthritis (PsA) alone or in combination with MTX, and active ankylosing spondylitis (AS) in adults. The other injectable TNFα inhibitors with multiple FDA-approved indications for use include adalimumab (Humira), etanercept (Enbrel), and certolizumab (Cimzia).

2. *Efficacy and Safety* — Golimumab was superior to placebo in the treatment of RA, PsA, and AS in the pivotal phase III trials used to obtain FDA approval. There are no direct comparative clinical trials between golimumab and other TNFα inhibitors. There is insufficient evidence to

determine whether treatment with golimumab would result in greater clinical response than other TNF inhibitors. The safety profile of golimumab reflects that of the other anti-TNF agents currently on the market.

3. *Other Factors* — The Pharmacy Outcomes Research Team (PORT) reported results of an analysis evaluating patterns of use of adalimumab (Humira) and etanercept (Enbrel) among 6,257 new Military Health System (MHS) users. Overall, persistence at ~3 years ranged from 35% to 57%. Switching between the two drugs occurred relatively rarely, as 15% (938/6,257) of patients switched once, and 2% subsequently switched back to the original agent. Most patients who were on MTX prior to starting adalimumab or etanercept continued to receive MTX (2,327/3,027 = 77%), but it was relatively uncommon for MTX to be started with or after the TIB for patients who were MTX-naive (642/3,230 = 20%). Overall, about 5% of patients were considered to be potentially "dissatisfied" with the available multi-indication TIBs, based on switching between etanercept and adalimumab, followed by discontinuation. Based on these data, the P&T Committee agreed that clinical coverage in the TIB class appears adequate overall as relatively few patients (17%) switch between the two multi-use TIBs in the first ~3 years of treatment, and only about 5% discontinue treatment after trying both.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) that although golimumab injection (Simponi) requires less frequent administration than the other multi-indication TIBs, it did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other TIBs currently included on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the multi-indication agents in the TIB 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 used to evaluate the cost-effectiveness of golimumab.

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (12 for, 0 opposed, 0 abstained, 1 absent) golimumab injection (Simponi) was not cost effective compared to

other agents currently on the UF. Results of the CMA confirmed that adalimumab remains the most cost-effective TIB agent available on the UF.

a) ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness, relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (12 for, 0 opposed, 0 abstained, 1 absent) golimumab injection (Simponi) be designated non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the determination that adalimumab (Humira) remains the most cost effective multi-indication TIB on the UF compared to golimumab (Simponi).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

b) ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** — Based on the clinical evaluation of golimumab injection (Simponi) and the conditions for establishing medical necessity (MN) of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (12 for, 0 opposed, 0 abstained, 1 absent) MN criteria for golimumab injection (Simponi). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

c) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee voted (11 for, 0 opposed, 1 abstained, 1 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at Military Treatment Facilities (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

d) ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA*** — Currently PA requirements apply to etanercept (Enbrel), adalimumab (Humira) and the other TIBs. The P&T Committee agreed that the following PA criteria should apply to golimumab injection, consistent with the FDA-approved labeling and PA requirements for the other TIBs.

(1) Coverage would be approved for the treatment of adult patients with moderate to severely active RA in combination with MTX, moderate to severely active PsA alone or in combination with MTX, and active AS in adults.

(2) Coverage would not be provided for concomitant use with abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), or rituximab (Rituxan).

The P&T Committee voted (12 for, 0 opposed, 0 abstained, 1 absent) to recommend the PA criteria outlined above. See Appendix C for full PA criteria.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

e) ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) IMPLEMENTATION PLAN*** — The P&T Committee voted (11 for, 0 opposed, 1 abstained, 1 absent) to recommend the effective date for the golimumab injection (Simponi) be timed to coincide with that established for the UF decision for golimumab injection (Simponi).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

f) ***COMMITTEE ACTION: QUANTITY LIMITS*** — Quantity limits (QLs) or days supply limits currently apply to etanercept (Enbrel) and adalimumab (Humira) as outlined in Appendix C, and the other TIBs. The P&T Committee voted (12 for, 0 opposed, 0 abstained, 1 absent) to recommend QLs for golimumab injection (Simponi) consistent with FDA-approved labeling and the requirements for the other TIBs. See Appendix C for full recommended QLs.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Targeted Immunomodulatory Biologics (TIBs) — Certolizumab Injection (Cimzia)

Relative Clinical Effectiveness — Certolizumab injection (Cimzia) is a TNFα inhibitor that is conjugated to polyethylene glycol to increase the duration of action. Certolizumab injection is classified in the Targeted Immunomodulatory Biologic (TIB) drug class that was reviewed for Uniform Formulary (UF) placement in November 2007.

1. *Background* — The certolizumab (Cimzia) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). Certolizumab (Cimzia) is available as a lyophilized powder for reconstitution and a solution for SQ injection. It is dosed once monthly for Crohn's disease and every two weeks (with the option of once monthly dosing) for RA. Certolizumab (Cimzia) is FDA-approved for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severely active disease refractory to conventional therapy. It is also approved for the treatment of moderate to severely active RA in adults.

2. *Efficacy and Safety* — There are no direct comparative clinical trials between certolizumab and other TNF inhibitors. Phase III trials demonstrated that certolizumab (Cimzia) was more effective than placebo in achieving and maintaining clinical response in Crohn's disease and RA, and was also more effective than placebo in delaying the progression of structural damage in patients with active RA. There is insufficient evidence to determine whether certolizumab would result in greater response than other anti-TNF agents, and pegylation did not appear to confer added benefits in efficacy or toxicity profile. In general, the safety profile of certolizumab is similar to that of the other TNF inhibitors.

3. *Other Factors* — Based on the Pharmacy Outcomes Research Team (PORT) analysis previously discussed, the P&T Committee agreed that clinical coverage in the TIB class appears adequate overall as relatively few patients (17%) switch between the two multi-use TIBs in the first ~3 years of treatment, and only about 5% discontinue treatment after trying both.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 1 absent) that although certolizumab injection (Cimzia) has the potential for less frequent administration than adalimumab (Humira) and etanercept (Enbrel), it did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other TIBs currently included on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the multi-indication agents in the TIBs 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 used to evaluate the cost-effectiveness of certolizumab (Cimzia).

Relative Cost-Effectiveness Conclusion — The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 1 absent) certolizumab injection (Cimzia) is not cost effective relative to other formulary TIBs agents.

a) ***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 (12 for, 0 opposed, 0 abstained, 1 absent) that certolizumab

injection (Cimzia) be designated non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the determination that adalimumab (Humira) remains the most cost effective multi-indication TIB on the UF compared to certolizumab injection (Cimzia).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

b) ***COMMITTEE ACTION: MN CRITERIA*** — Based on the clinical evaluation of certolizumab (Cimzia) and the conditions for establishing MN of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (12 for, 0 opposed, 0 abstained, 1 absent) MN criteria for certolizumab injection (Cimzia). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

c) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee voted (12 for, 0 opposed, 0 abstained, 1 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at Military Treatment Facilities (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

d) ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA*** — Currently PA requirements apply to etanercept (Enbrel), adalimumab (Humira) and the other TIBs. The P&T Committee agreed that the following PA criteria should apply to certolizumab injection (Cimzia), consistent with the FDA-approved labeling and PA requirements for the other TIBs.

(1) Coverage would be approved for reducing signs and symptoms of Crohn's disease, maintaining clinical response in adult patients with moderate to severely active disease refractory to conventional therapy, and for the treatment of moderate to severely active RA in adults.

(2) Coverage would not be provided for concomitant use with abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), or rituximab (Rituxan).

The P&T Committee voted (11 for, 0 opposed, 1 abstained, 1 absent) to recommend the PA criteria outlined above. See Appendix C for full PA criteria.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

e) ***COMMITTEE ACTION: PA IMPLEMENTATION PLAN*** — The P&T Committee voted (12 for, 0 opposed, 0 abstained, 1 absent) to recommend the effective date for the certolizumab injection (Cimzia) be timed to coincide with that established for the UF decision for certolizumab Cimzia).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

f) ***COMMITTEE ACTION: QUANTITY LIMITS*** —The P&T Committee voted (12 for, 0 opposed, 0 abstained, 1 absent) to recommend QLs for certolizumab injection (Cimzia) consistent with FDA-approved labeling and the requirements for the other TIBs. See Appendix C for full recommended QLs.

ActingDirector, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

C. Alpha Blockers for Benign Prostatic Hyperplasia (BPH) — Silodosin capsules (Rapaflo)

Relative Clinical Effectiveness — Silodosin (Rapaflo) is an alpha blocker FDA-approved for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). The alpha blockers for BPH were last reviewed for UF placement in November 2007. Silodosin (Rapaflo) is similar to tamsulosin (Flomax); it is a highly selective antagonist of α1A-adrenoceptors (α1A-AR) in the prostate. Alfuzosin (Uroxatral) is the third uroselective alpha blocker for BPH in the class.

The silodosin capsules (Rapaflo) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no direct comparative clinical trials between silodosin and the other alpha blockers for BPH, and no trials are available that evaluate outcomes other than changes in signs and symptoms of BPH. The clinical trials used to obtain FDA approval reported silodosin is effective at reducing International Prostate Symptom Score (IPSS) (which signifies reduction in symptoms) and increasing maximum urinary flow rate (Qmax) in patients with BPH. Improvements in the IPSS score and Qmax are comparable to the changes seen with the other alpha blockers. The safety profile of silodosin (Rapaflo) appears to be comparable to other uroselective agents.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) silodosin capsules (Rapaflo) do not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other alpha blockers for BPH currently included on the UF.

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the Alpha Blocker 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). Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of silodosin capsules (Rapaflo) relative to other UF alpha blocking agents. Results from the CMA showed the projected weighted average cost per day for silodosin (Rapaflo) is higher than alfuzosin (Uroxatral). The CMA also revealed the projected weighted average cost per day for silodosin (Rapaflo) is lower than the non-formulary alpha blocking agent, tamsulosin (Flomax). Alfuzosin (Uroxatral) remains the most cost effective alpha blocking agents on the UF.

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that silodosin capsules (Rapaflo) are not cost effective relative to other alpha blockers for BPH included on the UF. Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

1. Results of the CMA revealed that silodosin (Rapaflo) was more cost effective than tamsulosin (Flomax) and was not cost-effective compared to alfuzosin (Uroxatral).

2. Results of the CMA confirmed that alfuzosin (Uroxatral) remains the most cost-effective alpha blocking agent available on the UF.

a) ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness, relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent) that silodosin capsules (Rapaflo) be designated non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion and the

determination that alfuzosin (Uroxatral) remains the most cost effective uroselective alpha blocker for BPH on the UF compared to silodosin capsules (Rapaflo).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

b) ***COMMITTEE ACTION: MN CRITERIA*** — Based on the clinical evaluation of silodosin and the conditions for establishing MN of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent) MN criteria for silodosin capsules (Rapaflo) when use of formulary alternatives is contraindicated, when the patient has experienced significant adverse effects from formulary alternatives, when formulary agents have resulted in therapeutic failure, or when the patient requires a drug that can be crushed or sprinkled on food. (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

c) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at Military Treatment Facilities (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

d) ***COMMITTEE ACTION: PA CRITERIA*** —An automated prior authorization (APR) or *step therapy* is currently in effect and requires use of UF alfuzosin (Uroxatral) before other non-formulary alpha blockers for BPH, unless there is therapeutic failure, intolerance, or hypersensitivity. The Committee agreed that the following PA criteria should apply to silodosin capsules (Rapaflo). Coverage would be approved if the patient met any of the following criteria:

(1) Automated PA criteria:

(a) The patient has received a prescription for either silodosin (Rapaflo) or alfuzosin (Uroxatral) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

(2) PA criteria if automated criteria are not met:

(a) The patient has tried alfuzosin (Uroxatral) and had an inadequate response or was unable to tolerate treatment due to adverse effects.

(b) Treatment with alfuzosin (Uroxatral) is contraindicated.

(c) The patient requires an alpha blocker that can be crushed and sprinkled on food.

e) ***COMMITTEE ACTION:*** The P&T Committee voted (12 for, 0 opposed, 1 abstained, 0 absent) to recommend the PA criteria outlined above.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

f) ***COMMITTEE ACTION: PA IMPLEMENTATION PLAN*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend the effective date for the silodosin (Rapaflo) PA be timed to coincide with that established for the UF decision for silodosin.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

D. Narcolepsy/Attention Deficit Hyperactivity Disorder (ADHD) — Armodafinil tablets (Nuvigil)

Relative Clinical Effectiveness — Armodafinil (Nuvigil) is a non-amphetamine wakefulness promoting agent. It is the single R-enantiomer of modafinil (Provigil), which is a racemic mixture. The R-enantiomer has been shown to have a longer half-life than its S-counterpart; however, the half-lives of armodafinil and modafinil are similar. The subclass of narcolepsy agents was last reviewed in November 2006 as part of the ADHD and narcolepsy drug class. The other narcolepsy agents on the uniform formulary are modafinil (Provigil) and sodium oxybate.

Armodafinil (Nuvigil) is FDA-approved for the treatment of excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder. These are the same FDA indications as the current UF agent modafinil (Provigil). Generic formulations of modafinil (Provigil) are expected in mid-2010.

The armodafinil (Nuvigil) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no head-to-head trials comparing armodafinil (Nuvigil) to modafinil (Provigil) and there is no conclusive data to support longer-lasting effects of armodafinil (Nuvigil) as compared to modafinil (Provigil). After review of the clinical literature, armodafinil (Nuvigil) does not have compelling clinical advantages over existing narcolepsy agents on the UF. There is currently insufficient data to conclude that armodafinil (Nuvigil) offers improved efficacy, safety, or tolerability compared to modafinil (Provigil).

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (12 for, 0 opposed, 1 abstained, 0 absent) there is currently insufficient data to conclude that armodafinil (Nuvigil) offers improved efficacy, safety, or tolerability compared to the UF product modafinil (Provigil).

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the Narcolepsy/ADHD 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 used to evaluate the cost-effectiveness of armodafinil tablets (Nuvigil).

Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (10 for, 2 opposed, 0 abstained, 1 absent) that armodafinil tablets (Nuvigil) are cost effective relative to modafinil (Provigil). Results of the CMA revealed that armodafinil was more cost effective than modafinil, the only UF agent.

a) ***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 (12 for, 0 opposed, 1 abstained, 0 absent) that armodafinil tablets (Nuvigil) be designated formulary on the UF.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

b) ***COMMITTEE ACTION: BCF RECOMMENDATION*** — Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 0 opposed, 0 abstained, and 0 absent) to recommend armodafinil (Nuvigil) not be added to the BCF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Allen P. Dalbey

c) ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA*** — Taking into consideration the clinical review, the P&T Committee recommended the following PA criteria should apply to armodafinil (Nuvigil). Coverage would be approved if a patient met any of the following criteria and would expire in 1 year:

(1) Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing;

(2) Obstructive sleep apnea associated with persistent and excessive daytime sleepiness (CPAP treatment adequately titrated and patient is compliant with treatment); and

(3) Nightshift worker with diagnosis of shift-work sleep disorder associated with excessive sleepiness.

d) ***COMMITTEE ACTION:*** The P&T Committee voted (12 for, 1 opposed, 0 abstained, 0 absent) to recommend PA criteria for armodafinil (Nuvigil) as outlined above.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Allen P. Dalbey

e) ***COMMITTEE ACTION: PA IMPLEMENTATION PLAN*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

IV. UNIFORM FORMULARY DRUG CLASS REVIEWS

A. Phosphodiesterase-Type 5 (PDE-5) Inhibitors

Relative Clinical Effectiveness — The P&T Committee evaluated the clinical effectiveness of the Phosphodiesterase Type-5 (PDE-5) inhibitors for the treatment of erectile dysfunction (ED). The drug class was previously reviewed for UF placement in May 2005. The class is comprised of two subclasses, PDE-5 inhibitors for ED; sildenafil (Viagra), tadalafil (Cialis), vardenafil (Levitra); and those for pulmonary artery hypertension (PAH): sildenafil (Revatio) and tadalafil (Adcirca). The PDE-5 inhibitors for PAH will be evaluated at a future P&T Committee meeting.

Information regarding the safety, effectiveness, and clinical outcomes of the PDE-5s for ED subclass was considered. The clinical review included, but was not limited to, the requirements stated in the UF Rule, 32 CFR 199.21(e)(1).

MHS expenditures for the PDE-5 inhibitors exceeded $54M in FY 2008 (MTF: $9.75M; TRICARE Retail Network [TRRx]: $36M; and TRICARE Mail Order Pharmacy [TMOP]: $9M). At the MTFs, vardenafil (Levitra) designated an Extended Core Formulary agent, is the highest utilized PDE-5 inhibitor, while sildenafil (Viagra) is the highest utilized drug at the TRRx.

Relative Clinical Effectiveness Conclusion — The P&T Committee recommended the following clinical effectiveness conclusions regarding PDE-5 inhibitors:

1. With regard to efficacy, the following conclusions were made:
   a) ED: Sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra) are FDA-approved for the treatment of ED. There are no head-to-head trials comparing the three PDE-5 inhibitors.
      (1) There is insufficient evidence to conclude that there are clinically relevant differences in efficacy of PDE-5 inhibitors for ED. Although all PDE-5s are clinically superior to placebo, the variability in study design, demographics, and outcome measures

precludes the ability to designate one PDE-5 as clinically superior.

(2) Based on meta-analyses by Agency for Healthcare Research and Quality, the Cochrane reviewers, and BioMed Central, indirect comparisons suggest that there are similar improvements between the three PDE-5 inhibitors in endpoints or International Index of Erectile Function (IIEF) domain change score for erectile function, the percentage of patients responding "yes" on the Global Assessment Questionnaire, question one, the percentage of patients with improved erections, and numbers needed to treat for these endpoints.

(3) One Cochrane analysis found that PDE-5 inhibitors improve erections in diabetic patients.

(4) There is insufficient evidence to conclude that daily therapy for ED is superior to on-demand therapy.

b) PAH: Sildenafil (under the trade name Revatio), and tadalafil (under the trade name Adcirca) both have FDA-approved indications for treating PAH.

c) Preservation/restoration of erectile function after prostatectomy: The P&T Committee agreed that the evidence, based on positive results from published clinical trials, was supportable for daily use of the PDE-5 inhibitors for this off-label indication.

d) Raynaud's Phenomenon: Although results are conflicting and larger, longer-term trials are needed, benefits have been shown with daily use of PDE-5 inhibitors in terms of improvements in digital blood flow in patients with Raynaud's disease. The P&T Committee agreed that this was a supportable off-label use.

e) Other off-label uses: The P&T Committee agreed that the current published literature is insufficient to support use of PDE-5 inhibitors for female sexual dysfunction, hypertension, esophageal motility disorders, ocular blood flow disorders, Eisenmenger's Syndrome, premature ejaculation, recurrent ischemic priapism, and lower urinary tract symptoms due to benign prostatic hypertrophy (BPH).

2. With regards to safety and tolerability, the P&T Committee agreed that there is insufficient evidence to conclude that there are clinically relevant differences in safety between PDE-5s for ED. The product labeling for the three drugs is similar with regard to contraindications, precautions, and warnings. The causal relationship of PDE-5 inhibitors to non-arteritic anterior ischemic optic neuropathy or hearing loss are uncertain at this time.

3. With regards to other factors between the PDE-5s, results from a questionnaire sent to a convenience sample of MTF providers found that about 34% of the respondents ranked sildenafil (Viagra) as their first choice of PDE-5 for treating ED; over 25% stated no preference; 22% ranked tadalafil (Cialis) as their first choice; and 19% ranked vardenafil (Levitra) as their first choice. Approximately 82% of providers felt that on-demand therapy was sufficient to meet the needs of their patients, and approximately 73% of respondents did not feel that it was important to have a PDE-5 inhibitor approved for daily therapy available on the UF. About half of respondents (49%) indicated that the current quantity limit of PDE-5 for ED (6 tablets per month) was appropriate. However, for providers who felt the quantity limit should be increased, the median and mode response was 10 tablets/30 days. Currently, PDE-5 inhibitors do not require prior authorization (PA) for organic ED in men over 50 years old. Responses showed a majority (63%) of providers felt that the current age limit is not appropriate. Over half of respondents (55%) indicated a new automated prior authorization age limit of 40 years was appropriate.

   (1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to accept the clinical effectiveness conclusions stated above.

Relative Cost Effectiveness — In considering the relative cost-effectiveness of pharmaceutical agents in the PDE-5 for ED subclass, 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 subclass. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost effectiveness of the PDE-5 agents.

Relative Cost Effectiveness Conclusion — Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) the following. Results from the CMA of PDE-5s for ED agents revealed that vardenafil (Levitra) was the most cost effective PDE-5 agent. The potential impact of scenarios with selected PDE-5 was evaluated with a BIA. Results from the BIA of PDE-5s for ED revealed that placing vardenafil (Levitra) on the UF in conjunction with a PA requiring a trial of Levitra for new patients was the most cost effective scenario overall. Lowering the age limit for automatic PA approval of the treatment of typical organic erectile dysfunction in

males from 50 to 40 years old would add about 3.7% to the cost of each scenario reviewed. Increasing the quantity limits would increase the cost.

(2) ***COMMITTEE ACTION:*** The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusions stated above.

(3) ***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, 0 abstained, 0 absent):

(a) Vardenafil (Levitra 2.5 mg, 5 mg, 10 mg, and 20 mg) be classified as formulary on the UF.

(b) Sildenafil (Viagra 25 mg, 50 mg, and 100 mg) and tadalafil (Cialis 2.5 mg, 5 mg, 10 mg, and 20 mg) be designated as nonformulary under the UF, based on cost effectiveness.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

(5) ***COMMITTEE ACTION: UNIFORM FORMULARY (UF) IMPLEMENTATION PERIOD*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

(6) ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) CRITERIA*** — The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 0 absent, with the exceptions noted below) the following PA criteria should apply to PDE-5 inhibitors other than vardenafil (Levitra). Coverage would be approved if a patient met any of the following criteria, and would expire in one year:

(a) Automated PA criteria:
- (i) The patient has received a prescription for sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.
- (ii) The patient is a male, aged 40 years or older (12 for, 1 opposed, 0 abstained, 0 absent)

(b) PA if automated criteria are not met:
- (i) The patient has tried vardenafil (Levitra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects.
- (ii) Treatment with vardenafil (Levitra) is contraindicated.
- (iii) Sildenafil (Viagra or Revatio) or tadalafil (Cialis or Adcirca) is for treatment of Pulmonary Artery Hypertension (PAH).

(iv) Use is for preservation/restoration of erectile function after prostatectomy.

(v) Use is for Raynaud's Phenomenon (12 for, 1 opposed, 0 abstained, 0 absent).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

(7) ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) IMPLEMENTATION PLAN*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend an implementation plan for the PA be timed to coincide with that established for the UF decision for sildenafil and tadalafil.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

(8) ***COMMITTEE ACTION: QUANTITY LIMITS*** — The P&T Committee considered the QL for the treatment of ED as well as QL for other indications. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 0 opposed, 0 abstained, and 0 absent) to recommend maintaining the existing QL for the treatment of typical organic ED of a collective 18 tablets/90 days in the TMOP and 6 tablets/30 days in the TRRx and to accommodate daily therapy for PAH, preservation or restoration of erectile function after prostatectomy, and Raynaud's Phenomenon by setting QLs at a 90-day supply in the TMOP and a 30-day supply in the TRRx.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

(9) ***COMMITTEE ACTION: BASIC CORE FORMULARY DECISION*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend that vardenafil (Levitra) 2.5 mg, 5 mg, 10 mg, and 20 mg tablets be designated as BCF immediately on signing of the August 2009 P&T Committee minutes by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

V. UTILIZATION MANAGEMENT — PRIOR AUTHORIZATIONS (PA) / Quantity Limits (QL) / MEDICAL NECESSITY (MN)

A. Modafinil (Provigil) — Prior Authorization. New data published since the original Narcolepsy drug class review in November 2006 was evaluated to determine if the modafinil (Provigil) PA required updating. The P&T Committee agreed the evidence for using modafinil (Provigil) for sleepiness associated with Parkinson's disease was not supportable. Recommendations for treating fatigue associated with traumatic brain injury (TBI) were mentioned in a recent VA/DoD guideline, and this usage was deemed supportable by the P&T Committee. In the one published, double-blinded, randomized, controlled trial conducted in patients with varying severities of TBI, there was no difference in fatigue or sleepiness associated with TBI between the modafinil groups and placebo. The VA/DoD guidelines pertaining to mild TBI state there is no evidence regarding use of medications in patients recovering from mild TBI and recommend avoiding medications; however, modafinil would be a first-line agent for fatigue based on expert opinion, if medications were initiated. The P&T Committee also recommended updating the criteria used for objectively diagnosing narcolepsy via polysomnogram or mean sleep latency testing (MSLT).

1. ***COMMITTEE ACTION — PA CRITERIA:*** The Committee voted (11 for, 2 opposed, 0 abstained, 0 absent) the following PA criteria should apply to modafinil (Provigil). Coverage would be approved if a patient met any of the following criteria and would expire in 1 year.

a) Narcolepsy associated with persistent and excessive daytime sleepiness as diagnosed by polysomnogram or MSLT objective testing;

b) Obstructive sleep apnea associated with persistent and excessive daytime sleepiness AND continuous positive airway pressure (CPAP) treatment adequately titrated and patient compliant with treatment;

c) Nightshift worker with diagnosis of shift work sleep disorder associated with excessive sleepiness;

d) Multiple sclerosis with excessive fatigue and secondary causes have been addressed;

e) Myotonic dystrophy associated with excessive fatigue;

f) A diagnosis of depression AND primary antidepressant therapy (defined as 4–6 week trial of at least one antidepressant agent) has failed AND the use of other stimulant augmentation (such as methylphenidate products) is contraindicated due to adverse effects, previous failure, or hypersensitivity;

g) Idiopathic hypersomnia diagnosed by a sleep specialist;

h) Fatigue associated with mild traumatic brain injury.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

2. ***COMMITTEE ACTION — PA IMPLEMENTATION PLAN:*** The Committee voted (12 for, 0 opposed, 1 abstained, 0 absent) to recommend an implementation date effective date of the first Wednesday one week after the minutes are signed. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

B. Tramadol extended release (Ryzolt) — QL: A new extended-release formulation of tramadol extended release (ER) (Ryzolt) has been marketed. Tramadol ER will be reviewed for UF status at an upcoming P&T Committee meeting as a newly-approved drug. QLs are currently in place for both immediate and extended-release tramadol (Ultram, Ultram ER, generics), which are consistent with the product labeling.

1. ***COMMITTEE ACTION — QL:*** The Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend QLs for Ryzolt as outlined in Appendix D.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. QL Updates: In anticipation of the forthcoming TPHARM contract implementation, the P&T Committee updated the quantity limits (QLs) for several drugs: mometasone dry powder inhaler (Asmanex Twisthaler), fluticasone dry powder inhaler (Flovent diskus), fluoxetine for weekly dosing (Prozac weekly), azelastine (Astelin), and azelastine with sucrose nasal inhalers (Astepro), which is consistent with QLs for other drugs in the class, and approved product dosing. See Appendix D.

1. ***COMMITTEE ACTION:*** The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend the QLs for mometasone dry powder inhaler (Asmanex Twisthaler), fluticasone dry powder inhaler (Flovent Diskus), fluoxetine for weekly dosing (Prozac Weekly), azelastine (Astelin) and azelastine with sucrose (Astepro) nasal inhalers, as outlined in Appendix D.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) SECTION 703 — INCLUSION OF TRICARE RETAIL PHARMACY PROGRAM IN FEDERAL PROCUREMENT OF PHARMACEUTICALS UPDATE

The committee reviewed drugs that were not included on a Department of Defense Retail Refund Pricing Agreement; these drugs are not compliant with FY2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated non-formulary under the Uniform Formulary and will require a pre-authorization prior to use in the retail point of service and medical necessity in military treatment facilities. These non-formulary drugs will remain available in the mail order point of service (POS) without pre-authorization. Pre-authorization will be determined at the November 2009 DoD P&T Committee meeting. Drugs with and without pricing agreements were systematically classified based along therapeutic and pharmacologic lines. The classification system was based on the American Hospital Formulary System Classification and First Data Bank classification. See Appendix E for the full list of affected medications.

A. ***COMMITTEE ACTION — DRUGS RETAINING UF STATUS:*** The P&T Committee voted (11 for, 1 against, 0 abstained, 1 absent) to recommend the drugs listed in Appendix E, Section A to retain formulary status on the Uniform Formulary.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

B. ***COMMITTEE ACTION — DRUGS DESIGNATED OR RETAINED AS NON-FORMULARY:*** The P&T Committee voted (11 for, 1 against, 0 abstained, 1 absent) to recommend the drugs listed in Appendix E, Section B to retain non-formulary status or be designated non-formulary on the Uniform Formulary.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

C. ***COMMITTEE ACTION — IMPLEMENTATION DATE FOR PRE-AUTHORIZATION:*** The P&T Committee voted (13 for, 0 against, 0 abstained, 0 absent) to recommend the implementation date will not be prior to 1 January 2010 and not later than 180 days after the minutes of this meeting are signed. Formulary status of a drug in these lists will revert back to previous formulary status if Price Agreements are received prior to October 14, 2009.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

D. ***COMMITTEE ACTION — TRANSITION DATE AT THE MTF POS:*** The P&T Committee voted (13 for, 0 against, 0 abstained, 0 absent) to recommend a transition period at the MTF POS as ending no later than 1 January 2011.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VII. ADJOURNMENT

The meeting adjourned at 1600 hours on August 12, 2009, and at 1300 hours on August 13, 2009. The next meeting will be in November 2009.

Appendix A — Attendance

Appendix B — Table of Medical Necessity Criteria

Appendix C — Table of Prior Authorization and Quantity Limits for the TIBs

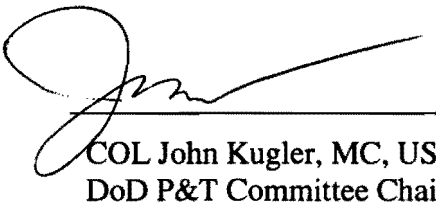
Appendix D — Table of Quantity Limits

Appendix E — National Defense Authorization Act (NDAA) Section 703 – Affected Medications

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

Appendix G — Table of Abbreviations

SUBMITTED BY:



COL JAMES CLLZY for

COL John Kugler, MC, USA
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Ellen P. Embrey
Acting Director

10/21/09
(Date)

Appendix A – Attendance

Voting Members Present	
COL John Kugler, MC	DoD P&T Committee Chair
LTC Stacia Spridgen, MSC	Director DoD Pharmacoeconomic Center (Recorder)
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician, Alternate
COL Peter Bulatao *for Col Carole Labadie, MSC*	Army, Pharmacy Officer, Alternate
CDR Phil Blaine *for CAPT Stephanie Simon, MSC*	Navy, Pharmacy Officer
CAPT Vernon Lew	Coast Guard, Pharmacy Officer
COL Ted Cieslak, MC	Army, Physician at Large
LTC Bruce Lovins	Army, Family Practice Physician, Alternate
CDR David Tanen, MC	Navy, Physician at Large
Col Everett McAllister BSC	Chief, Pharmaceutical Operations Directorate
Lt Col Mike Spilker	Consultant to the AF/SG
Lt Col Brian Crownover, MC	Air Force, Physician at Large
Major Jeremy King, MC	Air Force, OB/GYN Physician
Voting Members Absent	
COL Carole Labadie, MS	Army, Pharmacy Officer
CAPT Stephanie Simon, MSC	Navy Pharmacy Officer
Maj William Hannah	Air Force, Internal Medicine
Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
COL Kent Maneval, MS	Defense Medical Standardization Board
CDR James Ellzy	DoD P&T Vice Chairman
Ms. Carol Cooper	Deputy General Counsel, TMA
Mr. Jose Ramos *for Maj Peter Trang*	Defense Supply Center Philadelphia
Nonvoting Members Absent	
Mr. William Davies	TRRx/TMOP COR
Guests	
LCDR Joe Bryant	Indian Health Service
Others Present	
RADM Thomas McGinnis via VTC	TMA Pharmacy Operations Directorate
CDR Matthew Carlberg	DoD Pharmacoeconomic Center
Lt Col James McCrary, MC	DoD Pharmacoeconomic Center
Lt Col Cynthia Lee, BSC	DoD Pharmacoeconomic Center

Appendix A – Attendance – (continued)

LCDR Joe Lawrence	DoD Pharmacoeconomic Center
Maj Joshua Devine, BSC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez	DoD Pharmacoeconomic Center
CAPT Brian Haney	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. Jeremy Briggs	DoD Pharmacoeconomic Center
Mr. 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
Dr. Roger Potyk	DoD Pharmacy Outcomes Research Team contractor
Dr. Dean Valibhai	DoD Pharmacy Operations Center contractor
Dr. Elaine Furmaga	VA PBM
Mr. John Casciotti via teleconference	Office of General Counsel, TMA
Mr. David Hurt	Assistant General Counsel, TMA
Ms. Lisa McNair	DoD Pharmacy Operations Directorate

Appendix B — Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Sildenafil (Viagra) Tadalafil (Cialis) **Phosphodiesterase-5 (PDE-5) Inhibitors**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives. • Formulary agents have resulted in therapeutic failure • There is no formulary alternative available for patients with pulmonary arterial hypertension (note: does not apply to erectile dysfunction).
Certolizumab injection (Cimzia) Golimumab injection (Simponi) **Targeted Immunomodulatory Biologics (TIBs)**	• 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
Silodosin capsules (Rapaflo) **Alpha Blockers for BPH**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives. • Formulary agents have resulted in therapeutic failure. • There is no alternative formulary agent, and the patient requires a drug that can be crushed or sprinkled on food.

Appendix C —Existing Prior Authorization Criteria and Quantity Limits and Recommended PAs and QLs for the Multi-indication Targeted Immunomodulatory Biologics

	Adalimumab (Humira)	Etanercept (Enbrel)	Certolizumab (Cimzia)	Golimumab (Simponi)
Prior Authorization (approved PAs are good indefinitely)	Coverage provided for the treatment of: ▪ Moderately to severely active RA in patients 18 years of age or older. ▪ Active arthritis in patients with PsA 18 years of age or older. ▪ Active AS in patients 18 years of age or older. ▪ Mod to severe active polyarticular JIA (pediatric patients: 4-17 years. ▪ Chronic moderate to severe plaque psoriasis when the patient has tried and failed traditional therapy, such as phototherapy (e.g. UVB, PUVA) or systemic therapy (e.g., methotrexate, acitretin or cyclosporine) OR is not a candidate for phototherapy or systemic therapy. ▪ Moderately to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to infliximab, or an inability to tolerate infliximab in patients 18 years of age or older. ▪ Coverage NOT provided for concomitant use with anakinra, etanercept, infliximab, abatacept, rituximab, golimumab, or certolizumab.	Coverage provided for the treatment of: ▪ Moderately to severely active RA ▪ Active PsA ▪ Active AS ▪ JRA when the patient has an inadequate response to at least one DMARD ▪ Chronic moderate to severe plaque psoriasis when the patient has tried and failed traditional therapy, such as phototherapy (e.g. UVB, PUVA) or systemic therapy (e.g., methotrexate, acitretin or cyclosporine) OR is not a candidate for phototherapy or systemic therapy ▪ Coverage NOT provided for concomitant use with anakinra, etanercept, infliximab, 31batacept, rituximab, golimumab, or certolizumab	Coverage provided for the treatment of: ▪ Moderately to severely active rheumatoid arthritis in patients 18 years of age or older. ▪ Moderate to severely active Crohn's Disease following inadequate response to conventional therapy in patients 18 years of age or older. ▪ Coverage NOT provided for concomitant use with abatacept, adalimumab, anakinra, etanercept, golimumab, infliximab or rituximab.	Coverage provided for the treatment of the following conditions in patients 18 years of age or older: ▪ Mod to severe active RA in combination with MTX ▪ Mod to severe active PsA ▪ Active AS ▪ Coverage NOT provided for concomitant use with abatacept, adalimumab, anakinra, certolizumab, etanercept, infliximab or rituximab
Quantity Limits	Retail Network: 4 wks supply (2 packs of 2 syringes) Mail Order: 8 wks supply (4 packs of 2 syringes) Other Issues: Crohn's disease starter pack includes 6 pens for first 4 wks, no refills	Retail Network: 4 wks supply (based on instructions for use) Mail Order: 8 wks supply (based on instructions for use)	Retail Network: 4 wks supply (3 packs of 2 syringes) Mail Order: 8 wks supply (3 packs of 2 syringes) Other Issues: 3 packs of 2 syringes will allow for loading dose at initiation of therapy	Retail Network: 4 wks supply (1 autoinjector or 1 syringe) Mail Order: 8 wks supply (2 auto-injectors or 2 syringes)

AS: ankylosing spondylitis; DMARD: disease-modifying anti-rheumatic drug; JIA: juvenile idiopathic arthritis; JRA: juvenile rheumatoid arthritis; MTX: methotrexate; PsA: psoriatic arthritis; RA: rheumatoid arthritis

Appendix D — Quantity Limit Updates

Drug	Quantity Limits	Comments
Mometasone (Asmanex Twisthaler) 110 mcg dry powder inhaler	Retail: 2 inhaler/30 days TMOP: 6 inhalers/90 days	Max dose (adults) is 2 puffs/day
Fluticasone (Flovent Diskus) 50-, 100-, and 250 mcg dry powder inhaler	Retail: 1 inhaler/30 days; TMOP: 3 inhalers/90 days	Diskus has 60 doses per inhaler; recommended dose is 1 puff twice daily
Fluoxetine 90 mg (Prozac Weekly)	Retail: 4 capsules/28 days; TMOP: 12 capsules/84 days	Packing issue: each capsule is a 7 day supply with 4 capsules /box for a 28 day supply; will decrease "refill too soon" rejected claims
Azelastine (Astelin) nasal inhaler; Azelastine with sucralose (Astepro) nasal inhaler	Retail: 2 inhalers/30 days TMOP 6 inhalers/90 days	In line with ESI best commercial practices QL applies to both drugs collectively
Tramadol extended release tablets 100-, 200-, and 300 mg(Ryzolt)	Retail: 30 tablets/30 days TMOP: 90 tablets/90 days	Safety issue; consistent with recommended dosing instructions from product labeling

Appendix E — National Defense Authorization Act (NDAA)

Section 703 Affected Medications

A. Drugs Retained as Formulary on the Uniform Formulary			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
ACTIMMUNE	Immunomodulators	INTERMUNE	25
APOKYN	Parkinson's medications	TERCICA INC	47
DERMA-SMOOTHE-FS	Topical corticosteroids	HILL DERM	1,421
DERMOTIC	Otic medications anti-inflammatory	HILL DERM	1,886
INTAL	Mast cell stabilizers, inhalation	KING PHARM	439
PANRETIN	Topical antineoplastic & premalignant lesion medic	EISAI INC.	1
RADIOGARDASE	Radiation exposure (cesium, thallium)	HEYLTEX CORPORA	
STROMECTOL	Antihelmintic	MERCK & CO.	514
THIOLA	Kidney stone agents	MISSION PHARM.	12
VANCOCIN HCL	Misc antibiotics	VIROPHARMA INCO	1,491
B. Drugs moved to or retained as non-formulary on the Uniform Formulary			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
ACIPHEX	PPIs	EISAI INC.	25,129
ACLOVATE	Topical corticosteroids	Pharmaderm	1
AGRYLIN	Platelet reducing agents	SHIRE US INC.	8
ALA-HIST	1st gen AH	POLY PHARM.	216
ALA-HIST D	1st gen AH-decongestant	POLY PHARM.	590
ALTACE	ACE inhibitors	MONARCH PHRM	69
ANAPROX	NSAIDs	ROCHE LABS.	
ANAPROX DS	NSAIDs	ROCHE LABS.	3
ANDROID	Androgens/anabolic steroids	VALEANT	57
APTIVUS	HIV antivirals, protease inhibitors	BOEHRINGER ING.	6
ATROVENT	Nasal anticholinergics	BOEHRINGER ING.	11
ATROVENT HFA	Inhaled anticholinergics	BOEHRINGER ING.	3,565
AZOR	ARB / CCB combo	DAIICHI SANKYO,	4,471
BREVOXYL-4	Keratolytics	STIEFEL LABS.	296
BREVOXYL-8	Keratolytics	STIEFEL LABS.	325

B. Drugs moved to or retained as non-formulary on the Uniform Formulary (cont)			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
BROVEX	1st gen antihistamines	MCR/AMERICAN PH	1
BROVEX CT	1st gen antihistamines	MCR/AMERICAN PH	
BROVEX SR	1st gen AH-decongestant	MCR/AMERICAN PH	
BROVEX-D	1st gen AH-decongestant	MCR/AMERICAN PH	
BUPHENYL	Ammonia inhibitors	MEDICIS DERM	7
CADUET	Statin/CCB combo	PFIZER US PHARM	129
CARBATROL	Anticonvulsants	SHIRE US INC.	1,311
CARNITOR	Metabolic deficiency agents	SIGMA-TAU	15
CARNITOR SF	Metabolic deficiency agents	SIGMA-TAU	2
CATAPRES	Sympatholytics	BOEHRINGER ING.	19
CETROTIDE	LHRH (GNRH) antagonist, pituitary suppressant agent	EMD SERONO, INC	34
CHROMAGEN	Iron replacement	THER-RX	511
CHROMAGEN FORTE	Iron replacement	THER-RX	225
CORDRAN	Topical corticosteroids	AQUA PHARMACEUT	145
CORGARD	Beta blockers	KING PHARM	42
CORTISPORIN	Otic medications, anti-infective	MONARCH PHRM	3
CORTISPORIN	Topical antibiotics & combos	MONARCH PHRM	298
CUTIVATE	Topical corticosteroids	Pharmaderm	1,355
CYTOMEL	Thyroid replacement	KING PHARM	2,955
CYTOXAN	Alkylating agents	BMS ONCO/IMMUN	
DAYTRANA	ADHD medications	SHIRE US INC.	2,700
DECLOMYCIN	Tetracycline	STONEBRIDGE PHA	2
DEGARELIX	Antineoplastic LHRH agonists	FERRING PH INC	
DEPAKENE	Anticonvulsants	ABBOTT LABS.	12
DERMA-SMOOTHE-FS	Topical corticosteroids	HILL DERM	2,239
DIBENZYLINE	Alpha blockers, cardiovascular	WELLSPRING PHAR	46
DIPENTUM	Medications for inflammatory bowel disease	ALAVEN PHARMACE	3
DYNEX 12	antitussive-decongestant	ATHLON PHARM	
DYNEX LA	decongestant-expectorant	ATHLON PHARM	4
DYNEX VR	antitussive-expectorant	ATHLON PHARM	
DYRENIUM	Potassium sparing diuretics	WELLSPRING PHAR	277
ELDEPRYL	Parkinson's medications	SOMERSET PHARM	1

B. Drugs moved to or retained as non-formulary on the Uniform Formulary (cont)			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
ELESTRIN	Estrogens	AZUR PHARMA, IN	26
ELIGARD	Antineoplastic LHRH agonists	SANOFI PHARM	20
EMSAM	MAOIs	BMS PRIMARYCARE	137
ENDOMETRIN	Pregnancy facilitating/maintaining agent	FERRING PH INC	350
ESTRACE	Vaginal estrogen preparations	WC PROF PRODS	8,663
EURAX	Topical antiparasitic	RANBAXY BRAND D	54
EVOXAC	Parasympathetic agents	DAIICHI SANKYO,	1,399
EXELDERM	Topical antifungals	RANBAXY BRAND D	231
FIORICET	Analgesic combos	WATSON PHARMA	300
FLEXERIL	Skeletal muscle relaxants	MC NEIL CONS.	1
FLOMAX	selective alpha blockers for BPH	BOEHRINGER ING.	29,039
FLOXIN	Otic medications, anti-infective	DAIICHI SANKYO,	77
FOSRENOL	Phosphate binders	SHIRE US INC.	635
GESTICARE	Prenatal vitamins	AZUR PHARMA, IN	57
GYNAZOLE-1	Vaginal antifungals	THER-RX	908
HALOG	Topical corticosteroids	RANBAXY BRAND D	261
HEMATRON	Iron replacement	SEYER INC.	22
HEMATRON-AF	Iron replacement	SEYER INC.	131
HYCODAN	antitussive-anticholinergic	ENDO PHARM INC.	
INTELENCE	HIV antivirals, NNRTIs	ORTHO BIOTECH	20
KADIAN	Higher potency single analgesic agents	ALPHARMA BPD	1,512
KAON-CL 10	Potassium replacement	SAVAGE LAB.	35
KAPIDEX	PPIs	TAKEDA PHARM	1,435
KENALOG	Topical corticosteroids	RANBAXY BRAND D	638
KINERET	Targeted immunomodulatory biologics	BIOVITRUM	27
KLONOPIN	Anticonvulsants	ROCHE LABS.	199
K-PHOS NO.2	Urinary pH modifiers	BEACH PRODUCTS	7
K-PHOS ORIGINAL	Urinary pH modifiers	BEACH PRODUCTS	85
KYTRIL	5HT3 antiemetics	ROCHE LABS.	3
LAC-HYDRIN	Emollients	RANBAXY BRAND D	25
LACTINOL	Emollients	PEDINOL PHARM.	13
LACTINOL-E	Emollients	PEDINOL PHARM.	22

B. Drugs moved to or retained as non-formulary on the Uniform Formulary (cont)			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
LEVULAN	Acne meds	DUSA PHARM	
LIALDA	Medications for inflammatory bowel disease	SHIRE US INC.	1,677
LIMBITROL	TCAs & combos	VALEANT	
LITHOSTAT	Ammonia inhibitors	MISSION PHARM.	1
LOCOID	Topical corticosteroids	TRIAX PHARMACEU	
LUVERIS	Luteinizing hormones	EMD SERONO, INC	17
METANX	Vitamin B preparations	PAN AMERICAN	7,475
MICRO-K	Potassium replacement	THER-RX	55
MINOCIN	Tetracyclines	TRIAX PHARMACEU	
MIRAPEX	Parkinson's medications	BOEHRINGER ING.	8,405
MOBIC	NSAIDs	BOEHRINGER ING.	18
MONODOX	Tetracyclines	AQUA PHARMACEUT	2
MS CONTIN	Higher potency single analgesic agents	PURDUE PHARMA L	18
MUSE	Prostaglandins for ED	VIVUS	686
MYAMBUTOL	Antitubercular medications	X-GEN PHARMACEU	1
NEOBENZ MICRO	Keratolytics	SKINMEDICA	223
NIFEREX GOLD	Iron replacement	THER-RX	44
NIFEREX-150 FORTE	Iron replacement	THER-RX	378
NIRAVAM	Anxiolytics	AZUR PHARMA, IN	181
NOVASTART	Prenatal vitamins	AZUR PHARMA, IN	2
NUZON	Topical corticosteroids	WRASER PHARMA	25
OBSTETRIX EC	Prenatal vitamins	SEYER INC.	81
OMNICEF	3rd gen cephalosporins	ABBOTT LABS.	7
OXANDRIN	Androgens/anabolic steroids	SAVIENT PHARMAC	2
OXISTAT	Topical antifungals	Pharmaderm	2,460
OXSORALEN	Hyperpigmentation agents	VALEANT	9
PAMINE	Anticholinergics/antispasmodics	KENWOOD LAB.	4
PAMINE FORTE	Anticholinergics/antispasmodics	KENWOOD LAB.	1
PAMINE FQ	Anticholinergics/antispasmodics	KENWOOD LAB.	2
PCE	Macrolide	ABBOTT LABS.	16
PEDIAPRED	Oral corticosteroids	UCB PHARMA	4

B. Drugs moved to or retained as non-formulary on the Uniform Formulary (cont)			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
PENTASA	Medications for inflammatory bowel disease	SHIRE US INC.	1,553
PERCODAN	Higher potency narcotic analgesic combos	ENDO PHARM INC.	34
PERPHENAZINE	Typical antipsychotics	SANDOZ	356
PERSANTINE	Platelet aggregation inhibitors	BOEHRINGER ING.	4
PHOSLO	Phosphate binders	FRESENIUS MED	24
PLETAL	Platelet aggregation inhibitors	OTSUKA AMERICA	9
POLY HIST DM	antitussive-1st gen AH-decongestant	POLY PHARM.	98
POLY HIST FORTE	1st gen AH-decongestant	POLY PHARM.	514
POLY HIST PD	1st gen AH-decongestant	POLY PHARM.	19
POLY TAN D	1st gen AH-decongestant	POLY PHARM.	63
POLY TAN DM	antitussive-1st gen AH-decongestant	POLY PHARM.	154
POLY-TUSSIN DHC	antitussive-1st gen AH-decongestant	POLY PHARM.	939
POLY-TUSSIN DM	antitussive-1st gen AH-decongestant	POLY PHARM.	132
POTASSIUM CHLORIDE	Potassium replacement	SCHERING CORP G	8,159
PRECARE	Prenatal vitamins	THER-RX	245
PRECARE CONCEIVE	Prenatal vitamins	THER-RX	51
PRECARE PREMIER	Prenatal vitamins	THER-RX	473
PREFERA-OB	Prenatal vitamins	ALAVEN PHARMACE	279
PREMESIS RX	Prenatal vitamins	THER-RX	68
PROAMATINE	Adrenergic vasopressors	SHIRE US INC.	4
PROCRIT	RBC Stimulants	ORTHO BIOTECH	2,201
P-TEX	1st gen antihistamines	POLY PHARM.	
QUIXIN	Ophthalmic antibiotics, quinolones	VISTAKON PHARMA	350
RESPA A.R.	1st gen AH-decongestant-anticholinergic	RESPA PHARM.	503
RESPA-BR	1st gen antihistamines	RESPA PHARM.	85
RHEUMATREX	Antirheumatics	DAVA PHARMACEUT	10
RIOMET	Biguanides	RANBAXY BRAND D	105
SAIZEN	Growth hormone	EMD SERONO, INC	31
SALAGEN	Parasympathetic agents	EISAI INC.	10
SEDAPAP	Analgesic combos	MERZ	
SEPTRA	Sulfonamides/folate antagonists	MONARCH PHRM	

B. Drugs moved to or retained as non-formulary on the Uniform Formulary (cont)			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
SEPTRA DS	Sulfonamides/folate antagonists	MONARCH PHRM	3
SEROSTIM	Growth hormone	EMD SERONO, INC	3
SILVADENE	Topical sulfonamides	MONARCH PHRM	7
SONATA	Newer sedative hypnotics	KING PHARM	282
SORIATANE CK	Psoriasis medications, oral	STIEFEL LABS.	577
SULFAMYLON	Topical sulfonamides	UDL	13
TAPAZOLE	Antithyroid medications	KING PHARM	6
TEMOVATE	Topical corticosteroids	Pharmaderm	4
TEMOVATE EMOLLIENT	Topical corticosteroids	Pharmaderm	2
TENEX	Sympatholytics	PROMIUS PHARMA	19
TESTRED	Androgens/anabolic steroids	VALEANT	72
THALITONE	Thiazides	MONARCH PHRM	29
TIGAN	Other antiemetics	MONARCH PHRM	2
TINDAMAX	Antiprotozoal	MISSION PHARM.	691
TRANSDERM-SCOP	Other antiemetics	BAXTER HEALTHCA	974
TRANSDERM-SCOP	Other antiemetics	NOVARTIS CONSUM	6,163
TRETIN-X	Acne meds	TRIAX PHARMACEU	94
ULTRAVATE	Topical corticosteroids	RANBAXY BRAND D	8
ULTRAVATE PAC	Topical corticosteroids	RANBAXY BRAND D	144
VALIUM	Anxiolytics	ROCHE LABS.	249
VESANOID	Misc antineoplastics	ROCHE LABS.	7
VIRAMUNE	HIV antivirals, NNRTIs	BOEHRINGER ING.	52
VIROPTIC	Ophthalmic antivirals	MONARCH PHRM	5
VYVANSE	ADHD medications	SHIRE US INC.	14,885
WELCHOL	Bile acid sequestrants	DAIICHI SANKYO,	7,541
WESTCORT	Topical corticosteroids	RANBAXY BRAND D	
ZAROXOLYN	Thiazides	UCB PHARMA	9
ZONEGRAN	Anticonvulsants	EISAI INC.	85
ZORBTIVE	Growth hormone	EMD SERONO, INC	

C. Action deferred until November 2009 DoD P&T Committee Meeting			
Product Name	**Subclass**	**Manufacturer**	**Number of Affected Patients**
ARESTIN	Periodontal collagenase inhibitors	ORAPHARMA	
FARESTON	Selective estrogen receptor modulators	GTX INC.	24
GLUCAGEN	Hyperglycemics	BEDFORD LABS	37
GLUCAGEN	Hyperglycemics	NOVO NORDISK	208
GONAL-F	Injectable gonadotropins	EMD SERONO, INC	15
GONAL-F RFF	Injectable gonadotropins	EMD SERONO, INC	160
LEVOTHYROXINE SODIUM	Thyroid replacement	SANDOZ	13,762
PAREMYD	Mydriatics	AKORN INC.	
REBIF	MS-DMDs	EMD SERONO, INC	774
ROZEREM	Newer sedative hypnotics	TAKEDA PHARM	3,835
UROCIT-K	Urinary pH modifiers	MISSION PHARM.	6
VOLTAREN	NSAIDs	ENDO PHARM INC.	16,845

Appendix F — 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)
Aug 09 (update; original review Nov 2007)	Targeted Immunomodulatory Biologics	**Recommended for non-formulary status Aug 09; no change to non-formulary status from Nov 07** ▪ golimumab injection (Simponi) ▪ certolizumab injection (Cimzia)	ECF	**No changes to ECF recommendation Nov 07**	pending approval	pending approval
		▪ etanercept injection (Enbrel) ▪ anakinra injection (Kineret)	ECF	▪ adalimumab injection (Humira)	13 Feb 08	18 Jun 08 (120 days)
Aug 09 (update; original review May 05)	Phosphodiesterase Type-5 Inhibitors	**No change to non-formulary status from May 05** Automated PA requiring trial of vardenafil (Levitra) applies to new users of non-formulary PDE5s (no use of PDE5s in last 180 days)	Now BCF	Previously ECF Class ▪ vardenafil (Levitra)	pending approval	pending approval
		▪ sildenafil (Viagra) ▪ tadalafil (Cialis)	ECF	▪ vardenafil (Levitra)	14 Jul 05	12 Oct 05 (90 days)
Aug 09 (update; updated Nov 07; original review Aug 05)	Alpha Blockers for BPH	**Recommended for non-formulary status Aug 09; no change to non-formulary status from Nov 07 or Aug 05** ▪ silodosin (Rapaflo)	BCF	**No changes to BCF recommendation Nov 07**	pending approval	pending approval
		▪ tamsulosin (Flomax) Automated PA requiring trial of alfuzosin (Uroxatral) 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)
Aug 09 (update; updated Nov 07; original review Nov 06)	ADHD / Narcolepsy Agents	**No change to non-formulary status from Aug 05 or Nov 07**	BCF	**No changes to BCF recommendation from Aug 05**	pending approval	pending approval
		Recommended for non-formulary status Nov 07 ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (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)
		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
May 09 (update; reviewed Jun 08; original review May 07)	Antilipidemic Agents-II	**Recommended for non-formulary status May 09; no change to non-formulary status in Jun 08** ▪ fenofibrate acid (Trilipix)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	24 July 07	21 Nov 07 (120 days)
May 09 update; reviewed Aug 08; Feb 06 original review)	Overactive Bladder Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Aug 08** ▪ fesoterodine (Toviaz)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
May 09 (update; reviewed Nov 08) update to include nasal antihistamines; nasal steroids	Nasal Allergy Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Nov 08** ▪ azelastine with sucralose (Astepro)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09

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)
reviewed Nov 05 & Aug 07 for Veramyst)		▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
May 09 (update; reviewed May 07& Feb 05)	Proton Pump Inhibitors	**Recommended for non-formulary status May 09 no change to non-formulary status in May 07** ▪ Dexlansoprazole (Kapidex)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		▪ 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 09 (update; reviewed May 06)	Antiemetics	**Recommended for non-formulary status May 09; no change to non-formulary status in** ▪ granisetron transdermal system (Sancuso)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		▪ dolasetron (Anzemet)	BCF	▪ promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)
Feb 09	Inhaled Corticosteroids	▪ Beclomethasone HFA MDI (Qvar) ▪ Budesonide MFA MDI (Pulmicort Flexhaler) ▪ Ciclesonide HFA MDI (Alvesco) ▪ Flunisolide CFC MDI (Aerobid, Aerobid M) ▪ Triamcinolone CFC MDI (Azmacort)	BCF	▪ Fluticasone DPI (Flovent Diskus) ▪ Fluticasone HFA MDA (Flovent HFA) ▪ Mometasone DPI (Asmanex Twisthaler)	12 May 2009	16 Sep 09 (120 days)
Feb 09	Long-Acting Beta Agonists	▪ formoterol inhalation solution (Perforomist)	BCF	▪ Salmeterol DPI (Serevent Diskus)	12 May 2009	16 Sep 09 (120 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 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(No ICS/LABA combinations recommended for NF placement Feb 09)	BCF	▪ Fluticasone/salmeterol DPI (Advair Diskus) ▪ Fluticasone/salmeterol HFA MDI (Advair HFA)	12 May 2009	16 Sep 09 (120 days)
Nov 08	Short-Acting Beta Agonists	▪ albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured) ▪ metaproterenol (Alupent) CFC MDI (no longer marketed) ▪ metaproterenol inhalation solution ▪ pirbuterol (Maxair) MDI	BCF	▪ Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI ▪ Albuterol inhalation solution; Note – does not include the following: Accuneb 0.021% [0.63 mg/mL] Accuneb 0.042% [1.25 mg/3mL] Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial]	10 Feb 09	8 Apr 09 (60 days)
Nov 08 & Aug 08 (update; reviewed Nov 05)	Antidepressants I	**Recommended for non-formulary status Aug 08; no change to non-formulary status in Nov 08** ▪ desvenlafaxine (Pristiq)	BCF	No changes to BCF recommended Aug 08	10 Feb 09; original signing date 24 Oct 08	7 Jan 09 (60 days)
		To remain NF ▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg weekly admin. (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL)	BCF	Currently BCF ▪ citalopram ▪ fluoxetine (excluding weekly regimen & special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	19 Jan 06	19 Jul 06 (180 days)
Nov 08	ACE inhibitors – Renin Angiotensin Antihypertensives	Previously non-formulary, recommended for UF status Nov 08 ▪ ramipril (Altace generic)	BCF	▪ No changes recommended to BCF at Nov 08 meeting; ramipril removed from Non-formulary status and designated as Uniform Formulary immediately upon signing of the minutes	10 Feb 09	N/A
Oct 08 (interim teleconference meeting) & 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	24 Oct 08;; original signing date: 27 Aug 08	26 Nov 08 (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)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	▪ OneTouch Ultra 2 strips (for OneTouch Ultra 2, Ultra Mini, and Ultra Smart meters) ▪ TrueTrack strips (for TrueTrack meter) ▪ Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) ▪ Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) ▪ Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check ▪ Plus all other store/private label brand strips not included on the UF (see BCF/ECF column)	BCF	**Basic Core Formulary SMBGS test strips** ▪ Precision Xtra strips (for Precision Xtra meter) **Uniform Formulary SMBGS test strips** ▪ Accu-chek Aviva (for Accu-chek Aviva meter) ▪ Ascensia Contour (for Ascensia Contour meter) ▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters)	24 Oct 08	17 Mar 09 (120 days)
Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	**Recommended for non-formulary status Aug 08** ▪ nisoldipine geomatrix (Sular geomatrix)	BCF	No changes to BCF recommended Aug 08	24 Oct 08	7 Jan 09 (60 days)
		Previously non-formulary, recommended for UF status Nov 07 ▪ amlodipine besylate (Norvasc generic)		Recommended for addition to BCF Nov 07 ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08
		To Remain Non-Formulary ▪ isradipine IR, ER (Dynacirc; Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER HS dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently BCF ▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting) ▪ nifedipine ER (Adalat CC, generics) ▪ verapamil SR ▪ diltiazem ER (Tiazac, generics)	13 Oct 05	15 Mar 06 (150 days)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (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)
Jun 08 (update; reviewed Nov 07)	Adrenergic Blocking Agents	**Recommended for non-formulary status Jun 08** ▪ nebivolol (Bystolic)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		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	No changes to BCF rec Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		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,	Renin Angiotensin Antihypertensives	**Recommended for non-formulary status Jun 08** ▪ olmesartan/amlodipine (Azor)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (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)
including ACE/CCB combos. Feb 06 ▪ ARBs: May 07 ▪ Renin inhibitors. Aug 07 ▪ CCB/ARB combos Nov 07 update		To remain NF ▪ valsartan amlodipine (Exforge)		No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ Moexipril +/- HCTZ (Univasc; Uniretic) ▪ perindopril (Aceon) ▪ ramipril (Altace) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) (D/C'd from market) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan+/- HCTZ (Avapro, Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- (Diovan; Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) 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 (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	No change to BCF recommended Nov 07	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 / noreth. 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
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)

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 07	5-Alpha Reductase Inhibitors	▪ dutasteride (Avodart)	BCF	▪ finasteride	24 July 07	24 Oct 07 (90 days)
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	Monoamine Oxidase Inhibitors	▪ selegiline transdermal patch (Emsam)	ECF	▪ phenelzine (Nardil)	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	-
Nov 06 (update; reviewed Nov 06)	Dermatologic Topical Antifungals*	**Recommended for non-formulary status Nov 06:** 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)	BCF	No change to BCF recommended Nov 06	14 Jul 05	17 Aug 05 (30 days)
		▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm)		▪ nystatin ▪ clotrimazole	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)
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)
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)
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
CFC = chlorofluorocarbon; ER = extended release; HFA = hydrofluoroalkane; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle;
AD-1s: Antidepressant-1 Drugs; 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; LIP-1 = Antihyperlipidemic-1 Drugs; LIP-2 = Antihyperlipidemic-2 Drugs; MDIs = metered dose inhalers; MOAIs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NADs = Nasal Allergy Drugs; OABs = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAs = Renin Angiotensin Antihypertensives Drugs; SABAs = Short-Acting Beta Agonists; SMBGS: Self-Monitoring Blood Glucose Systems; TIBs = Targeted Immunomodulatory Biologics; TZDs= Thiazolidinediones
*The Dermatologic Topical Antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])

Appendix G — Table of Abbreviations

ADHD	Attention Deficit Hyperactivity Disorder drug class
AE	adverse event
APR	Automated profile review
AS	ankylosing spondylitis
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BPH	benign prostatic hyperplasia
BIA	budget impact analysis
CEA	Cost-effectiveness analysis
CFR	Code of Federal Regulations
CHCS	Composite Health Care System
CMA	cost minimization analysis
CPAP	continuous positive airway pressure
DoD	Department of Defense
ECF	Extended Core Formulary
ED	erectile dysfunction
ER	extended release
ESI	Express Scripts, Inc
FCP	Federal Ceiling Price
FDA	Food and Drug Administration
FSS	Federal Supply Schedule Price
FY	fiscal year
HA	Health Affairs
IPSS	International Prostate Symptom Score
MHS	Military Health System
MN	medical necessity
MSLT	mean sleep latency testing
MTF	Military Treatment Facility
MTX	methotrexate
NDAA	National Defense Authorization Act
OMB	Office of Management and Budget
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAH	pulmonary arterial hypertension
PDE-5	Phosphodiesterase-type 5 inhibitor drug class
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
POS	point of service
PsA	psoriatic arthritis
QL	quantity limit
Qmax	maximum urine flow rate
RA	rheumatoid arthritis
SQ	subcutaneous
TBI	traumatic brain injury
TIB	Targeted Immunomodulatory Drug Class
TNF-α	Tumor necrosis factor alpha
TFL	TRICARE for life beneficiary
TMA	TRICARE Management Activity
TMOP	TRICARE Mail Order Pharmacy
TRRx	TRICARE Retail Pharmacy Network
UF VARR	Uniform Formulary Voluntary Agreement for Retail Refunds

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
May 2009

1) CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened a web conference at 10:00 on May 13, 2009.

2) ATTENDANCE

The attendance roster is found in Appendix A.

3) REVIEW MINUTES OF LAST MEETINGS

A. Revisions to the minutes—Revisions to the February 2009 minutes will be reviewed at the August 2009 DoD P&T Committee meeting.

B. Approval of February minutes—Ms. Ellen P. Embrey, performing the duties of the Assistant Secretary of Defense, Health Affairs, approved the minutes of the November 2008 DoD P&T Committee meeting on May 12, 2009.

4) REVIEW OF RECENTLY FDA-APPROVED AGENTS

A. Antilipidemic-II Agents (LIP-2)—Fenofibrate acid capsules (Trilipix)

Relative Clinical Effectiveness—Fenofibrate acid (Trilipix) is the choline salt of fenofibrate; the active moiety is the same as the other fenofibrate formulations. The fenofibrates are classified in the Antilipidemic-II (LIP-2) drug class that was reviewed for Uniform Formulary (UF) placement in May 2007. Fenofibrate acid is Food and Drug Administration (FDA)-approved for use as monotherapy, and in combination with a statin to lower triglycerides (TGs) and increase high density lipoprotein (HDL) cholesterol in patients with coronary heart disease (CHD) or CHD risk equivalent to those who are receiving optimal statin therapy.

The fenofibrate acid (Trilipix) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, Title 32, Code of Federal Regulations (CFR), Section 199.21(e)(1). There are no comparative clinical trials between fenofibrate acid and the other LIP-2 drugs, and no trials evaluating outcomes other than changes in lipid parameters. The clinical trials used to obtain FDA approval reported fenofibrate acid combined with either a low-dose or moderate-dose statin resulted in additive effects on raising HDL cholesterol and lowering TGs, compared to the statin administered alone. The safety profile of fenofibrate acid reflects that of the other fenofibrate products.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) that although fenofibrate acid (Trilipix) is the only fenofibrate drug specifically approved by the FDA for use in combination with a statin, there was insufficient evidence to compare its safety in combination with a statin versus the other fenofibrates. The P&T Committee concluded fenofibrate acid (Trilipix) did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other fenofibrate formulations currently included on the UF because they all contain the same active ingredient.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of fenofibrate acid capsules (Trilipix) in relation to efficacy, safety, tolerability, and clinical outcomes of other agents in the class, particularly to the following LIP-2 medications: micronized fenofibrate (Lofibra/generic), fenofibrate meltdose (Fenoglide), and nanomicronized fenofibrate (Tricor). Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2).

Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of fenofibrate acid capsules (Trilipix) relative to other UF LIP-2s. Results from the CMA showed the projected weighted average cost per day for fenofibrate acid capsules (Trilipix) is higher than fenofibrate micronized (Lofibra/generics) and fenofibrate meltdose (Fenoglide). The CMA also revealed the projected weighted average cost per day for fenofibrate acid capsules (Trilipix) is slightly lower than the non-formulary LIP-2 agent, nanomicronized fenofibrate (Tricor). Micronized fenofibrate (Lofibra/generic) and fenofibrate meltdose (Fenoglide) remain the most cost effective LIP-2 agents on the UF compared to fenofibrate acid capsules (Trilipix).

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that fenofibrate acid capsules (Trilipix) are not cost effective relative to other formulary LIP-2 agents.

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, 0 abstained, 0 absent) fenofibrate acid capsules (Trilipix) be designated non-formulary on the UF. This

recommendation was based on the clinical effectiveness conclusion and the determination that micronized fenofibrate (Lofibra/generic) and fenofibrate meltdose (Fenoglide) remain the most cost effective LIP-2 agents on the UF compared to fenofibrate acid capsules (Trilipix).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at military treatment facilities (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

B. Overactive Bladder Drugs—Fesoterodine extended release (ER) tablets (Toviaz)

Relative Clinical Effectiveness—The muscarinic antagonist fesoterodine (Toviaz) is a prodrug that undergoes conversion by plasma esterases to the same active metabolite as tolterodine (Detrol, Detrol LA). Like the other OAB

drugs, fesoterodine extended release (ER) tablets are FDA-approved for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. The OAB drug class was previously reviewed for UF placement in August 2008 and February 2006.

The fesoterodine ER tablets (Toviaz) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). There are no direct comparative clinical trials between fesoterodine ER and the other OAB drugs. Statistically significant improvements in the endpoints of urinary frequency, urge urinary incontinence, and urinary urgency vs. placebo were noted in the clinical trials used to obtain FDA approval. The incidence of dry mouth and constipation reported with fesoterodine ER 8 milligrams (mg) was higher than tolterodine ER (Detrol LA) 4 mg in the one indirect active comparator trial available. Product labeling states that fesoterodine does not prolong the QT interval.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) fesoterodine ER tablets (Toviaz) did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other OAB drugs currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of fesoterodine ER tablets (Toviaz) in relation to efficacy, safety, tolerability, and clinical outcomes of other agents in the class, particularly to oxybutynin XL (Detrol XL/generics), tolterodine LA (Detrol LA), solifenacin (Vesicare), and darifenacin (Enablex). 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 fesoterodine (Toviaz) relative to other UF OABs. Results from the CMA showed the projected weighted average cost per day for fesoterodine (Toviaz) is higher than other UF OABS.

Relative Cost-Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) fesoterodine ER tablets (Toviaz) are not cost effective relative to other formulary OAB agents.

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, 0 abstained, 0 absent) that fesoterodine ER tablets (Toviaz) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of fesoterodine ER tablets (Toviaz) 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, 0 absent) MN criteria for fesoterodine extended release (ER) tablets (Toviaz). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

C. Nasal Allergy Drugs (NADs)—Azelastine with sucralose nasal spray (Astepro)

Relative Clinical Effectiveness—Azelastine with sucralose nasal spray (Astepro) is a Nasal Allergy Drug (nasal antihistamine) containing the same active ingredient (azelastine) and dosage strength as Astelin nasal spray. Sucralose and sorbitol have been added to the Astepro formulation to help mask the bitter taste reported with Astelin. Astepro is FDA-approved for treating seasonal allergic rhinitis (SAR) in patients 12 years of age and older. Astelin has additional indications (SAR in patients ≥5 years, and non-allergic rhinitis). The Nasal Allergy Drugs (NADs) were previously reviewed for UF placement in November 2008.

The azelastine with sucralose nasal spray (Astepro) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). One unpublished study reported statistically significant improvements in nasal congestion, rhinorrhea, sneezing, and nasal itching with both Astepro and Astelin, compared to the placebo vehicle. The improvements in nasal symptoms were similar with Astepro and Astelin. Bitter taste and epistaxis are the adverse events reported most frequently with Astepro.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) azelastine with sucralose nasal spray (Astepro) does not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other NADs currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of azelastine with sucralose nasal spray (Astepro) in relation to efficacy, safety, tolerability, and clinical outcomes of the other nasal antihistamine subclass agents in the NAD class, particularly to azelastine (Astelin) and olopatadine (Patanase). 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 azelastine with sucralose nasal spray (Astepro) relative to other nasal antihistamine subclass agents in the NAD class. Results from the CMA showed the projected weighted average cost per day for azelastine with sucralose nasal spray (Astepro) is higher than azelastine (Astelin) but less than olopatadine (Patanase), which is a non-formulary medication.

Relative Cost-Effectiveness Conclusion–P&T Committee, based upon its collective professional judgment, voted (12 for, 0 opposed, 0 abstained, 1 absent) that azelastine with sucralose nasal spray (Astepro) is not cost effective relative to other UF nasal antihistamine subclass agents in the NAD 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 (12 for, 1 opposed, 0 abstained, 0 absent) that azelastine with sucralose nasal spray (Astepro) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of azelastine with sucralose nasal spray (Astepro) 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, 0 absent) MN criteria for azelastine with sucralose nasal spray (Astepro). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (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.

Acting Director, TMA, Decision: ☑Approved ☐ Disapproved

Approved, but modified as follows:

D. Proton Pump Inhibitors—Dexlansoprazole delayed release capsules (Kapidex)

Relative Clinical Effectiveness—The Proton Pump Inhibitor (PPI) dexlansoprazole (Kapidex) is a sustained-release formulation of the R-enantiomer of lansoprazole (Prevacid). Generic formulations of lansoprazole are anticipated in late 2009. The PPIs were reviewed for UF placement in May 2007 and February 2005.

The dexlansoprazole delayed release (DR) capsules (Kapidex) evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). Dexlansoprazole DR capsules are FDA-approved for use in adults for healing of erosive esophagitis (EE), maintenance of EE healing, and gastroesophageal reflux disease. Lansoprazole (Prevacid) has additional FDA-approved indications. The clinical studies used to obtain FDA-approval compared dexlansoprazole DR 60 mg capsules with lansoprazole 30 mg capsules or with placebo; there are no studies directly comparing the drug with other PPIs. The most common adverse events with dexlansoprazole DR capsules are diarrhea, nausea, and abdominal pain, which are similar to the other PPIs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) dexlansoprazole DR capsules (Kapidex) did not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other PPI drugs currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of dexlansoprazole DR capsules (Kapidex) in relation to efficacy, safety, tolerability, and clinical outcomes of selected UF agents in the PPI 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).

CMA was used to evaluate the cost-effectiveness of dexlansoprazole DR capsules (Kapidex) relative to selected PPIs, including omeprazole (Prilosec) and esomeprazole (Nexium). Results from the CMA showed the projected weighted average cost per day for dexlansoprazole DR capsules (Kapidex) is higher than all other comparators.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that dexlansoprazole DR capsules (Kapidex) are not cost effective relative to other formulary PPI agents.

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, 0 abstained, 0 absent) that dexlansoprazole DR capsules (Kapidex) be designated non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of dexlansoprazole DR capsules (Kapidex) 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, 0 absent) MN criteria for dexlansoprazole DR capsules (Kapidex). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

3) ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday 1 week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (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.

Acting Director, TMA, Decision: ☑Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

E. Antidepressant-1 Agents—Venlafaxine Extended Release Tablets

Relative Clinical Effectiveness—Relative Clinical Effectiveness—Venlafaxine is a serotonin norepinephrine reuptake inhibitor (SNRI) antidepressant. The Antidepressant-I (AD-1) drug class was reviewed for UF placement in November 2005. Venlafaxine Extended Release (ER) Tablets (brand name) contain the same active ingredient as venlafaxine ER capsules (Effexor XR), but employ a different mechanism to extend the dosing interval. The FDA does not consider Venlafaxine ER Tablets an AB-rated generic formulation of Effexor XR capsules. Venlafaxine ER Tablets and Effexor XR capsules are not considered therapeutically interchangeable by the FDA due to the different marketed dosage formulations (i.e., capsule vs. tablet). AB-rated generic formulations of Effexor XR capsules are expected in 2010–2011. Venlafaxine ER Tablets have demonstrated bioequivalence with Effexor XR capsules in pharmacokinetic studies.

The Venlafaxine ER Tablets clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). Venlafaxine ER Tablets are FDA-approved for treating Major Depressive Disorder and Social Anxiety Disorder; Effexor XR has additional indications. No clinical trials have been conducted with Venlafaxine ER Tablets. Venlafaxine ER Tablets were FDA-approved under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, based on demonstrated bioequivalence with Effexor XR. Adverse events with Venlafaxine ER Tablets reflect those contained in the Effexor XR product labeling.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (12 for, 1 opposed, 0 abstained, 0 absent) there was no evidence to suggest there are clinically relevant differences in the efficacy, safety, and clinical outcomes of Venlafaxine ER Tablets compared to Effexor XR capsules because both products contain the same active ingredient.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of Venlafaxine ER Tablets in relation to efficacy, safety,

tolerability, and clinical outcomes of selected formulary SSRIs and other SNRI subclass agents in the AD-1 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).

CMA was used to evaluate the relative cost-effectiveness of Venlafaxine ER Tablets relative to selected SSRIs, particularly to sertraline (Zoloft/generics) citalopram (Celexa/generics), and other SNRI subclass agents in the AD-1 class. The SNRIs reviewed in the CMA were venlafaxine ER capsules (Effexor XR), duloxetine (Cymbalta), and desvenlafaxine (Pristiq). Results from the CMA showed the projected weighted average cost per day for Venlafaxine ER Tablets is higher than both SSRIs reviewed. The CMA also revealed Venlafaxine ER Tablets are the most cost-effective agent in the SNRI subclass.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that Venlafaxine ER Tablets are cost effective relative to other UF SNRI subclass agents in the AD-1 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 (13 for, 0 opposed, 0 abstained, 0 absent) that Venlafaxine ER Tablets remain formulary on the UF.

Acting Director, TMA, Decision ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

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, 0 abstained, and 0 absent) to recommend Venlafaxine ER Tablets not be added to the BCF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

F. Antiemetics—Granisetron transdermal system (Sancuso)

Relative Clinical Effectiveness—The granisetron transdermal system (TDS) (Sancuso) is a serotonin subtype-3 (5-HT3) receptor antagonist. It is the only newer antiemetic available in a transdermal dosage form. Granisetron (Kytril, generics) is also available in tablets, an oral solution, and intravenous formulation. The newer antiemetics were evaluated for UF placement in May 2006.

Granisetron TDS is FDA-approved for the prevention of nausea and vomiting in adult patients receiving moderately or highly emetogenic chemotherapy regimens lasting for ≤5 consecutive days. Other newer antiemetics (granisetron and ondansetron [Zofran, generics]) have indications in addition to chemotherapy-induced nausea and vomiting (CINV).

The granisetron TDS (Sancuso) clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). In clinical studies, granisetron TDS has shown non-inferiority (but not superiority) to oral granisetron in controlling nausea and vomiting associated with CINV. There is insufficient evidence to determine whether granisetron TDS would control nausea and vomiting to a greater extent than the other 5-HT3 antagonists. There are no studies evaluating differences in the adverse events between granisetron TDS and 5-HT3 antagonists other than oral granisetron.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 0 absent) although granisetron TDS (Sancuso) is the only newer antiemetic available in a transdermal formulation, it does not have a significant, clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other newer antiemetics currently included on the UF.

Relative Cost-Effectiveness—The P&T Committee evaluated the relative cost-effectiveness of granisetron TDS (Sancuso) in relation to efficacy, safety, tolerability, and clinical outcomes of selected UF agents in the antiemetic 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).

CMA was used to evaluate the relative cost-effectiveness of granisetron TDS (Sancuso) relative to ondansetron (Zofran/generics) oral and oral dissolving tablets and granisetron (Kytril/generics) tablets. Results from the CMA showed the projected weighted average cost per week for granisetron TDS (Sancuso) is higher than all other comparators.

Relative Cost-Effectiveness Conclusion—The P&T Committee, based upon its collective professional judgment, voted (13 for, 0 opposed, 0 abstained, 0 absent) that granisetron TDS (Sancuso) is not cost effective relative to other antiemetic agents.

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, 0 abstained, 0 absent) granisetron TDS (Sancuso) be designated as non-formulary on the UF.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

2) ***COMMITTEE ACTION: MN CRITERIA***—Based on the clinical evaluation of granisetron TDS (Sancuso) 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, 0 absent) MN criteria for granisetron TDS (Sancuso). (See Appendix B for full MN criteria).

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

*3) **COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (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.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P Embrey

5) UTILIZATION MANAGEMENT—PRIOR AUTHORIZATIONS (PA) / Quantity Limits (QL) / MEDICAL NECESSITY (MN)

A. PPI—Prior Authorization / Medical Necessity Criteria (MN): The P&T Committee reviewed current published literature, national guidelines/expert consensus statements, and FDA guidance related to reports of a drug interaction between clopidogrel (Plavix) and PPIs, and the corresponding potential for decreased antiplatelet effect and adverse cardiovascular outcomes. An automated prior authorization (APR) or *step therapy* is currently in effect and requires use of UF generic omeprazole or esomeprazole (Nexium) before other non-formulary PPIs, unless there is therapeutic failure, intolerance, or hypersensitivity. MN criteria also applies to non-formulary PPIs. The P&T Committee concluded the evidence was not sufficient at this time to recommend a change in the current PA/MN criteria, but agreed with continued monitoring of the literature for possible changes to the PA/MN criteria.

1) ***COMMITTEE ACTION:*** The Committee voted (12 for, 0 opposed, 1 abstained, 0 absent) to recommend no change to the existing PPI PA/MN criteria.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. QL Updates: In anticipation of the forthcoming TPHARM contract implementation, the P&T Committee updated the quantity limits (QLs) for several drugs. See Appendix C.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to recommend the QLs for ondansetron (Zofran), dasatinib (Sprycel), budesonide nebulizer solution (Pulmicort Respules), cromolyn inhaler (Intal), azelastine nasal spray (Astelin), azelastine with sucralose nasal spray (Astepro), metaproterenol nebulizer solution (Alupent, generics), ipratropium/albuterol inhaler (Combivent), methylnaltrexone subcutaneous injection (Relistor), as outlined in Appendix C.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

C. Extended Core Formulary (ECF) Clarification—The P&T Committee was briefed in August 2008 on efforts to implement electronic prescribing in the Military Health System (MHS). As part of the ongoing plan to systematically review drugs represented on the Basic Core Formulary (BCF)/Extended Core Formulary (ECF), the P&T Committee periodically reviews recommendations for changes to the BCF/ECF. At this meeting, the ECF was reviewed because greater specificity in the drug listings is required to assist with e-prescribing efforts. Appendix D outlines drugs currently designated as ECF.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 1 abstained, 1 absent) to recommend the listing of the ECF drugs, as outlined in Appendix D.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

D. Oral Fentanyl Citrate Automated PA—The P&T Committee was briefed on an analysis examining MHS utilization of oral fentanyl citrate buccal lozenges (Actiq) and buccal tablets (Fentora) among opioid-naïve patients (i.e., those without prior opioid exposure). Both Actiq and Fentora are indicated for breakthrough pain in combination with long-acting opioids in opioid-tolerant patients. A total of 1,217 TRICARE beneficiaries received prescriptions for oral fentanyl citrate during the 5-month observation period from November 1, 2009 to May 31, 2009. The oral fentanyl prescriptions were dispensed in majority (89 percent) from the TRRx. Forty percent of patients (492/1,217) were identified as new oral fentanyl citrate users. A total of 375 (76 percent) new users received an opioid prescription within the last 60-days of their first oral fentanyl citrate prescription; 81 percent of new users had prior exposure to a strong opioid. In total, 10 percent (117/1,217) of all oral fentanyl citrate users were opioid-naïve. Sensitivity analysis showed results to be dependent on length of look-back period.

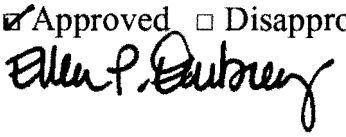
Due to potential patient safety and inappropriate prescribing concerns, the P&T Committee recommended inclusion of oral fentanyl citrate products (Actiq and Fentora) in the current Automated Profile Review (APR) for transdermal fentanyl. The APR is available at retail and mail order points of service and allows pharmacists to override the requirement for evidence of a previous opioid prescription in the 60-day look- back period with intervention and outcome codes (to avoid disrupting chronic therapy). The fentanyl APR

process differs from other PAs that require review by ESI (Express Scripts, Inc., DoD contractor for retail and mail order), have more stringent criteria to allow overrides, and take longer to resolve. The Pharmacy Program Office has requested and will begin testing a similar function in the Composite Health Care System for the MTF pharmacies.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (11 for, 0 opposed, 0 abstained, 2 absent) to recommend addition of the oral formulations of fentanyl citrate, Actiq and Fentora be added to the automated PA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:



6) FUTURE UF DRUG CLASS REVIEWS

A drug class overview for the Phosphodiesterase type-5 inhibitors (PDE-5s) was presented to the P&T Committee. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important for the Pharmacoeconomic Center 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 completed for August 2009 P&T Committee meeting.

7) ITEMS FOR INFORMATION

A. **National Defense Authorization Act (NDAA) Section 703—Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals Update**—The Office of General Counsel (OGC) updated the P&T Committee on the litigation and status of the final rule that will implement Section 703 of the 2008 NDAA. The judge has not rendered a decision regarding the current litigation. The final rule is at the Office of Management and Budget (OMB). Key members from the TMA Pharmacy Operations Department and OGC have met with OMB personnel. The timetable for approval and impact on the DoD P&T Committee process are not known.

8) ADJOURNMENT

The meeting adjourned at 3:00 on March 13, 2009. The next meeting will be in August 2009.

Appendix A—Attendance
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Quantity Limits
Appendix D—Table of Extended Core Formulary Clarification
Appendix E—Table of Implementation Status of UF Recommendations/Decisions
Appendix F—Table of Abbreviations

SUBMITTED BY:

17 Aug 09

COL John Kugler, MC, USA
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Acting Director, TMA, decisions are as annotated above.

Ellen P. Embrey
Performing the Duties of the
Assistant Secretary of Defense,
Health Affairs

08/17/09
(Date)

Appendix A — Attendance

Voting Members Present	
COL John Kugler, MC	DoD P&T Committee Chair
LTC Stacia Spridgen, MSC	DoD P &T Committee Recorder
COL Doreen Lounsbery , MC	Army, Internal Medicine Physician, Alternate
COL Peter Bulatao *for Col Isiah Harper, MSC*	Army, Pharmacy Officer, Alternate
CAPT Stephanie Simon, MSC	Navy, Pharmacy Officer
CAPT Vernon Lew	Coast Guard, Pharmacy Officer
LTC Bruce Lovins	Army, Family Practice Physician, Alternate
CDR Walter Downs, MC	Navy, Internal Medicine Physician, Alternate
CDR David Tanen, MC	Navy, Physician at Large
Lt Col Thomas Bacon, BSC *for Col Everett McAllister*	Chief, Pharmaceutical Operations Directorate
Lt Col Michael Lee, BSC *for Col Mark Butler*	Consultant to the AF/SG
Lt Col Brian Crownover, MC	Air Force, Physician at Large
Major Jeremy King, MC	Air Force, OB/GYN Physician
Voting Members Absent	
COL Carole Labadie, MS	Army, Pharmacy Officer
COL Ted Cieslak, MC	Army, Physician at Large
Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
CDR James Ellzy	DoD P&T Vice Chairman
Mr. David Hurt	Deputy General Counsel, TMA
Nonvoting Members Absent	
COL Kent Maneval, MS	Defense Medical Standardization Board
Mr. William Davies	TRRx/TMOP COR
Maj Peter Trang	Defense Supply Center Philadelphia
Guests	
LCDR Tracie Patten *for CDR Robert Hayes*	Indian Health Service
Others Present	
CDR Matthew Carlberg	DoD Pharmacoeconomic Center
Lt Col James McCrary, MC	DoD Pharmacoeconomic Center
MAJ Misty Carlson, MC	DoD Pharmacoeconomic Center
LCDR Joe Lawrence	DoD Pharmacoeconomic Center

Appendix A — Attendance — (continued)

Others Present	
Maj Joshua Devine, BSC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez	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. Jeremy Briggs	DoD Pharmacoeconomic Center
Dr. Brian Beck	DoD Pharmacy Operations Center contractor
Dr. Dean Valibhai	DoD Pharmacy Operations Center contractor
Dr. Carl R. Summers	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Dr. Roger Potyk	DoD Pharmacy Outcomes Research Team contractor
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Appendix B — Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Azelastine with sucralose nasal spray (Astepro) **Nasal Allergy Drugs (NADs)**	• Use of formulary alternatives is contraindicated
Dexlansoprazole delayed release capsules (Kapidex) **Proton Pump Inhibitors (PPIs)**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives.
Fenofibrate acid delayed release capsules (Trilipix) **Antilipidemic-II Drugs (LIP-2s)**	• Use of formulary alternatives is contraindicated
Fesoterodine extended release tablets (Toviaz) **Overactive Bladder Drugs (OABs)**	• Use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from formulary alternatives.
Granisetron transdermal system (Sancuso) **Antiemetics**	• 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 — Quantity Limit Updates

Drug	TMOP QL	TRRx QL	Comments
Ondansetron (Zofran) 24 mg tablets	3 tabs/Rx	1 tab/Rx	-Indicated for single dose highly emetogenic chemo; -Not studied in multiple-day regimens -Other strengths of ondansetron are available for delayed nausea and vomiting
Dasatinib (Sprycel) 100 mg tablets	90 tabs/45 days	60 caps / 30 days	-Starting dose is 100mg/d -Max dose is 200mg/d in advanced phase CML -Therapy is continued until disease worsens or patient can't tolerate
Budesonide (Pulmicort Respules) nebulizer soln 1 mg/ml	180 ml (90 ampules) / 90 days	60 ml (30 ampules) / 30 days	Max dose is 1 mg (2ml) per day
Cromolyn (Intal) inhaler 8.1 gm	9 inhalers / 90 days	3 inhalers / 30 days	112 puffs/inhaler, max 240 inhalations/month
Azelastine (Astelin) nasal spray	6 bottles / 90 days	2 bottles / 30 days	Clarified TMOP quantity for consistency
Azelastine with sucralose (Astepro) nasal spray	6 bottles / 90 days	2 bottles/30 days	New product in already reviewed class
Metaproterenol nebulizer solution	600 amps / 90 days	200 amps/30 days	Max dose based on labeling
Ipratropium /albuterol (Combivent) inhaler 14.7 gm	6 inhalers / 90 days	2 inhalers/30 days	Max dose based on labeling
Methylnaltrexone SQ Injection (Relistor)	No Refills	No Refills	Intended for palliative care

Appendix D — Extended Core Formulary Clarification

Therapeutic Category	Generic Name	Brand Name	Dosage	Dosage Form	P&T Meeting
ANTIARTHRITICS	ADALIMUMAB	HUMIRA	40 MG/0.8ML	KIT	Nov 2007 & Feb 2008
AUTONOMIC DRUGS	DONEPEZIL HCL	ARICEPT	10 MG	TABLET	Nov 2005
AUTONOMIC DRUGS	DONEPEZIL HCL	ARICEPT	5 MG	TABLET	Nov 2005
UNCLASSIFIED DRUG PRODUCTS	INTERFERON BETA-1A	AVONEX	30 MCG/.5ML	KIT	May 2005
PSYCHOTHERAPEUTIC DRUGS	PHENELZINE SULFATE	NARDIL	15 MG	TABLET	Feb 2007
HORMONES	SOMATROPIN	NORDITROPIN	5 MG/1.5ML	CARTRIDGE	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN NORDIFLEX	5 MG/1.5ML	PEN INJCTR	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN NORDIFLEX	10 MG/1.5ML	PEN INJCTR	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN	15 MG/1.5ML	CARTRIDGE	Aug 2007
HORMONES	SOMATROPIN	NORDITROPIN NORDIFLEX	15 MG/1.5ML	PEN INJCTR	Aug 2007
UNCLASSIFIED DRUG PRODUCTS	VARDENAFIL HCL	LEVITRA	5 MG	TABLET	May 2005
UNCLASSIFIED DRUG PRODUCTS	VARDENAFIL HCL	LEVITRA	10 MG	TABLET	May 2005
UNCLASSIFIED DRUG PRODUCTS	VARDENAFIL HCL	LEVITRA	20 MG	TABLET	May 2005

Appendix E — 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)
May 09 (update; reviewed Jun 08; original review May 07)	Antilipidemic Agents-II	**Recommended for non-formulary status May 09; no change to non-formulary status in Jun 08** ▪ fenofibrate acid (Trilipix)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
Jun 08 (update; reviewed May 07)	Antilipidemic - Agents II	No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	24 July 07	21 Nov 07 (120 days)
May 09 update; reviewed Aug 08; Feb 06 original review)	Overactive Bladder Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Aug 08** ▪ fesoterodine (Toviaz)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
Aug 08 (re-review; Feb 06 original review)	Overactive Bladder (OAB) Agents	▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
May 09 (update; reviewed Nov 08)	Nasal Allergy Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Nov 08** ▪ azelastine with sucralose (Astepro)	BCF	No changes to BCF recommendation May 09	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)
Nov 08 (update to include nasal antihistamines; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst)	Nasal Allergy Drugs	▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
May 09 (update; reviewed May 07& Feb 05)	Proton Pump Inhibitors	**Recommended for non-formulary status May 09 no change to non-formulary status in May 07** ▪ Dexlansoprazole (Kapidex)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
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 09 (update; reviewed May 06)	Antiemetics	**Recommended for non-formulary status May 09; no change to non-formulary status in** ▪ granisetron transdermal system (Sancuso)	BCF	No changes to BCF recommendation May 09	pending approval	pending approval
May 06	Antiemetics	▪ dolasetron (Anzemet)	BCF	▪ promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)
Feb 09	Inhaled Corticosteroids	▪ Beclomethasone HFA MDI (Qvar) ▪ Budesonide MFA MDI (Pulmicort Flexhaler) ▪ Ciclesonide HFA MDI (Alvesco) ▪ Flunisolide CFC MDI (Aerobid, Aerobid M) ▪ Triamcinolone CFC MDI (Azmacort)	BCF	▪ Fluticasone DPI (Flovent Diskus) ▪ Fluticasone HFA MDA (Flovent HFA)	12 May 2009	16 Sep 09 (120 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 09	Long-Acting Beta Agonists	▪ formoterol inhalation solution (Perforomist)	BCF	▪ Salmeterol DPI (Serevent Diskus)	12 May 2009	16 Sep 09 (120 days)
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(No ICS/LABA combinations recommended for NF placement Feb 09)	BCF	▪ Fluticasone/salmeterol DPI (Advair Diskus) ▪ Fluticasone/salmeterol HFA MDI (Advair HFA)	12 May 2009	16 Sep 09 (120 days)
Nov 08	Short-Acting Beta Agonists	▪ albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured) ▪ metaproterenol (Alupent) CFC MDI (no longer marketed) ▪ metaproterenol inhalation solution ▪ pirbuterol (Maxair) MDI	BCF	▪ Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI ▪ Albuterol inhalation solution; Note – does not include the following: Accuneb 0.021% [0.63 mg/mL] Accuneb 0.042% [1.25 mg/3mL] Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial]	10 Feb 09	8 Apr 09 (60 days)
Nov 08 (update to include nasal antihistamines; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst)	Nasal Allergy Drugs	▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
Nov 08 & Aug 08 (update; reviewed Nov 05)	Antidepressants I	**Recommended for non-formulary status Aug 08; no change to non-formulary status in Nov 08** ▪ desvenlafaxine (Pristiq)	BCF	No changes to BCF recommended Aug 08	10 Feb 09; original signing date 24 Oct 08	7 Jan 09 (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)
Aug 08 (update; reviewed Nov 05)	Antidepressants I	To remain NF ▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg weekly admin. (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL)	BCF	Currently BCF ▪ citalopram ▪ fluoxetine (excluding weekly regimen & special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	19 Jan 06	19 Jul 06 (180 days)
Nov 08	ACE inhibitors – Renin Angiotensin Antihypertensives	Previously non-formulary, recommended for UF status Nov 08 ▪ ramipril (Altace generic)	BCF	▪ No changes recommended to BCF at Nov 08 meeting; ramipril removed from Non-formulary status and designated as Uniform Formulary immediately upon signing of the minutes	10 Feb 09	N/A
Oct 08 (interim teleconference meeting) & 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	24 Oct 08;; original signing date: 27 Aug 08	26 Nov 08 (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)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	▪ OneTouch Ultra 2 strips (for OneTouch Ultra 2, Ultra Mini, and Ultra Smart meters) ▪ TrueTrack strips (for TrueTrack meter) ▪ Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) ▪ Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) ▪ Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check ▪ Plus all other store/private label brand strips not included on the UF (see BCF/ECF column)	BCF	**Basic Core Formulary SMBGS test strips** ▪ Precision Xtra strips (for Precision Xtra meter) **Uniform Formulary SMBGS test strips** ▪ Accu-chek Aviva (for Accu-chek Aviva meter) ▪ Ascensia Contour (for Ascensia Contour meter) ▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters)	24 Oct 08	17 Mar 09 (120 days)
Aug 08 (**re-review**; Feb 06 original review)	Overactive Bladder (OAB) Agents	▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	**Recommended for non-formulary status Aug 08** ▪ nisoldipine geomatrix (Sular geomatrix)	BCF	No changes to BCF recommended Aug 08	24 Oct 08	7 Jan 09 (60 days)
		Previously non-formulary, recommended for UF status Nov 07 ▪ amlodipine besylate (Norvasc generic)		Recommended for addition to BCF Nov 07 ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08
		To Remain Non-Formulary ▪ isradipine IR, ER (Dynacirc; Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER HS dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently BCF ▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting) ▪ nifedipine ER (Adalat CC, generics) ▪ verapamil SR ▪ diltiazem ER (Tiazac, generics)	13 Oct 05	15 Mar 06 (150 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)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (90 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		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)

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 (update; reviewed Aug 07)	Leukotriene Modifiers	**Recommended for non-formulary status Jun 08** ▪ Zileuton ER (Zyflo CR)	BCF	No changes to BCF rec Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ valsartan amlodipine (Exforge)		No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ Moexipril +/- HCTZ (Univasc; Uniretic) ▪ perindopril (Aceon) ▪ ramipril (Altace) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) (D/C'd from market) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan+/- HCTZ (Avapro, Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- (Diovan; Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) 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 (Uroxatral) 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)

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)
Nov 07 (update, original review Nov 06)	ADHD / Narcolepsy Agents	**Recommended for non-formulary status Nov 07** ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	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	No change to BCF recommended Nov 07	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 / noreth. 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)	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)		▪ 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)	17 Jan 07	18 Mar 07
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)
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)

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 07 re-review (Feb 05 original)	ARBs	▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan +/-HCTZ (Avapro; Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- HCTZ (Diovan; 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)
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	Monoamine Oxidase Inhibitors	▪ selegiline transdermal patch (Emsam)	ECF	▪ phenelzine (Nardil)	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	-
Nov 06 (update; reviewed Nov 06)	Dermatologic Topical Antifungals*	**Recommended for non-formulary status Nov 06:** 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)	BCF	No change to BCF recommended Nov 06	14 Jul 05	17 Aug 05 (30 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)
		▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm)		▪ nystatin ▪ clotrimazole	17 Jan 07	18 Mar 07 (60 days)
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)
Feb 06 (re-classified Aug 07; and updated Jun 08; see above)	Misc Antihypertensive Agents (ACE/CCB combos now part of RAAs class)	(ACE/CCB combos now part of RAAs class) ▪ felodipine/enalapril (Lexxel) ▪ verapamil/trandolapril (Tarka)	BCF	(ACE/CCB combos now part of RAAs class) ▪ 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)
May 05	PDE5 Inhibitors	▪ sildenafil (Viagra) ▪ tadalafil (Cialis)	ECF	▪ vardenafil (Levitra)	14 Jul 05	12 Oct 05 (90 days)
May 05	MS-DMDs	-	ECF	▪ interferon beta-1a intramuscular injection (Avonex)	14 Jul 05	-

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)
BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary CFC = chlorofluorocarbon; ER = extended release; HFA = hydrofluoroalkane; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle; AD-1s: Antidepressant-1 Drugs; 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; LIP-1 = Antihyperlipidemic-1 Drugs; LIP-2 = Antihyperlipidemic-2 Drugs; MDIs = metered dose inhalers; MOAIs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NADs = Nasal Allergy Drugs; OABs = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAs = Renin Angiotensin Antihypertensives Drugs; SABAs = Short-Acting Beta Agonists; SMBGS: Self-Monitoring Blood Glucose Systems; TIBs = Targeted Immunomodulatory Biologics; TZDs= Thiazolidinediones *The Dermatologic Topical Antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])						

Appendix F — Table of Abbreviations

5-HT3	serotonin subtype 3
AE	adverse event
APR	Automated profile review
AD-1	Antidepressant-I drug class
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	Cost-effectiveness analysis
CFR	Code of Federal Regulations
CHCS	Composite Health Care System
CHD	coronary heart disease
CINV	chemotherapy induced nausea and vomiting
CMA	cost minimization analysis
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EE	erosive esophagitis
ESI	Express Scripts, Inc
ER	extended release
FCP	Federal Ceiling Price
FDA	Food and Drug Administration
FSS	Federal Supply Schedule Price
FY	fiscal year
HA	Health Affairs
HDL	high density lipoprotein
LIP-2	Antilipidemic-II drug class
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NAD	Nasal Allergy drug class
NDAA	National Defense Authorization Act
OAB	Overactive Bladder drug class
OMB	Office of Management and Budget
P&T	Pharmacy and Therapeutics
PA	prior authorization
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
PPI	Proton Pump Inhibitor drug class
PDE-5	Phosphodiesterase-type 5 inhibitor drug class
QL	quantity limit
SAR	seasonal allergic rhinitis
SNRI	serotonin norepinephrine reuptake inhibitor
TDS	transdermal system
TFL	TRICARE for life beneficiary
TG	triglyceride
TMA	TRICARE Management Activity
TMOP	TRICARE Mail Order Pharmacy
TRRx	TRICARE Retail Pharmacy Network
UF VARR	Uniform Formulary Voluntary Agreement for Retail Refunds

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
February 2009

1. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on 18 February 2009 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 MEETINGS

A. Revisions to the minutes — There were no revisions to the November 2008 DoD P&T Committee meeting minutes.

B. Approval of November minutes — S. Ward Casscells, III, MD, approved the minutes of the November 2008 DoD P&T Committee meeting on 10 February 2009.

4. REVIEW OF RECENTLY FDA-APPROVED AGENTS

Self-Monitored Blood Glucose System (SMBGS) Test Strips — TRUETest Test Strip

Relative Clinical Effectiveness — The self-monitored blood glucose system (SMBGS) test strips were evaluated for Uniform Formulary (UF) placement at the August 2008 DoD P&T Committee meeting. The other SMBGS test strips designated as formulary on the UF include Accu-chek Aviva, Precision Xtra, Freestyle Lite, and Ascensia Contour. The TRUEtest SMBGS test strip was approved by the FDA in late August 2008 and, therefore, was not included in the original UF decision. The TRUEtest test strip clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1).

The TRUEtest SMBGS test strip meets the requirements for accuracy by the FDA and the International Standard for Organization, does not require coding, is compatible with 2 SMBGS meters (TRUEresult and TRUE2go meters), requires a 0.5 microliter blood sample size, is approved for both fingertip and forearm testing, and provides results in 4 to 10 seconds. The TRUEtest SMBGS test strip employs glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) as the reagent. Other SMBGS test strips with GDH-PQQ have been rarely associated with falsely high blood glucose readings and potential patient harm when used concurrently with products containing maltose (e.g., dialysis patients receiving icodextrin dialysate solutions). The TRUEtest package label contains warnings for this interaction.

Relative Clinical Effectiveness Conclusion — The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent): 1) the TRUEtest SMBGS test strip is similar to other SMBGS test strips included on the UF, in terms of meeting the minimum technical requirements; 2) there is a high degree of therapeutic interchangeability between TRUEtest and the other SMBGS test strips included on the UF; and 3) in

terms of safety, TRUEtest is similar to other SMBGS test strips included on the UF that also use the GDH-PQQ reagent.

Relative Cost-Effectiveness — The P&T Committee evaluated the relative cost-effectiveness of TRUEtest SMBGS test strips in relation to efficacy, safety, tolerability, and clinical outcomes of the other test strips in the SMBGS 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 TRUEtest blood glucose strips. The cost-effectiveness of TRUEtest was evaluated relative to the following agents: Accu-chek Aviva, Contour, Freestyle Lite, OneTouch Ultra, Precision Xtra, and TrueTrack. The results of the CMA showed that the projected weighted average daily cost of TRUEtest was significantly lower than the weighted average daily cost of all the other SMBGS test strips.

Relative Cost-Effectiveness Conclusion — The P&T Committee concluded (14 for, 0 opposed, 1 abstained, 0 absent) that the TRUEtest SMBGS test strip for the TRUEresult and TRUE2go meters is cost effective relative to the other SMBGS test strips included on the UF when future market conditions were considered.

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, 0 opposed, 1 abstained, 0 absent) that the TRUEtest SMBGS test strip remain designated as formulary on the UF.

   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 (14 for, 0 opposed, 1 abstained, and 0 absent) to recommend: 1) the TRUEtest test strips not be added to the BCF.

   Director, TMA, Decision: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

5. DRUG CLASS REVIEW — PULMONARY I AGENTS — INHALED CORTOCOSTEROIDS (ICS)

Relative Clinical Effectiveness — The P&T Committee evaluated the clinical effectiveness of the inhaled corticosteroids (ICS) as part of the Pulmonary I drug

class. The ICS are available in several dosage formulations, including pressurized metered-dose inhalers (MDIs) and dry powder inhalers (DPIs). The MDIs use either chlorofluorocarbon (CFC) or hydrofluoroalkane (HFA) as the propellant. The ICS available as oral inhalers include beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid-M [menthol added to improve taste]), fluticasone HFA MDI (Flovent HFA), fluticasone DPI (Flovent Diskus), mometasone DPI (Asmanex Twisthaler), and triamcinolone CFC MDI (Azmacort). Budesonide (Pulmicort Respules) is also available as an inhalation solution.

The current ICS Basic Core Formulary (BCF) products are budesonide inhalation solution (Pulmicort Respules as the specified product), fluticasone oral inhaler, and triamcinolone oral inhaler. None of the oral ICS inhalers are available as generic formulations. One authorized generic formulation of budesonide inhalation solution became available in December 2008.

The US Food and Drug Administration (FDA) recommended the removal of ICS metered-dose inhalers containing a CFC propellant (flunisolide and triamcinolone) by 31 December 2009. A final decision regarding this proposed date is pending.

The Military Health System (MHS) spent over $35M on oral ICS inhalers and over $13M on ICS inhalation solutions in FY 2008. In FY 2008, for the oral ICS inhalers, expenditures in the Military Treatment Facilities (MTFs) were $16.6M, expenditures in the TRICARE Retail Network (TRRx) were $15.2M, and expenditures in the TRICARE Mail Order Pharmacy (TMOP) were $3.5M. Expenditures for the inhalation solutions in FY 2008 are as follow: MTF $2.4M, TRRx $10.0M, and TMOP $0.8M. In terms of numbers of prescriptions dispensed, fluticasone (Flovent) is the highest utilized ICS in the MHS, followed by triamcinolone (Azmacort).

Information regarding the safety, effectiveness, and clinical outcomes of the ICS was considered by the Committee. The clinical review included, but was not limited to, the requirements stated in the UF Rule, 32 CFR 199.21(e)(1). The P&T Committee was advised that there is a statutory presumption that pharmaceutical agents in a therapeutic class are clinically effective and should be included on the UF, unless the P&T Committee finds by a majority vote that a pharmaceutical agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over the pharmaceutical agents included on the UF in that therapeutic class.

Relative Clinical Effectiveness Conclusion — The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent), as part of the Pulmonary I overall relative clinical effectiveness conclusion, to accept the following regarding the clinical effectiveness of the ICS products:

A. With regard to efficacy/clinical effectiveness of the ICS, the following conclusions were made:

- FDA-approved indications — The Committee recognized that the ICS products are approved only for the maintenance treatment of asthma, and FDA-approved age ranges for pediatric patients differ between the products.

- Clinical Practice Guidelines — Evidence-based guidelines from the National Asthma Education and Preventive Program (NAEPP) consider the ICS the preferred treatment for the maintenance treatment of persistent asthma. Guidelines for the use of ICS in Chronic Obstructive Pulmonary Disease (COPD) generally recommend an ICS for severe or very severe disease. The Guidelines do not state a preference for one ICS over another.
- Pharmacodynamic/pharmacokinetic properties — The Committee concluded that despite differences in topical potency, receptor binding affinity, pulmonary bioavailability, and systemic bioavailability, the overall clinical response does not appear to vary significantly between the ICS, when equipotent doses are compared.
- Overall clinical efficacy for asthma — The Committee concluded that for asthma, there is fair-to-moderate evidence that ICS do not differ with regards to symptom control, need for rescue medication, and exacerbations in patients with asthma.
- Overall clinical efficacy for COPD — The Committee concluded that for COPD, there is insufficient evidence to conclude there are clinically relevant differences regarding the efficacy of ICS in patients with COPD.

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

- Minor adverse events — There do not appear to be clinically relevant differences in the incidence and severity of common adverse events associated with the ICS, such as dysphonia and oral candidiasis.
- Pharmacodynamic/pharmacokinetic properties — Differences in binding affinity, lipophilicity, pulmonary bioavailability, and systemic bioavailability between the ICS products have not correlated to clinically relevant differences in safety.
- Systemic adverse effects — For systemic adverse effects of hypothalamic-pituitary-adrenal (HPA) axis suppression, growth suppression, cataract formation, fracture risk, and pneumonia risk in COPD, there is insufficient evidence to determine whether one ICS is more likely to cause these effects than another. When given in recommended doses, the ICS are not generally associated with clinically significant systemic adverse effects. Providers and patients must assess the risks and benefits if higher than recommended doses are required.
- Overall safety/tolerability — The Committee concluded there is insufficient evidence to determine whether there are clinically relevant differences between ICS in terms of minor adverse events or systemic adverse events

C. With regards to differences in other factors, the following conclusions were made:

- Special Populations – Pregnancy — Budesonide is the only ICS with a pregnancy category B rating (low evidence of risk) from the FDA; the other ICS are rated pregnancy category C. The pregnancy category B rating for

budesonide was granted based on information from 3 Swedish registries and 1 prospective study. However, national guidelines for asthma from the NAEPP state there is no data to indicate the other ICS preparations are unsafe during pregnancy, and that untreated asthma in pregnancy poses a risk to the fetus, including intrauterine growth retardation, premature delivery, and low birth weight.

- Special Populations – Children — Budesonide inhalation solution (Pulmicort Respules) is approved for treating asthma in children ranging between the ages of 1 and 8 years. Fluticasone (Flovent Diskus and Flovent HFA) and mometasone (Asmanex) are approved for treating asthma in children 4 years of age and older.
- Clinical Coverage — Responses from a survey of MTF providers revealed that to meet the needs of the majority of MHS beneficiaries, both HFA metered-dose inhalers and dry powder inhalers are required for inclusion on the UF.
- Therapeutic Interchangeability — There is a high degree of therapeutic interchangeability between the ICS products.

Relative Cost-Effectiveness — In considering the relative cost-effectiveness of pharmaceutical agents in the ICS as part of the Pulmonary I 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). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost-effectiveness of the ICS.

ICS Relative Cost-Effectiveness Conclusion — Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

A. Results of the CMA revealed that beclomethasone DPI (QVAR) was the most cost-effective ICS based on acquisition cost; and

B. Results of the BIA revealed that the ICS formulary scenario that included budesonide inhalation solution, fluticasone HFA metered-dose inhaler (Flovent HFA), fluticasone dry powder inhaler (Flovent DPI), and mometasone dry powder inhaler (Asmanex Twisthaler) was the most cost-effective overall.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the cost-effectiveness conclusions stated above.

2) ***COMMITTEE ACTION: UF RECOMMENDATION*** — In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the ICS products and other relevant factors, the P&T

Committee, based upon its collective professional judgment, voted (8 for, 5 opposed, 2 abstained, 0 absent) to recommend:

a) Budesonide inhalation solution (Pulmicort Respules, generic), fluticasone HFA MDI (Flovent HFA), fluticasone DPI (Flovent Diskus), and mometasone DPI (Asmanex Twisthaler) be classified as formulary under the UF; and

b) Beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid M) and triamcinolone CFC MDI (Azmacort) be designated as non-formulary on the UF, based on cost-effectiveness.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3) ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA*** — Based on the clinical evaluation for beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid M), triamcinolone CFC MDI (Azmacort), 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 beclomethasone HFA MDI (QVAR), budesonide DPI (Pulmicort Flexhaler), ciclesonide HFA MDI (Alvesco), flunisolide CFC MDI (Aerobid, Aerobid M) and triamcinolone CFC MDI (Azmacort). (See Appendix B for full MN criteria).

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

4) ***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 one week following a 120-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 120-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin the first Wednesday one week following approval by the Director, TMA.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

5) ***COMMITTEE ACTION: BCF RECOMMENDATION*** — The P&T Committee considered the BCF status of the ICS agents. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted 14 for, 0 opposed, 1 abstained, 0 absent) to recommend: 1) fluticasone HFA MDI and DPI (Flovent HFA and Flovent Diskus) oral inhalers remain designated as BCF; and 2) mometasone DPI (Asmanex Twisthaler) be designated as BCF immediately upon signing of the February 2009 DoD P&T Committee minutes by the Director, TMA. As a result of the above actions, budesonide inhalation solution (Pulmicort Respules) would no longer be designated as BCF, but maintained as formulary on the UF.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

6. DRUG CLASS REVIEW — PULMONARY I AGENTS – LONG-ACTING BETA AGONISTS (LABAs)

Relative Clinical Effectiveness — The P&T Committee evaluated the clinical effectiveness of the long-acting beta agonists (LABAs), as part of the Pulmonary I drug class. The LABAs include 2 DPIs, salmeterol (Serevent Diskus) and formoterol (Foradil Aerolizer), and 2 inhalation solutions, formoterol solution (Perforomist) and arformoterol solution (Brovana). There are no generic formulations available for the LABAs. The current BCF LABA is salmeterol DPI (Serevent Diskus).

MHS expenditures for the LABAs in FY 2008 in the entire MHS exceeded $9.1M ($1.6M in the MTFs, $5.8M in the TRRx, and $1.7M in the TMOP). Salmeterol DPI (Serevent Diksus) is the most frequently used LABA in the entire MHS with approximately 250,000 prescriptions dispensed monthly. However overall, there is a trend for decreasing LABA use in the MHS.

Relative Clinical Effectiveness Conclusion — The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent), as part of the Pulmonary I overall relative clinical effectiveness conclusion, to accept the following regarding the clinical effectiveness of the LABA products:

A. With regard to efficacy/clinical effectiveness between the LABA oral inhalers, salmeterol DPI (Serevent Diskus) and formoterol DPI (Foradil Aerolizer), the following conclusions were made:

- FDA-approved indications — Salmeterol and formoterol have similar FDA-approved indications (asthma, COPD, and exercise-induced bronchospasm [EIB]), with the exception that their pediatric-approved ages for asthma differ.
- Pharmacokinetics — Formoterol has a faster onset of action than salmeterol, but clinical efficacy is similar for changes in forced expiratory volume in one second (FEV_1) and peak expiratory flow (PEF).

- Guidelines — Evidence-based guidelines from the NAEPP for asthma and the Global Initiative for Obstructive Lung Disease (GOLD) for COPD do not state a preference for one LABA over another.
- Asthma — For treating asthma, both salmeterol and formoterol have been shown to reduce the occurrence of asthma symptoms and reduce the need for rescue medications, when compared to placebo. Head-to-head studies show no difference between salmeterol and formoterol in relieving asthma symptoms, reduced use of rescue medications, or improvement in spirometry measures.
- COPD and EIB — There is insufficient evidence to determine if clinically relevant differences exist when treating COPD or EIB.

B. With regard to efficacy/clinical effectiveness between the LABA-inhaled solutions, formoterol solution (Perforomist), and arformoterol solution (Brovana), the following conclusions were made:

- COPD — There is insufficient evidence to determine if clinically relevant differences exist when treating COPD.
- Place in therapy — The LABA inhalation solutions are relatively new additions to the market. Recommendations regarding their most appropriate use in patients with COPD have not been discussed in national guidelines.

C. With regard to safety between the LABA oral inhalers, salmeterol DPI (Serevent Diskus), and formoterol DPI (Foradil Aerolizer):

- In patients with asthma, a higher risk of death was associated with salmeterol and formoterol use. This is based on data from the Salmeterol Multicenter Asthma Research Trial, an FDA meta-analysis conducted in 2008, and 2 Cochrane reviews. The risk of death is highest in subpopulations of African American patients and children 4 to 11 years of age. Using a LABA with an ICS reduces the risk of death in asthma. The FDA Advisory subcommittee is recommending removal of the LABA indication for asthma. These recommendations are pending approval at the FDA.
- In patients with COPD, 1 meta-analyses (Rodrigo 2008) and 1 pooled analysis have reported no increased risk of death with salmeterol or formoterol.
- For other serious adverse events, there do not appear to be clinically relevant differences between salmeterol and formoterol, based on similar numbers needed to harm (188 vs. 179, respectively) from 2 Cochrane reviews.

D. With regard to safety between the LABA-inhaled solutions, formoterol solution (Perforomist) and arformoterol solution (Brovana) for treating COPD, there is insufficient evidence to determine if clinically relevant differences exist in the adverse effect profile. The LABA-inhaled solutions are not approved for treating asthma.

E. With regard to other factors between the LABAs, the following conclusions were made:

- Ease of use: The formoterol DPI (Foradil Aerolizer) is more difficult for patients to use than salmeterol DPI (Serevent Diskus).
- Special Populations: For asthma, salmeterol is approved for a younger patient population (approved for children as young as 4 years old) compared to formoterol (approved for children as young as 5 years old).
- Storage conditions: Storage conditions are more favorable with formoterol inhalation solution (Perforomist), which is stable at room temperature for up to 12 weeks vs. 6 weeks with arformoterol inhalation solution (Brovana).
- Clinical Coverage: A survey of MTF providers showed that the majority of respondents require a LABA oral inhaler to treat their patients with COPD.
- Therapeutic Interchangeability: The Committee concluded there is a high degree of therapeutic interchangeability between the two LABA inhalation solutions and, with the exception of convenience/ease of use, there is a high degree of therapeutic interchangeability between the two LABA oral inhalers.
- Use of LABAs without concomitant use of ICS in MHS:
  - Results of a preliminary analysis reported by the Pharmacy Outcomes Research Team (PORT) indicated that of the 13,533 DoD beneficiaries who filled at least 1 prescription for a LABA during a 6-month study period (June – November 2008) at any DoD point of service, 6,118 (45%) had not filled a prescription for an ICS or an ICS/LABA combination during the 180 days prior to or the 60 days following the date of their first LABA prescription during the study period. The pronounced skew in this group toward older ages (mean: 69 years [SD 14]; median age: 72 years) and the fact that about 30% had filled an anticholinergic prescription during the same time period suggested a predominantly COPD population. Patients under 55 years of age who had not filled an anticholinergic prescription (characteristics suggesting asthma rather than COPD) made up only about 11% (655 patients) of this group. The analysis included both new and previous LABA users. It did not control for use of other health insurance or starting/stopping TRICARE coverage, both of which could result in missing data regarding concomitant ICS use.
  - The Committee agreed that the great majority of DoD beneficiaries receiving LABAs without concomitant ICS are probably COPD patients, in whom "unopposed" use of LABAs has not been associated with safety concerns, and that the absolute number of asthma patients in this category is likely to be small. However, they suggested that further analysis utilize asthma or COPD diagnoses (e.g., medical claims data or patient records) to identify patient groups and that available data be analyzed to investigate anecdotal reports of asthmatic patients discontinuing use of ICS without the knowledge of their providers after being placed on a LABA (either

because of greater perceived symptom relief or because of the difficulty of keeping up with multiple inhalers).

Relative Cost-Effectiveness — In considering the relative cost-effectiveness of pharmaceutical agents in the LABAs as part of the Pulmonary I 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). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost-effectiveness of the LABAs.

LABA Relative Cost-Effectiveness Conclusion — Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

A. Results of the CMA of the LABA oral inhalers revealed that formoterol DPI (Foradil Aerolizer) was the most cost-effective LABA oral inhaler overall;

B. Results of the CMA of the LABA inhalation solutions revealed that arformoterol solution (Brovana) was the most cost-effective overall; and

C. The BIA evaluated the potential impact of scenarios with selected LABA agents designated formulary or non-formulary on the UF. Results from the BIA revealed that the scenario that designated formoterol inhalation solution (Perforomist) non-formulary under the UF was most favorable to the MHS.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the cost-effectiveness conclusions stated above.

2) ***COMMITTEE ACTION: UF RECOMMENDATION*** — In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the LABA products 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:

   1. Salmeterol DPI (Serevent Diskus), formoterol DPI (Foradil Aerolizer) and arformoterol inhalation solution (Brovana) be classified as formulary under the UF; and

   2. Formoterol inhalation solution (Perforomist) be designated as non-formulary on the UF, based on cost-effectiveness.

Director, TMA, Decision: Ellen P. Embrey ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3) ***COMMITTEE ACTION: MN CRITERIA*** — Based on the clinical evaluation for formoterol inhalation solution (Perforomist) 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, 1 opposed, 1 abstained, 0 absent) MN criteria for formoterol inhalation solution (Perforomist). (See Appendix B for full MN criteria).

Director, TMA, Decision: Allen P. Aubrey ☑ Approved ☐ Disapproved

Approved, but modified as follows:

4) ***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 one week following a 120-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 120-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin the first Wednesday one week following approval by the Director, TMA.

Director, TMA, Decision: Allen P. Aubrey ☑ Approved ☐ Disapproved

Approved, but modified as follows:

5) ***COMMITTEE ACTION: BCF RECOMMENDATION*** — The P&T Committee considered the BCF status of the LABA agents. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 0 opposed, 2 abstained and 0 absent) to recommend that salmeterol DPI (Serevent Diskus) remain designated as BCF.

Director, TMA, Decision: Allen P. Aubrey ☑ Approved ☐ Disapproved

Approved, but modified as follows:

7. DRUG CLASS REVIEW — PULMONARY I AGENTS – INHALED CORTICOSTEROID / LONG-ACTING BETA AGONIST COMBINATIONS (ICS/LABA COMBINATIONS)

Relative Clinical Effectiveness — The P&T Committee evaluated the clinical effectiveness of the ICS/LABA combinations, as part of the Pulmonary I drug class. There are 2 ICS/LABA combinations available. Fluticasone/salmeterol (Advair Diskus) is available as both a dry powder inhaler and as an HFA metered-dose inhaler (Advair HFA). Budesonide/formoterol (Symbicort) is available as an HFA metered-dose inhaler. MHS expenditures for the ICS/LABA combinations exceeded $153M

in FY 2008 (MTF $55.2M, TRRx $75.1M, TMOP $23.4M). In terms of number of prescriptions dispensed, fluticasone/salmeterol DPI (Advair Diskus) is by far the highest utilized ICS/LABA across all 3 points of service. The current BCF product is fluticasone/salmeterol (Advair).

Relative Clinical Effectiveness Conclusion — The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent), as part of the Pulmonary I overall relative clinical effectiveness conclusion, to accept the following regarding the clinical effectiveness of the ICS/LABA combination oral inhalers:

A. With regard to efficacy/clinical effectiveness between the ICS/LABA oral inhalers, the following conclusions were made:

- FDA-approved Indications — The Committee recognized that the ICS/LABA combinations are all approved for the long-term treatment of asthma, and that pediatric age ranges differ between the products. Additionally, fluticasone/salmeterol DPI (Advair Diskus) dry powder inhaler is FDA-approved to reduce air flow obstruction and reduce exacerbations in COPD. These FDA indications for COPD apply only to the fluticasone 250 mcg /salmeterol 50 mcg Advair Diskus dosage strength. Note: Following the meeting on 27 Feb 2009, the FDA approved formoterol/budesonide DPI (Symbicort) for treating COPD.

- Efficacy/clinical effectiveness for asthma — The Committee concluded that there was fair evidence to suggest that there are no clinically relevant differences in efficacy between fluticasone/salmeterol and budesonide/formoterol for the treatment of asthma. This is based on the conclusions of 2 systematic reviews (Cochrane and the state of Oregon Drug Effectiveness Review Project) and head-to-head trials showing similar improvements in PEF, mean reduction of asthma exacerbations, and increases in the percentage of symptom-free days.

- Efficacy/clinical effectiveness for COPD — The Committee concluded that there was insufficient evidence to determine whether there are clinically relevant differences in efficacy between fluticasone/salmeterol and budesonide/formoterol for the treatment of COPD.

B. With regard to safety/tolerability:

- Product labeling — The Committee recognized that the safety information contained in the product labeling for the ICS/LABA combinations closely reflects the product labels for the individual ICS and LABA components.

- Minor adverse events — Comparative trials of the ICS/LABA combinations show that the products are generally well-tolerated. The most common adverse events are nasopharyngitis, headache, upper respiratory infection, oral candidiasis, and dysphonia. Adverse events for ICS/LABA combination are similar to those reported with an equipotent dose of the individual ICS component.

C. With regard to other factors between the ICS/LABA combination oral inhalers:

- Clinical Coverage – The Committee concluded that, to meet the needs of the majority of MHS beneficiaries, MHS providers require availability of both a metered-dose inhaler and dry powder inhaler formulation of the ICS/LABA combinations.
- Therapeutic Interchangeability — The Committee concluded that there is a high degree of therapeutic interchangeability between fluticasone/salmeterol (Advair) and budesonide/formoterol (Symbicort).
- DoD Persistence Data —
    - The PORT reported preliminary results of an analysis of persistence on treatment among DoD beneficiaries who are new users of ICS/LABA combinations (Advair or Symbicort). The study sample consisted of 3,857 patients randomly sampled from the population of DoD beneficiaries who 1) received at least 1 prescription for an ICS/LABA combination from 1 Jul 2007 to 31 Dec 2007; 2) had not received an ICS/LABA prescription in the last 365 days; 3) were between 12–55 years of age (to focus on use in adults and adolescents with asthma); and 4) were enrolled in TRICARE Prime or Plus with prescription coverage throughout the study. Persistence was measured as percentage of days covered (PDC) over 1 year. Based on ICD-9 diagnosis codes from medical claims data during the baseline and accrual periods and prescription fills for anticholinergics (indicative of COPD), 72% of the study sample had a diagnosis of asthma and 12% had a diagnosis of COPD or had received an anticholinergic prescription, with 8% of patients falling into both groups. Of the remaining 24% (n=920), about two-thirds had diagnoses for acute respiratory illness and/or allergic rhinitis, while about one-third did not have a claim coded for any study diagnosis.
    - Persistence was low compared to those found for other chronic medications, with a mean PDC over 1 year of 28.3% (SD 25.2%). Overall, only 7% of patients had a PDC of at least 80% (i.e., a cumulative days supply of at least 292 days), while 16% had a PDC of at least 50%. These findings were influenced by patients who received only an initial ICS/LABA prescription (47%), with no other fills during the 365-day follow-up period. Notably, the percentage of patients receiving only 1 ICS/LABA prescription was greatest (69%) among the 920 patients without an asthma or COPD diagnosis, compared to about 40% among the 2,957 patients who did not have asthma or COPD diagnosis. This group was also less likely than the asthma or COPD groups to be treated with any other controller medication (ICS, LABAs, leukotrienes, methylxanthines, or anticholinergics). These results suggest that a considerable proportion of ICS/LABA use may be for acute rather than chronic conditions.
    - The Committee suggested that MTFs may wish to review appropriateness of ICS/LABA combination use at their facilities,

particularly with regard to acute vs. chronic use. They also agreed that formulary management documents sent to MTFs should call attention to the potential for low persistence among new users of ICS/LABAs, even those diagnosed with chronic conditions such as asthma or COPD. They agreed with plans for further analysis in this area.

Relative Cost-Effectiveness — In considering the relative cost-effectiveness of pharmaceutical agents in the ICS/LABA combination oral inhalers as part of the Pulmonary I 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). Cost minimization analysis (CMA) and budget impact analysis (BIA) were used to evaluate the cost-effectiveness of the ICS/LABA combinations.

LABA Relative Cost-Effectiveness Conclusion — Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded the following:

A. Results of the CMA of the ICS/LABA combination oral inhalers revealed that budesonide/ formoterol (Symbicort) was the most cost-effective combination inhaler agent overall; and

B. The BIA evaluated the potential impact of scenarios with selected ICS/LABA combination agents designated formulary or non-formulary on the UF. Results from the BIA revealed that the scenario that designated budesonide/ formoterol (Symbicort) inhaler non-formulary (with an automated prior authorization) under the UF was most favorable to the MHS.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (15 for, 0 opposed, 0 abstained, 0 absent) to accept the cost-effectiveness conclusions stated above.

2) ***COMMITTEE ACTION: UF RECOMMENDATION*** — In view of the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the ICS/LABA combination products and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (12 for, 2 opposed, 1 abstained, 0 absent) to recommend that:

   1. Fluticasone/salmeterol HFA (Advair HFA) and DPI (Advair Diskus) and budesonide/formoterol (Symbicort) inhaler be classified as formulary on the UF; and

   2. That no ICS/LABA combination agents be designated as non-formulary under the UF, based on cost-effectiveness.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

3) ***COMMITTEE ACTION: BCF RECOMMENDATION*** — The P&T Committee considered the BCF status of the ICS/LABA agents. 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 fluticasone/salmeterol DPI (Advair Diskus) and fluticasone/salmeterol HFA MDI (Advair HFA) remain designated as BCF immediately on signing of the February 2009 DoD P&T Committee minutes by the Director, TMA.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

8. UTILIZATION MANAGEMENT — PRIOR AUTHORIZATIONS (PA) / Quantity Limits (QL) / MEDICAL NECESSITY (MN)

A. Nasal Allergy Drugs — Quantity Limits (QLs): The Nasal Allergy Drugs were reviewed for UF placement at the November 2008 DoD P&T Committee meeting. The class is comprised of the nasal inhaled corticosteroids, nasal antihistamines, and nasal anticholinergic agents. The 2 newest products in the class are the nasal corticosteroid ciclesonide (Omnaris) and the nasal antihistamine olopatadine (Patanase). QLs are in place for the other members of the nasal allergy drug class, which take into account FDA-approved dosing. The Committee recommended QLs for ciclesonide and olopatadine nasal inhalers, consistent with the other members in the class.

1) ***COMMITTEE ACTION:*** The Committee voted (13 for, 1 opposed, 1 abstained, 0 absent) to recommend quantity limits for ciclesonide nasal inhaler (Omnaris) of 6 bottles per 90 days in the TMOP, and 2 bottles per 30 days in the TRRx; and for olopatadine nasal inhaler (Patanase) of 6 bottles per 90 days in the TMOP, and 2 bottles per 30 days in the TRRx.

Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Fluticasone/salmeterol Oral HFA MDI (Advair HFA) — QLs: The ICS/LABA combination oral inhalers have QLs in place that take into account FDA-approved dosing and safety information. The fluticasone/salmeterol oral DPI (Advair Diskus) has current QLs of 3 inhalers (180 doses) per 90 days in the TMOP, and 1 inhaler (60 doses)/30 days in the TRRx.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend QLs for fluticasone/salmeterol HFA MDI (Advair HFA) of 2 inhalers per 30 days in the TRRx, and 6 inhalers per 90 days in the TMOP.

Director, TMA, Decision: Ellen P. Embrey ☑ Approved ☐ Disapproved
Approved, but modified as follows:

C. **Antifungal Prior Authorization** — The prior authorization (PA) was reviewed for terbinafine (Lamisil and generics), itraconazole (Sporanox and generics) and ciclopirox lacquer (Penlac and generics). The PA was placed due to the high cost of the drugs and potential hepatotoxic adverse effects. With the introduction of generic products, the price of the drugs has significantly fallen. COL Trinka Coster, MD, from the Pharmacovigilance Center presented data that indicated the rates for signals for these drugs in the safety databases were very low.

1) ***COMMITTEE ACTION:*** The P&T Committee voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend removing the Antifungal Prior Authorization requirement for terbinafine (Lamisil), itraconazole (Sporonax), and ciclopirox nail lacquer (Penlac).

Director, TMA, Decision: Ellen P. Embrey ☑ Approved ☐ Disapproved
Approved, but modified as follows:

9. ITEMS FOR INFORMATION

A. **Ezetimibe / Simvastatin (Vytorin) Safety Update** — LtCol James McCrary provided the Committee with an update on recent safety information for ezetimibe/simvastatin (Vytorin). The Antilipidemic I class, which includes the statins, ezetimibe, niacin and their combination products, will be re-reviewed for UF status at an upcoming meeting

B. **MTF and TMOP Pricing Update** — Contracts for products with Federal Supply Schedule prices are in the review stage of the contract cycle. The contracts are reviewed at the Veteran's Administration National Acquisition Center (VA NAC). As of 1 February 2009, the VA NAC had completed 200 out of 246 contract reviews. Drug manufacturers are able to adjust prices due to changes in market conditions. A review of the impact of price changes on spending indicated that spending in the MTFs could increase by approximately 7% and spending at the TMOP point of service could increase by 6%. These price changes should have little effect on spending in TRRx.

C. **Patient Safety / Pharmacovigilance** — COL Coster provided the Committee with information on data mining in the Adverse Event Reporting System (AERS) database. The goal of data mining is to detect increased signals of adverse events that can be further evaluated for significance. Definitions and term hierarchy of the Medical Dictionary for Regulated Activities were presented. Limitations were discussed; e.g., no denominator data, missing data, drug name errors, underreporting, over reporting

due to publicity, lack of consistent diagnostic criteria. AERS data mining information will be presented during initial drug class committee presentations.

D. Extended Core Formulary (ECF) — The PEC had previously briefed the Committee on efforts to implement electronic prescribing in the MHS. As part of the ongoing plan to systematically review drugs represented on the BCF and ECF, the Committee periodically reviews recommendations for changes to the BCF and ECF, which will also assist with electronic prescribing. The Committee previously reviewed changes to the BCF at the November 2008 DoD P&T Committee meeting. Further information will be presented at an upcoming meeting for recommendations for changes to the ECF; no action necessary.

10) ADJOURNMENT

The meeting adjourned at 1700 hours on 18 February 2009. The next meeting will be 13–14 May 2009.

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:

COL John Kugler, MC, USA
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

~~S. Ward Casscells, III, M.D.~~
Ellen P. Embrey
(performing the Duties of
ASD/HA)

Appendix A – Attendance

Voting Members Present	
COL John Kugler, MC	DoD P&T Committee Chair
LTC Stacia Spridgen, MSC	Director DoD Pharmacoeconomic Center (Recorder)
COL Ted Cieslak, MC	Army, Physician at Large
COL Peter Bulatao *for Col Carol Labadie, MSC*	Army, Pharmacy Officer, Alternate
Col Everett McAllister, BSC	Chief, Pharmaceutical Operations Directorate
CAPT Stephanie Simon, MSC	Navy, Pharmacy Officer
CAPT Vernon Lew	Coast Guard, Pharmacy Officer
Col Mark Butler, BSC	Consultant to the AF/SG
LTC Bruce Lovins, MC	Army, Family Practice Physician, Alternate
COL Doreen Lounsbery, MC	Army, Internal Medicine Physician, Alternate
CDR Walter Downs, MC *for LCDR Scott Akins*	Navy, Internal Medicine Physician, Alternate
CDR David Tanen, MC	Navy, Physician at Large
Lt Col Brian Crownover, MC	Air Force, Physician at Large
Major Jeremy King, MC	Air Force, OB/GYN Physician
Mr. Joe Canzolino	Department of Veterans Affairs
Voting Members Absent	
LCDR Michelle Perrello, MC	Navy, Internal Medicine Physician
COL Carol Labadie, MSC	Army, Pharmacy Officer
Major William Hannah, MC	Air Force, Internal Medicine Physician
LCDR Scott Akins, MC	Navy, Pediatrics Physician Alternate
Nonvoting Members Present	
CDR James Ellzy	DoD P&T Vice Chairman
Ms. Carol Cooper	Deputy General Counsel, TMA
COL Kent Maneval, MSC	Defense Medical Standardization Board
Maj Peter Trang	Defense Supply Center Philadelphia
Mr. William Davies	TMOP/TRRx Contracting Officer on Record
Nonvoting Members Absent	
Lt Col Paul Hoerner, BSC	Deputy Director, DoD Patient Safety Center

Appendix A – Attendance – (continued)

Guests	
Col Trinka Coster, MC	Pharmacovigilance Center (PVC), Army, Office of the Surgeon General
CAPT Sheri Kirshner	Fort Detrick, Defense Medical Standardization Board
LtCol Teresa Bisnett, MC	Wilford Hall Medical Center
Lt Col Don Faust	Office of the Assistant Secretary of Defense, Health Affairs
LCDR Mike Lee	Indian Health Service
Debra Khachikian, PharmD	Department of Veterans Affairs PBM
Annabel Schumacher, PharmD	Wilford Hall Medical Center
Others Present	
CDR Matthew Carlberg	DoD Pharmacoeconomic Center
Lt Col James McCrary, MC	DoD Pharmacoeconomic Center
MAJ Misty Carlson, MC	DoD Pharmacoeconomic Center
Maj Joshua Devine, BSC	DoD Pharmacy Outcomes Research Team
Shana Trice, PharmD	DoD Pharmacy Outcomes Research Team
Eugene Moore, PharmD	DoD Pharmacoeconomic Center
Angela Allerman, PharmD	DoD Pharmacoeconomic Center
David Meade, PharmD	DoD Pharmacoeconomic Center
Jeremy Briggs, PharmD	DoD Pharmacoeconomic Center
Dean Valibhai, PharmD	DoD Pharmacy Operations Center contractor
Brian Beck, PharmD	DoD Pharmacy Operations Center contractor
Roger Potyk, PharmD	DoD Pharmacy Outcomes Research Team contractor
Stephen Yarger, PhD	DoD Pharmacy Outcomes Research Team contractor
Esmond Nwokeji, PhD	DoD Pharmacy Outcomes Research Team contractor
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor

Appendix B – Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Beclomethasone HFA MDI (Qvar) Budesonide MFA MDI (Pulmicort Flexhaler) Ciclesonide HFA MDI (Alvesco) Flunisolide CFC MDI (Aerobid, Aerobid M) Triamcinolone CFC MDI (Azmacort) **Inhaled Corticosteroids (ICS)**	• Use of formulary alternatives is contraindicated • Formulary agents have resulted or are likely to result in therapeutic failure. • No alternative formulary agent is available - specifically applies to budesonide, as it is pregnancy category B.
Formoterol (Perforomist) inhalation solution **Long-Acting Beta Agonists (LABAs)**	• Use of formulary alternatives is contraindicated • The patient has experienced or is likely to experience significant adverse effects from formulary alternatives. • The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.

CFC: chlorofluorocarbon

HFA: hydrofluroalkane

MDI: metered dose inhaler

*: CFC-containing pressurized MDIs likely will cease marketing as of 31 Dec 2009

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)
Feb 09	Inhaled Corticosteroids	▪ Beclomethasone HFA MDI (Qvar) ▪ Budesonide MFA MDI (Pulmicort Flexhaler) ▪ Ciclesonide HFA MDI (Alvesco) ▪ Flunisolide CFC MDI (Aerobid, Aerobid M) ▪ Triamcinolone CFC MDI (Azmacort)	BCF	▪ Fluticasone DPI (Flovent Diskus) ▪ Fluticasone HFA MDA (Flovent HFA)	pending approval	pending approval
Feb 09	Long-Acting Beta Agonists	▪ formoterol inhalation solution (Perforomist)	BCF	▪ Salmeterol DPI (Serevent Diskus)	pending approval	pending approval
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(No ICS/LABA combinations recommended for NF placement Feb 09)	BCF	▪ Fluticasone/salmeterol DPI (Advair Diskus) ▪ Fluticasone/salmeterol HFA MDI (Advair HFA)	pending approval	pending approval
Nov 08	Short-Acting Beta Agonists	▪ albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured) ▪ metaproterenol (Alupent) CFC MDI (no longer marketed) ▪ metaproterenol inhalation solution ▪ pirbuterol (Maxair) MDI	BCF	▪ Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI ▪ Albuterol inhalation solution; Note – does not include the following: Accuneb 0.021% [0.63 mg/mL] Accuneb 0.042% [1.25 mg/3mL] Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial]	10 Feb 09	8 Apr 09 (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)
Nov 08 (update to include nasal antihistamines; nasal steroids reviewed Nov 05 & Aug 07 for Veramyst)	Nasal Allergy Drugs	▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
Nov 08 & Aug 08 (update; reviewed Nov 05)	Antidepressants I	**Recommended for non-formulary status Aug 08; no change to non-formulary status in Nov 08** ▪ desvenlafaxine (Pristiq)	BCF	No changes to BCF recommended Aug 08	10 Feb 09; original signing date 24 Oct 08	7 Jan 09 (60 days)
Aug 08 (update; reviewed Nov 05)	Antidepressants I	To remain NF ▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg weekly admin. (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL)	BCF	Currently BCF ▪ citalopram ▪ fluoxetine (excluding weekly regimen & special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	19 Jan 06	19 Jul 06 (180 days)
Nov 08	ACE inhibitors – Renin Angiotensin Antihypertensives	Previously non-formulary, recommended for UF status Nov 08 ▪ ramipril (Altace generic)	BCF	▪ No changes recommended to BCF at Nov 08 meeting; ramipril removed from Non-formulary status and designated as Uniform Formulary immediately upon signing of the minutes	10 Feb 09	N/A
Oct 08 (interim teleconference meeting) & 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	24 Oct 08;; original signing date: 27 Aug 08	26 Nov 08 (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)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	▪ OneTouch Ultra 2 strips (for OneTouch Ultra 2, Ultra Mini, and Ultra Smart meters) ▪ TrueTrack strips (for TrueTrack meter) ▪ Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) ▪ Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) ▪ Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check ▪ Plus all other store/private label brand strips not included on the UF (see BCF/ECF column)	BCF	**Basic Core Formulary SMBGS test strips** ▪ Precision Xtra strips (for Precision Xtra meter) **Uniform Formulary SMBGS test strips** ▪ Accu-chek Aviva (for Accu-chek Aviva meter) ▪ Ascensia Contour (for Ascensia Contour meter) ▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters)	24 Oct 08	17 Mar 09 (120 days)
Aug 08 (**re-review;** Feb 06 original review)	Overactive Bladder (OAB) Agents	▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	**Recommended for non-formulary status Aug 08** ▪ nisoldipine geomatrix (Sular geomatrix)	BCF	No changes to BCF recommended Aug 08	24 Oct 08	7 Jan 09 (60 days)
		Previously non-formulary, recommended for UF status Nov 07 ▪ amlodipine besylate (Norvasc generic)		Recommended for addition to BCF Nov 07 ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08
		To Remain Non-Formulary ▪ isradipine IR, ER (Dynacirc; Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER HS dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently BCF ▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting) ▪ nifedipine ER (Adalat CC, generics) ▪ verapamil SR ▪ diltiazem ER (Tiazac, generics)	13 Oct 05	15 Mar 06 (150 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)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (90 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)		Currently BCF ▪ gemfibrozil	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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		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)

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 (update; reviewed Aug 07)	Leukotriene Modifiers	**Recommended for non-formulary status Jun 08** ▪ Zileuton ER (Zyflo CR)	BCF	No changes to BCF rec Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		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	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ valsartan amlodipine (Exforge)		No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ Moexipril +/- HCTZ (Univasc; Uniretic) ▪ perindopril (Aceon) ▪ ramipril (Altace) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) (D/C'd from market) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan+/- HCTZ (Avapro, Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- (Diovan; Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) 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 (Uroxatral) 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)

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)
Nov 07 (update, original review Nov 06)	ADHD / Narcolepsy Agents	**Recommended for non-formulary status Nov 07** ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	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	No change to BCF recommended Nov 07	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 / noreth. 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
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)
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)

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 07 re-review (Feb 05 original)	ARBs	▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan +/-HCTZ (Avapro; Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- HCTZ (Diovan; 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)
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	Monoamine Oxidase Inhibitors	▪ selegiline transdermal patch (Emsam)	ECF	▪ phenelzine (Nardil)	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	-
Nov 06 (update; reviewed Nov 06)	Dermatologic Topical Antifungals*	**Recommended for non-formulary status Nov 06:** 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)	BCF	No change to BCF recommended Nov 06	14 Jul 05	17 Aug 05 (30 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)
		▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm)		▪ nystatin ▪ clotrimazole	17 Jan 07	18 Mar 07 (60 days)
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)
Feb 06 (re-classified Aug 07; and updated Jun 08; see above)	Misc Antihypertensive Agents (ACE/CCB combos now part of RAAs class)	(ACE/CCB combos now part of RAAs class) ▪ felodipine/enalapril (Lexxel) ▪ verapamil/trandolapril (Tarka)	BCF	(ACE/CCB combos now part of RAAs class) ▪ 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)
May 05	PDE5 Inhibitors	▪ sildenafil (Viagra) ▪ tadalafil (Cialis)	ECF	▪ vardenafil (Levitra)	14 Jul 05	12 Oct 05 (90 days)
May 05	MS-DMDs	-	ECF	▪ interferon beta-1a intramuscular injection (Avonex)	14 Jul 05	-

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)
BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary CFC = chlorofluorocarbon; ER = extended release; HFA = hydrofluoroalkane; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle; AD-1s: Antidepressant-1 Drugs; 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; LIP-1 = Antihyperlipidemic-1 Drugs; LIP-2 = Antihyperlipidemic-2 Drugs; MDIs = metered dose inhalers; MOAIs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; NADs = Nasal Allergy Drugs; OABs = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAs = Renin Angiotensin Antihypertensives Drugs; SABAs = Short-Acting Beta Agonists; SMBGS: Self-Monitoring Blood Glucose Systems; TIBs = Targeted Immunomodulatory Biologics; TZDs= Thiazolidinediones *The Dermatologic Topical Antifungal drug class excludes vaginal products and products for onychomycosis (e.g., ciclopirox topical solution [Penlac])						