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.

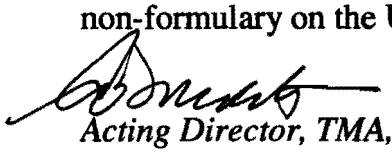
Relative Cost-Effectiveness — The P&T Committee evaluated the cost of milnacipran (Savella) in relation to the efficacy, safety, tolerability, and clinical outcomes of the other SNRIs in the AD-1 class, as well as other medically-accepted treatments for fibromyalgia. Information considered by the P&T 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.

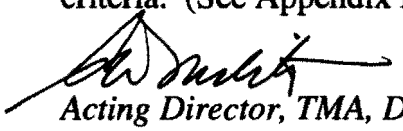
1. ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness, relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (14 for, 1 opposed, 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.

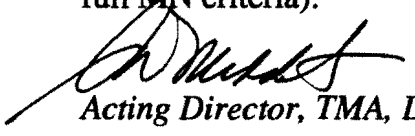
Relative Cost-Effectiveness Conclusion — The P&T Committee, based upon its collective professional judgment, voted (16 for, 0 opposed, 0 abstained, 0 absent) that tapentadol (Nucynta) is not cost effective relative to the other immediate release, single component high potency agents in the narcotic analgesic 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

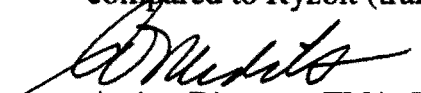
therapeutic advantage in terms of efficacy and safety, compared to the other tramadol products available on the UF.

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:

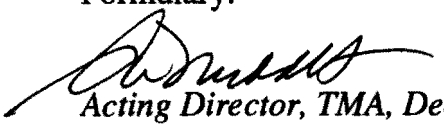
4. ***COMMITTEE ACTION — TRANSITION DATE AT THE MTF POS:*** The P&T Committee voted (13 for, 0 against, 0 abstained, 3 absent) to recommend a transition period at the MTF POS as ending no later than 1 January 2011.

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

[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]
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
[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]
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 Mailed Patients
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 Exempt
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**

[redacted]	[redacted]	[redacted]	[redacted]
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

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[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	BCF/ECF Placement	Implementation Date for Non-Formulary Recommendation	Implementation Date for BCF/ECF Placement
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)

Meeting	Drug Class	Non-Formulary Medications	[illegible]	BCF/ECF Medications	[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

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)

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)

Meeting	Drug Class	Non-Formulary Medications	BCF ECF Class	BCF/ECF Medications	Decision Date [illegible]	Effective Date of [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]	[illegible]	[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]	[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