DOD PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL

I. Uniform Formulary Review Process

Under 10 U.S.C. § 1074g, as implemented by 32 C.F.R. 199.21, the DoD P&T Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, TMA, on formulary status, pre-authorizations, and the effective date for a drug's change from formulary to non-formulary status receive comments from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director before making a final decision.

II. UNIFORM FORMULARY CLASS REVIEWS — Phosphodiesterase Type-5 (PDE-5) INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (PAH)

P&T Comments

A. PDE-5 INHIBITORS for 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).

Relative Clinical Effectiveness Conclusion — The P&T Committee recommended 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. Revatio 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, Revatio and Adcirca 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) Revatio and Adcirca 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 Revatio was shown in one trial that used doses four times higher than the FDA-approved dose, and used adjunctive IV Flolan treatment in all the patients.

(2) Adcirca 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 Revatio and Adcirca 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. Revatio and Adcirca 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).

COMMITTEE ACTION: The P&T Committee voted recommended (16 for, 0 opposed, 0 abstained, 0 absent) to accept the clinical effectiveness conclusion stated above.

B. PDE-5 INHIBITORS for PAH — Relative Cost-Effectiveness

The P&T Committee, based upon its collective professional judgment, agreed that:

1. Results from the cost minimization analysis (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.

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

COMMITTEE ACTION: The P&T Committee voted 16 for, 0 opposed, 0 abstained, 0 absent) to accept the cost effectiveness conclusion stated above.

C. PDE-5 INHIBITORS for PAH — Uniform Formulary 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.

D. PDE-5 INHIBITORS — Uniform Formulary Implementation Plan

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 TRICARE Pharmacy Benefits Program (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.

III. UNIFORM FORMULARY CLASS REVIEWS — Phosphodiesterase Type-5 (PDE-5) INHIBITORS FOR PSH

BAP Comments

A. PDE-5 INHIBITORS for PAH — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Phosphodiesterase Type-5 inhibitors for pulmonary arterial hypertension, and other relevant factors, the P&T Committee voted to recommend sildenafil (Revatio) remain classified as formulary on the UF, and tadalafil (Adcirca) be designated as non-formulary under the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. PDE-5 INHIBITORS — Uniform Formulary Implementation Plan

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

IV. NEWLY APPROVED DRUGS — Multiple Sclerosis - Disease-Modulating Drugs (MS-DMDs) — Interferon Beta-1b Injection (Extavia)

P&T Comments

A. 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 Extavia to 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.

COMMITTEE ACTION: The P&T Committee voted 15 for, 0 opposed, 0 abstained, 1 absent) to accept the clinical effectiveness conclusion stated above.

B. Extavia— 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).

COMMITTEE ACTION: 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.

C. Extavia — Uniform Formulary 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 injection (Extavia) be designated non-formulary on the UF.

D Extavia — Uniform Formulary Implementation Plan

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.

V. NEWLY APPROVED DRUGS – Multiple Sclerosis - Disease-Modulating Drugs (MS-DMDs) — Interferon Beta-1b Injection (Extavia)

BAP Comments

A. Extavia — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Multiple Sclerosis-Disease Modulating Drugs, and other relevant factors, the P&T Committee voted to recommend interferon beta-1b injection (Extavia) be designated non-formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Extavia — Uniform Formulary Implementation Plan

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur Additional Comments and Dissentions:

VI. NEWLY APPROVED DRUGS — Bupropion Hydrobromide Extended Release (Bupropion HBr ER) Tablets (Aplenzin)

P&T Comments

A. 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.

Aplenzin was approved under section 505(b)(2) of the Federal Food, Drug, and Cosmetic (FDC) Act after demonstrating bioequivalence to bupropion hydrochloride extended release tablets (Wellbutrin XL). The other NDRIs on the UF are bupropion HCl immediate release (Wellbutrin IR, generics) and bupropion HCl sustained release (Wellbutrin SR, generics). Aplenzin tablets are dosed daily, whereas the IR and SR formulations of Wellbutrin 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.

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: 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.

COMMITTEE ACTION: The P&T Committee voted (to accept the clinical effectiveness conclusion stated above.

B. Aplenzin — 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.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Aplenzin — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the AD-1s, and other relevant factors, the P&T Committee voted (14 for, 0 opposed, 2 abstained, 0 absent) to recommend bupropion HBr ER tablets (Aplenzin) be designated as non-formulary under the UF, based on cost effectiveness.

D. Aplenzin — Uniform Formulary Implementation Plan

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.

VII. NEWLY APPROVED DRUGS — Bupropion Hydrobromide Extended Release (Bupropion HBr ER) Tablets (Aplenzin)

BAP Comments

A. Aplenzin — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Antidepressant-1s drug class, and other relevant factors, the P&T Committee voted to recommend bupropion hydrobromide extended release tablets (Aplenzin) be designated as non-formulary under the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Aplenzin — Uniform Formulary Implementation Plan

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

VIII. NEWLY APPROVED DRUGS Antidepressant-1s (AD-1s) — Milnacipran Tablets (Savella)

P&T Comments

A. 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). Savella is approved for depression outside of the US, but the manufacturer will not seek FDA approval for depression.

In clinical trials, Savella significantly improved a composite of fibromyalgia symptoms when compared to placebo. There are no direct comparative clinical trials between Savella and the other medications that are FDA-approved or used off-label for the management of fibromyalgia. Meta-analyses have shown that the antidepressants (SSRIs and TCAs) and Flexeril are efficacious in treating fibromyalgia.

Other Factors — The Pharmacy Outcomes Research Team (PORT) reported results of an analysis comparing the frequency of ICD-9 diagnosis codes indicative of fibromyalgia or related conditions among patients receiving SNRIs (Cymbalta or Effexor), GABA analogs (Lyrica or gabapentin), or the SSRI citalopram (Celexa).

Based on the results of the PORT analysis, the Committee agreed that it was unlikely that fibromyalgia represents the most common use for any of the studied medications. Taken together with Savella's regulatory approval and use for depression outside the U.S. and multiple uses for the other study agents with a fibromyalgia FDA-approved indication, the Committee did not feel that the results supported consideration of a separate drug class for fibromyalgia, even given Savellas'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 Flexeril, 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Savella — 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

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Savella — Uniform Formulary 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.

D. Savella— Uniform Formulary Implementation Plan

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.

IX. NEWLY APPROVED DRUGS Antidepressant-1s (AD-1s) — Milnacipran Tablets (Savella)

BAP Comments

A. Savella — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Andtidepressant-1s drug class, and other relevant factors, the P&T Committee voted to recommend milnacipran tablets (Savella) be designated non-formulary on the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Savella — Uniform Formulary Implementation Plan

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

X. NEWLY APPROVED DRUGS — Overactive Bladder Drugs (OABs) — Oxybutynin Topical Gel (Gelnique)

P&T Comments

A. 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 gel available in a 1 gram packet 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).

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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Gelnique — 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.

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

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Gelnique — Uniform Formulary 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.

D. Gelnique — Uniform Formulary Implementation Plan

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..

XI. NEWLY APPROVED DRUGS Overactive Bladder Drugs (OABs) — Oxybutynin Topical Gel (Gelnique)

BAP Comments

A. Gelnique — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Overactive Bladder Drugs, and other relevant factors, the P&T Committee voted to recommend Gelnique be designated as non-formulary under the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Gelnique – Uniform Implementation Plan

The P&T Committee recommended 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..

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

XII. NEWLY APPROVED DRUGS — Narcotic Analgesics — Tapentadol Tablets (Nucynta)

P&T Comments

A. 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 is 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. Nucynta'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 pivotal trials used to obtain FDA approval reported that Nucynta 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 bunion

surgery. There are no published direct comparative trials between Nucynta and other narcotic analgesics. The safety profile of Nucynta 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 Nucynta may cause less constipation 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 of Nucynta in patient outcomes, in terms of efficacy and safety, compared to the other narcotic analgesics already on the UF

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Nucynta — Relative Cost Effectiveness

The P&T Committee evaluated the cost of Nucynta 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

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Nucynta — Uniform Formulary 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).

D. Nucynta — Uniform Formulary Implementation Plan

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.

XIII. NEWLY APPROVED DRUGS Narcotic Analgesics — Tapentadol Tablets (Nucynta)

BAP Comments

A. Nucynta — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Narcotic Analgesics and other relevant factors, the P&T Committee voted to recommend Nucynta be designated as non-formulary under the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Nucynta – Uniform Implementation Plan

The P&T Committee recommended 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

XIV. NEWLY APPROVED DRUGS — Narcotic Analgesics — Tramadol Extended Release Tablets (Ryzolt)

P&T Comments

A. 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

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Ryzolt — Relative Cost Effectiveness

The P&T Committee evaluated the cost of the tramadol ER (Ryzolt) 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)

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).

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Ryzolt — Uniform Formulary 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).

D. Ryzolt— Uniform Formulary Implementation Plan

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.

XV. NEWLY APPROVED DRUGS Narcotic Analgesics — Tramadol Extended Release Tablets (Ryzolt)

BAP Comments

A. Ryzolt — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Narcotic Analgesics and other relevant factors,

the P&T Committee voted to recommend Ryzolt be designated as non-formulary under the UF, based on cost effectiveness.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Ryzolt – Uniform Formulary Implementation Plan

The P&T Committee recommended) 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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

XVI. NEWLY APPROVED DRUGS — Renin Angiotensin Aldosterone Antihypertensive Agents (RAAs) —Valsartan / Amlodipine / Hydrochlorothiazide (HCTZ) Tablets (Exforge HCT)

P&T Comments

A. Exforge HCT — Relative Clinical Effectiveness

Exforge HCT is a fixed-dose combination product containing three drugs: the Angiotensin Receptor Blocker (ARB) valsartan (Diovan), the calcium channel blocker amlodipine (Norvasc, generics), and the diuretic hydrochlorothiazide (HCTZ, generics). It is the first three-drug combination product approved for hypertension. Exforge HCT 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 on the UF (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 Exforge HCT is similar to that of the individual ARB, calcium channel blocker, 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 and peripheral edema occurred less frequently with Exforge HCT than what is reported when two drugs combinations are administered.

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 by 15% when reducing from three tablets to two, and improve 10% when reducing from 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 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.

COMMITTEE ACTION: The P&T Committee voted to accept the clinical effectiveness conclusion stated above.

B. Exforge HCT — Relative Cost Effectiveness

The P&T Committee evaluated the cost of 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.

COMMITTEE ACTION: The P&T Committee voted to accept the cost effectiveness conclusion stated above.

C. Exforge HCT — Uniform Formulary 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) to recommend that valsartan/amlodipine/HCTZ (Exforge HCT) be designated as non-formulary on the UF, thus Exforge HCT will retain uniform formulary status.

D. Exforge HCT— Uniform Formulary Implementation Plan – does not apply

XVII NEWLY APPROVED DRUGS Renin Angiotensin Aldosterone Antihypertensive Agents (RAAs) —Valsartan / Amlodipine / Hydrochlorothiazide (HCTZ) Tablets (Exforge HCT)

BAP Comments

A. Exforge HCT — Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the Renin Angiotensin Antihypertensive Agents drugs class and other relevant factors, the P&T Committee voted to recommend Exforge HCT remain classified as formulary under the UF.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. Exforge HCT – Uniform Formulary Implementation Plan – Does not apply

XVIII. RE-EVALUATION OF WELLBUTRIN XL's UNIFORM FORMULARY STATUS: Status of Bupropion HCl ER Tablets (Wellbutrin XL) on the UF

P&T Comments

A. Wellbutrin XL Clinical and Cost Effectiveness:

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.

B. Wellbutrin XL – Uniform Formulary 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 (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.

XIX. RE-EVALUATION OF WELLBUTRIN XL's UNIFORM FORMULARY STATUS: Status of Bupropion HCl ER Tablets (Wellbutrin XL) on the UF

BAP Comments

A. Wellbutrin XL – Uniform Formulary 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 (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

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

XX. IMPLEMENTATION OF FEDERAL CEILING PRICE REGULATION

P&T Comments

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, and also reviewed drugs that were not included on a DoD Retail Refund Pricing Agreement at the November 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.

The DoD P&T Committee recommended the following:

A. The following branded drugs with generic equivalents follow the standard TRICARE rules for brand-generic prior-authorization criteria.

Aclovate	Altace	Carnitor, Carnitor SF
Cutivate	Cytoxan	Depakene
Kaon-CL	Mobic	Omnicef
Persantine	Pletal	Septra; Septra DS
Silvadene	Tapazole	Temovate
Viroptic	Zonegran	

B. The implementation date for the medical necessity criteria for the branded drugs will not be prior to 1 April 2010 and not later than 180 days after the minutes of this meeting are signed.

C. The transition period at the MTF POS for the medical necessity criteria for the branded drugs as ending no later than 1 January 2011.

D. The following drugs retain formulary status on the Uniform Formulary.

ARICEPT
ARICEPT ODT
DILANTIN
EPIPEN
EPIPEN JR
FARESTON
HEXALEN
MENOPUR
MESNEX
QUALAQUIN
TARGRETIN
VANCOCIN HC

E. The following drugs retain non-formulary status or be designated non-formulary on the Uniform Formulary.

ADOXA	CYCLOGYL	ESGIC	METHYLIN ER
ALLEGRA	CYCLOSPORINE	ESGIC-PLUS	MIMYX
ALOCRIL	DARVOCET A500	FML	MONONESSA
AMICAR	DARVOCET-N 100	FML FORTE	NATAFORT
ANTABUSE	DARVOCET-N 50	FML S.O.P.	NORCO
ARMOUR THYROID	DARVON	FRAGMIN	OCUFEN
AVAGE	DARVON-N	GENGRAF	OCUFLOX
AZASAN	DENAVIR	GLUCAGEN	OGEN
AZELEX	DILANTIN	GRANULEX	OPTASE
BANZEL	DILTZAC ER	HYCET	PACERONE
BETAGAN	DORAL	INDERAL LA	PERANEX HC
BIAXIN XL	DUET STUARTNATAL	KERAFOAM	PERPHENAZINE
BLEPHAMIDE	E.E.S. 200	LAMICTAL ODT	PHRENILIN FORTE
BLEPHAMIDE SOP	E.E.S. 400	LAMICTAL ODT (BLUE)	POLY-PRED
BRAVELLE	ELDOPAQUE FORTE	LAMICTAL ODT (GREEN)	POLYTRIM
BREVOXYL-4	ELDOQUIN FORTE	LAMICTAL ODT (ORANGE)	PRED MILD
BREVOXYL-8	ELESTAT	LAMICTAL XR	PRED-G
CAFCIT	ELIMITE	LINDANE	PRIMSOL
CAPITAL W-CODEINE	EMLA	LO-OVRAL-28	PROCTOCORT
CARDENE SR	EPIFOAM	LORCET 10-650	PROCTOFOAM-HC
CITRANATAL 90 DH	ERGOLOID MESYLATES	LORCET PLUS	PROGLYCEM
CITRANATAL DH	ERYPED 200	LORTAB	

Continued on next page

Drugs retaining non-formulary status or being designated as non-formulary continued from previous page

CITRANATAL RX	ERYPED 400	MAGNACET	REPRONEX
CLARIFOAM EF	ERY-TAB	MAVIK	RIMSO-50
CLINDESSE	ERYTHROCIN STEARATE	MAXIDONE	ROCALTROL
CORZIDE	ERYTHROMYCIN	MEBARAL	ROSAC
SALAGEN	TRINESSA	ULTRASE MT 20	VIVACTIL
SALKERA	TUSSICAPS	VICODIN ES	XENADERM
STIMATE	ULTRASE	VICOPROFEN	ZARONTIN
SYNTHROID	ULTRASE MT 12	VIMPAT	UROCIT-K
THEO-24	ULTRASE MT 18	VIOKASE	

F. The implementation date for pre-authorization will not be prior to 1 April 2010 and not later than 180 days after the minutes of this meeting are signed by the Director, TMA.

G. Formulary status of a drug recommended to move from Tier 2 to Tier 3 will stay in Tier 2 if a Price Agreement is received prior to 1 February, 2010.

H. The transition period at the MTF POS for drugs recommended to move from Tier 2 to Tier 3 as if there will still on Tier 2 for purposes of MTF availability until 1 January 2011.

XXI. ITEMS FOR INFORMATION — SECTION 703

BAP Comment

A. Branded drugs with generic equivalents will follow the standard TRICARE rules for brand-generic prior-authorization criteria. (See list above)

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. The implementation date for the medical necessity criteria for the branded drugs will not be prior to 1 April 2010 and not later than 180 days after the minutes of this meeting are signed.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions

C. Not applicable

D. Drug retaining formulary status (see list above):

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

E. Designated as non-formulary under the UF (see list above):

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

F. The implementation date will not be prior to 1 January 2010 and not later than 180 days after the minutes of this meeting are signed.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

G. Formulary status of a drug recommended to move from Tier 2 to Tier 3 in these lists will stay on Tier 2 if Pricing Agreement is received prior to 1 February 2010.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

H. Not applicable.