

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
August 2008

1) CONVENING

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

2) ATTENDANCE

The attendance roster is found in Appendix A.

3) REVIEW MINUTES OF LAST MEETING

- A. Corrections to the minutes** – Corrections to the June 2008 DoD P&T Committee meeting minutes were tabled until the next meeting.
- B. Approval of June minutes** – Dr. Samuel Ward Casscells, III., M.D., will review the minutes of the June 2008 DoD P&T Committee meeting on 27 Aug 2008.

4) REVIEW OF RECENTLY APPROVED AGENTS

A. Antidepressant -1 (AD-1) – Desvenlafaxine (Pristiq)

Relative Clinical Effectiveness –Desvenlafaxine (Pristiq) is a Serotonin Norepinephrine Re-Uptake Inhibitor (SNRI) that is classified as part of the Antidepressant-1 (AD-1) drug class. The AD-1s were reviewed for Uniform Formulary (UF) placement in November 2005. Other SNRIs included on the UF are venlafaxine immediate release (Effexor, generics) and venlafaxine extended release (ER) (Effexor XR). The desvenlafaxine clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1).

Desvenlafaxine is FDA-approved for the treatment of major depressive disorder in adults. Desvenlafaxine is an extended release formulation of the major active metabolite of venlafaxine ER. Generic formulations of venlafaxine ER (Effexor XR) are expected in 2010. To review the full clinical effectiveness evaluation of desvenlafaxine, see the Desvenlafaxine New Drug in Previously Reviewed Classes monograph found at <https://rxnet.army.mil/> (Forum: File Library; Folder DoD P&T library. Note that rxnet is restricted to those with a “.mil” e-mail address.)

Relative Clinical Effectiveness Conclusion – The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that desvenlafaxine does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other AD-1 agents currently included on the UF.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of desvenlafaxine (Pristiq) in relation to efficacy, safety, tolerability, and clinical outcomes of the other agents in the AD-1 class, particularly to the following medications: citalopram (Celexa, generics), sertraline (Zoloft, generics), venlafaxine (Effexor, generics), venlafaxine ER (Effexor XR), bupropion ER

(Wellbutrin XL), and duloxetine (Cymbalta). Information considered by the P&T Committee included, but was not limited to sources of information listed in 32 CFR 199.21 (e)(2).

A cost minimization analysis (CMA) was employed to evaluate the cost effectiveness of desvenlafaxine relative to the UF AD-1s citalopram, sertraline, venlafaxine, and venlafaxine ER, and the Non-formulary (NF) AD-1s bupropion ER, and duloxetine. Results of the CMA showed that the projected weighted average daily cost of desvenlafaxine was significantly higher than its AD-1 class comparators.

Relative Cost Effectiveness Conclusion – The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that desvenlafaxine (Pristiq) is not cost effective relative to the other AD-1s included on the UF.

- 1) **COMMITTEE ACTION: UF RECOMMENDATION** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (14 for, 0 opposed, 1 abstained, 0 absent) that desvenlafaxine (Pristiq) be designated as non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion, and the determination that citalopram (Celexa, generics), sertraline (Zoloft, generics), venlafaxine (Effexor, generics), and venlafaxine ER (Effexor XR) remain the most cost effective AD-1 agents on the UF compared to desvenlafaxine.

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:

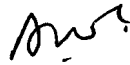


- 3) **COMMITTEE ACTION: IMPLEMENTATION PERIOD** – The P&T Committee voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend: 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



B. Calcium Channel Blockers (CCBs) – Nisoldipine (Sular geomatrix)

Relative Clinical Effectiveness – Nisoldipine (Sular geomatrix) is a dihydropyridine calcium channel blocker (DHP CCB) approved for treating hypertension. The CCBs were reviewed for UF placement at the August 2005 P&T Committee meeting. Other anti-hypertensive DHP CCBs included on the UF are amlodipine (Norvasc, generics), felodipine (Plendil, generics), nisoldipine coat core (Sular, generics), and nifedipine ER (Adalat CC, generics). The nisoldipine geomatrix clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1).

Nisoldipine geomatrix employs a different extended-release mechanism than the original nisoldipine product, nisoldipine coat core; both products are dosed once daily. Generic formulations of the original coat core product recently became commercially available. The geomatrix delivery system allows for a 15% lower dosage than the coat core product. To review the full clinical effectiveness evaluation of nisoldipine geomatrix, see the Nisoldipine geomatrix New Drug in Previously Reviewed Classes monograph found at <https://rxnet.army.mil/> (Forum: File Library; Folder DoD P&T library. Note that rxnet is restricted to those with a “.mil” e-mail address.)

Relative Clinical Effectiveness Conclusion – The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that there is no evidence to suggest that there are clinically relevant differences in the efficacy, safety, and clinical outcomes of nisoldipine geomatrix (Sular geomatrix) compared to nisoldipine coat core, as both products contain the same active ingredient. Additionally, the Committee agreed that nisoldipine geomatrix does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other CCB agents currently included on the UF.

Relative Cost Effectiveness – The P&T Committee evaluated the relative cost effectiveness of nisoldipine (Sular Geomatrix) in relation to efficacy, safety, tolerability, and clinical outcomes of other DHP CCBs, particularly to amlodipine (Norvasc, generics), felodipine (Plendil, generics) and nisoldipine (Sular coat core, generics). Information considered by the P&T Committee included, but was not limited to sources of information listed in 32 CFR 199.21 (e)(2).

A CMA was employed to determine the relative cost effectiveness of nisoldipine geomatrix relative to other UF DHP CCBs (nisoldipine coat core, felodipine, amlodipine). The results from the CMA revealed that the projected weighted average cost per day for therapy for nisoldipine geomatrix (Sular Geomatrix) is significantly higher than other UF CCBs amlodipine, felodipine, and nisoldipine (Sular coat core, generics).

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

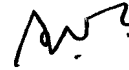
nisoldipine geomatrix (Sular Geomatrix) is not cost effective relative to other UF DHP CCB agents.

- 1) **COMMITTEE ACTION: UF RECOMMENDATION** – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness of nisoldipine geomatrix, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (14 for, 0 opposed, 1 abstained, 0 absent) to recommend that nisoldipine geomatrix (Sular geomatrix) be designated as non-formulary on the UF. This recommendation was based on the clinical effectiveness conclusion, and the determination that amlodipine (Norvasc, generics), felodipine (Plendil, generics) and generic nisoldipine coat core remain the most cost effective CCB agents on the UF compared to Sular Geomatrix.

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:

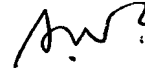


- 2) **COMMITTEE ACTION: MN CRITERIA** – Based on the clinical evaluation of nisoldipine geomatrix and the conditions for establishing medical necessity of a non-formulary medication provided for in the UF rule, the P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) MN criteria for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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



5) DRUG CLASS REVIEW – OVERACTIVE BLADDER AGENTS (OABs)

Relative Clinical Effectiveness: The DoD P&T Committee evaluated the clinical effectiveness of the Overactive Bladder Agents (OABs); this class was first reviewed for UF placement in February 2006. There are nine marketed anticholinergic drugs for overactive bladder (OAB) in the US, darifenacin (Enablex), oxybutynin immediate release (IR) (Ditropan, generics), oxybutynin extended release (ER) (Ditropan XL; generics), oxybutynin transdermal (Oxytrol patch) solifenacin (Vesicare), tolterodine IR (Detrol), tolterodine ER (Detrol LA), trospium IR (Sanctura) and trospium ER (Sanctura XR).

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

All nine drugs are FDA approved for the treatment of OAB with symptoms of urge incontinence, urgency and urinary frequency. Oxybutynin ER is also approved for the treatment of patients aged 6-years and older with symptoms of detrusor overactivity associated with a neurological condition (e.g. spina bifida), but was not reviewed for this indication by the Committee. Only oxybutynin IR and ER are available in generic formulations.

Military Health System expenditures for the OAB class exceeded \$74 million from July 07 to June 08. Tolterodine ER (Detrol LA) is the highest utilized OAB agent at the MTFs, followed by oxybutynin ER (Ditropan XL, generics). To review the full clinical effectiveness evaluation, see the OAB DoD Drug Class Review found at <https://rxnet.army.mil/> (Forum: File Library; Folder: DoD P&T library. Note that rxnet is restricted to those with a “.mil” e-mail address.)

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

- a) Evaluation of clinically relevant differences in efficacy of the OAB agents at relieving urinary symptoms is hampered by the high placebo response rate (30-50%), varying use of non-pharmacologic measures such as bladder training and behavioral modification, and differing outcome measures used in clinical trials.
- b) With regards to efficacy at reducing the number of urge incontinent episodes, urgency episodes, and micturation frequency, the available evidence does not support clinically relevant differences between oxybutynin IR (Ditropan, generics), oxybutynin ER (Ditropan XL, generics), oxybutynin patch (Oxytrol), tolterodine IR (Detrol), tolterodine ER (Detrol LA), trospium IR (Sanctura), trospium ER (Sanctura XR), solifenacin (Vesicare), and darifenacin (Enablex).
- c) With regards to safety and tolerability, the following conclusions were made:

- There are no differences between the OAB drugs in terms of black box warnings (e.g., acute urinary or gastric retention, acute angle-closure glaucoma, and myasthenia gravis), listed in the product labeling.
 - Oxybutynin IR had higher rates of withdrawals of therapy due to adverse events and occurrence of dry mouth than the other OAB agents, but no single agent has shown a clearly superior profile.
 - The incidence of adverse events including dry mouth, and constipation, overall was lower with extended release preparations compared with immediate release formulations of the agents. The oxybutynin patch has been associated with pruritis and rash.
 - The newer agents (trospium IR and ER, solifenacin, and darifenacin) do not appear to have a significantly lower incidence of dry mouth or constipation compared to extended-release forms of the older agents (oxybutynin ER, and tolterodine ER).
 - All the OAB agents may cross the blood brain barrier and result in significant central nervous system effects, although this may be less likely with trospium IR and ER.
 - Drug-drug interactions are less likely with trospium than the other agents.
- d) With regards to tolerability and persistence rates, the following conclusions were made:
- Persistence rates for OAB medications reported in the medical literature are in general low (<10%); and a 2005 PEC analysis reported that only about 11% of MHS patients continued to obtain prescriptions for OAB medications on a regular basis after 1 year.
 - An updated analysis performed by the Pharmacy Outcomes Research Team (PORT) included 35,121 DoD beneficiaries who were new users of OAB medications at any DoD pharmacy point of service from 1 Dec 06 to 31 May 07. Trospium ER was not commercially available at the time of the review and was not included in the analysis. The reported 1-year persistence rate with OAB therapy was 14% overall, with generally higher persistence for patients receiving newer agents and extended release versions of older agents, compared to those receiving immediate release versions of tolterodine and oxybutynin. About 28% of patients who were considered to be non-persistent continued to occasionally obtain prescription refills, consistent with use on an “as needed” rather than routine basis.
- e) With regard to special populations, only oxybutynin IR and oxybutynin ER are approved for use in children ages 6 years and older. For pregnancy, oxybutynin IR, oxybutynin ER, and the oxybutynin patch are labeled as category B drugs, while the other OAB drugs are labeled as category C drugs.

Relative Cost Effectiveness: In considering the relative cost-effectiveness of pharmaceutical agents in the OAB class, the P&T Committee evaluated the costs of the agents in relation to the efficacy, safety, tolerability, and clinical outcomes of the other

agents in the class. Information considered by the P&T Committee included but was not limited to sources of information listed in 32 CFR 199.21(e)(2).

Relative Cost Effectiveness Conclusion: The relative clinical effectiveness evaluation concluded that the newer OAB drugs darifenacin and solifenacin and the extended release formulations had higher persistence rates in the MHS than oxybutynin IR and tolterodine IR. Therefore, the cost effectiveness of the OAB agents was evaluated by CMA, cost effectiveness analysis (CEA), and by budget impact analysis (BIA). Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

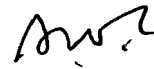
- a) Results from the CMA for the immediate release OAB agents (oxybutynin IR [Ditropan, generics], tolterodine IR [Detrol], and trospium IR [Sanctura]) revealed that oxybutynin IR was the most cost effective immediate release OAB agent overall.
 - b) Results from the CMA of extended release OAB agents (oxybutynin ER [Ditropan XL, generics], tolterodine ER [Detrol LA], trospium ER [Sanctura XR], oxybutynin transdermal [Oxytrol patch], darifenacin [Enablex], and solifenacin [Vesicare]) revealed that 1) trospium ER (Sanctura XR) was the most cost effective extended release OAB agent overall; and 2) when the price for generic formulations of oxybutynin ER (Ditropan XR) drops by 21.3% from the current price, oxybutynin ER will become the most cost-effective agent.
 - c) The results from a CEA comparing immediate release vs. extended release agents revealed that patients are more persistent with therapy when taking extended release products than when taking immediate release products. This is done at a significantly higher incremental cost per day of persistence gained by taking extended release products. However, the incremental cost per day of persistence gained is ~ 18% lower than when compared to MHS costs in 2005 when the OAB drugs were previously reviewed for UF placement.
 - d) The BIA evaluated the potential impact of scenarios with selected OAB agents designated formulary or non-formulary on the UF. Results from the BIA revealed that the scenario that designated tolterodine IR (Detrol) and trospium IR (Sanctura) as non-formulary under the UF was more favorable to the MHS.
- A. COMMITTEE ACTION: UF RECOMMENDATION** – In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the OAB agents, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (14 for, 0 opposed, 1 abstained, and 0 absent) to recommend to recommend that:
- 1) Oxybutynin IR (Ditropan, generics), oxybutynin ER (Ditropan XL, generics), oxybutynin patch (Oxytrol), tolterodine ER (Detrol LA), solifenacin (Vesicare), trospium ER (Sanctura XR), and darifenacin (Enablex) be classified as formulary on the UF.
 - 2) Tolterodine IR (Detrol) and trospium IR (Sanctura) be designated as non-formulary under the UF, based on cost effectiveness.

All OAB drugs recommended for inclusion on the UF were covered by Uniform Formulary Voluntary Agreement for Retail Refunds (UF VARR) submissions at or below the Federal Ceiling Price (FCP).

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:

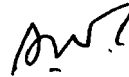


B. COMMITTEE ACTION: MN CRITERIA – Based on the clinical evaluation for tolterodine IR (Detrol) and trospium IR (Sanctura) and the conditions for establishing medical necessity for a non-formulary medication provided for in the UF rule, the P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:

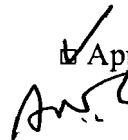


C. COMMITTEE ACTION: IMPLEMENTATION PERIOD –The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday one week after the minutes are signed following a 90-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 90-day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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:

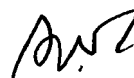


D. COMMITTEE ACTION: BCF RECOMMENDATION – The P&T Committee considered the BCF status of the OAB agents. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 1 opposed, 1 abstained, and 0 absent) to recommend that 1) tolterodine ER (Detrol LA) continue to be designated as BCF; 2) oxybutynin ER (Ditropan XL, generics) be designated as BCF; and that 3) oxybutynin IR (Ditropan, generics) be removed from the BCF, but maintained as formulary on the UF, starting the first Wednesday one week after the signing of the August 2008 DoD P&T Committee minutes by the Director, TMA. As a result of the above actions oxybutynin IR (Ditropan, generics) would no longer be designated as BCF, but maintained as formulary on the UF.

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



6) DRUG CLASS REVIEW – SELF-MONITORING BLOOD GLUCOSE TEST SYSTEMS (SMBGS) TEST STRIPS

Relative Clinical Effectiveness: The P&T Committee evaluated the relative clinical effectiveness of the Self-Monitoring Blood Glucose Test Systems (SMBGS) test strips. The clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). The primary goal for the UF recommendation is to ensure uniform availability of quality SMBGS test strips across the MHS (MTF, TRRx, and TMOP points of service). SMBGS meters are not included as part of the TRICARE outpatient pharmacy benefit (they are included under the medical benefit) and are not the focus of the review; however provisions have been made to provide SMBGS meters at no cost to MHS beneficiaries.

The FDA classifies SMBGS test strips and meters as medical devices, rather than drugs, thus the focus of the clinical effectiveness review centered on differences in the technical aspects/attributes among the products. The P&T Committee had previously determined that all SMBGS test strips considered for inclusion on the UF must meet minimum technical standards relating to accuracy, blood sample size, availability of testing sites other than the fingertips, result time, memory capacity, ease of use (e.g., calibration and coding, large visual display), manufacturer customer support services, downloading capabilities, availability of data management software, and size.

The test strips included in the SMBGS class were those products approved by the FDA and available in the marketplace as of May 2008. Due to the complexity of evaluating the more than 40 commercially marketed SMBGS test strip brands, the number of test strips eligible of inclusion on the UF was determined by DoD P&T Committee minimum technical requirements, operational limitations of the existing TMOP and TRRx contract, and Federal Government contracting regulations.

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

- a) With regard to efficacy, all meters that are approved by the FDA for licensing in the USA must meet the FDA standard of accuracy, which is a total analytical error of <5%. The International Organization for Standardization (ISO) also has standards. All the SMBGS test strips meeting the minimum technical requirements for inclusion on the UF met both FDA and ISO standards. There was insufficient published clinical trial data to determine if there were clinically relevant differences between the SMBGS test strips with regard to accuracy. The most common cause of inaccurate SMBGS test results is operator error.
- b) With regard to calibration and coding, the SMBGS test strips with the lowest risk of coding/calibration errors (as they do not require coding) are the Ascensia Contour and Freestyle Lite test strips. The Accu-check Aviva, Precision Xtra, and TrueTrack test strips require insertion of a coding chip or strip. The One Touch Ultra test strip requires manual coding.
- c) With regard to blood sample size, the Freestyle Lite test strip requires 0.3 microliter (μ L) blood; the Accu-check Aviva, Ascensia Contour, and Precision

Xtra require 0.6 µL; and the One Touch Ultra and TrueTrack test strips require 1 µL blood.

- d) With regard to alternate site testing, the Accu-chek Aviva and Freestyle Lite strips are FDA-approved for testing at 5 alternate sites other than the fingertips, the Ascensia Contour strip is approved for 4 alternate sites, the Precision Xtra and One Touch Ultra strips are approved for 3 alternate sites, and the TrueTrack strip is approved for one alternate testing site other than the fingertips.
- e) With regard to test result time, the Accu-chek Aviva, Ascensia Contour, Freestyle Lite, Precision Xtra, and One Touch Ultra provide test results within 5 seconds, while the TrueTrack strips provide test results in 10 seconds.
- f) With regard to SMBGS test strip degradation due to heat and humidity, the Precision Xtra test strips are individually foil-wrapped; however patients with dexterity problems may have difficulty opening the foil wrappers.
- g) With regard to safety, the Accu-chek Aviva and Freestyle Lite SMBGS test strips employ technology using glucose dehydrogenase (GDH) pyrroloquinolinequinone, which may cause falsely elevated blood glucose readings in patients receiving concomitant therapy with icodextrin-containing substances (Extrarenal peritoneal dialysis solution and the IV immunoglobulin product Octagam). SMBGS strips using GDH nicotinamide adenine dinucleotide [Precision Xtra], GDH flavin adenine dinucleotide [Ascensia Contour] or glucose oxidase technology [One Touch Ultra and TrueTrack] do not interfere with Extrarenal or Octagam.
- h) With regard to special populations, those patients requiring intensive blood glucose monitoring (e.g., women with gestational diabetes, Type 1 diabetics, children and adults using insulin pumps) may prefer SMBGS test strips used in certain meters that can communicate wirelessly with insulin pumps.
- i) With regard to provider opinion, a survey of MTF providers reported that accuracy and small blood sample size were the two technical requirements considered most important when comparing SMBGS.
- j) With regard to therapeutic interchangeability, there is a high degree of therapeutic interchangeability between the SMBGS test strips meeting the DoD P&T Committee minimum technical requirements.

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

The relative clinical effectiveness evaluation concluded that for those SMBGS test strips meeting the minimum technical criteria, there were no clinically relevant differences between the agents. As a result, a CMA and BIA were conducted.

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

- a) Results from the CMAs for the condition sets for both the 3 or less and 4 or more included on the UF revealed that Ascensia Contour was the most cost effective SMBG system while One Touch Ultra was the least cost effective. The ranking of most to least cost effective SMBGS test strips based on prices submitted for each condition set was: Ascensia Contour > TrueTrack > Freestyle Lite > Precision Xtra > Accu-chek Aviva > OneTouch Ultra.
- b) The BIA evaluated the potential impact of scenarios with selected SMBGS products designated formulary or non-formulary on the UF. The BIA results showed that the scenario that designated the One Touch Ultra and TrueTrack self SMBGS as non-formulary on the UF was more favorable to the MHS.

A. COMMITTEE ACTION: UF RECOMMENDATION – Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations of the SMBGS test strips, and other relevant factors, the P&T Committee, based upon its collective professional judgment, voted (12 for, 2 opposed, 0 abstained, 1 absent) to recommend that:


- 1) Accu-chek Aviva, Precision Xtra, Freestyle Lite, and the Ascensia Contour SMBGS test strips be designated as formulary on the Uniform Formulary.
- 2) One Touch Ultra, TrueTrack, Accu-chek Comfort Curve, Accu-chek Compact Plus, Accu-chek Simplicity, Ascensia Autodisc, 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, and all store/private label brands not specified as formulary in “1” above be designated as non-formulary on the UF.

The SMBGS test strips are a medical device and subject to wholesale acquisition cost, rather than FCP pricing.

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



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

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



C. COMMITTEE ACTION: IMPLEMENTATION PERIOD – The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday one week after the minutes are signed, following a 120-day implementation period in the TMOP and TRRx, and at the MTFs no later than a 120-day implementation period. 2) That TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following the approval by the Director, TMA

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



D. COMMITTEE ACTION: BCF RECOMMENDATION – The P&T Committee considered the BCF status of the SMBGS. Based on the results of the clinical and economic evaluations presented, the P&T Committee voted (13 for, 0 opposed, 1 abstained, and 1 absent) to recommend that Precision Xtra be designated as the BCF SMBGS the first Wednesday one week after the signing of the August 2008 DoD P&T Committee minutes by the Director, TMA

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



7) UTILIZATION MANAGEMENT – PRIOR AUTHORIZATIONS (PA)/ QUANTITY LIMITS (QL) / MEDICAL NECESSITY (MN)

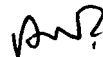
Ondansetron (Zofran) – QL – Currently QLs are in place for the oral anti-emetics used for chemotherapy-induced and post-operative nausea and vomiting. Generic formulations of ondansetron tablets recently became available, with a corresponding reduction in cost. The current ondansetron QLs of 45 tabs per 90 days in the TMOP, and 15 tabs per 30 days in the TRRx are not sufficient to meet current FDA-approved dosage recommendations. The Committee recommended increasing the QLs for ondansetron 4 mg and 8 mg oral tablets and orally disintegrating tablets, to reflect the dosages recommended in the FDA-approved product labeling.

COMMITTEE ACTION: The P&T Committee voted (12 for, 2 opposed, 1 abstained, 0 absent) to approve ondansetron QLs of 60 tablets per 30 days at the retail point of service, and 180 tablets per 90 days at the mail order point of service.

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



8) RE-EVALUATION OF NON-FORMULARY AGENTS

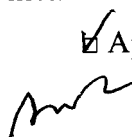
The P&T Committee's process for re-evaluation of non-formulary agents established at the May 2007 meeting was approved by the Director, TMA on 24 June 2007. At the August 2008 meeting, the P&T Committee reviewed an updated list of non-formulary drugs identified that were: 1) from drug classes in which UF status was NOT awarded based on condition sets that specified the number of similar agents on the UF (i.e., agents in the same class or subclass); and 2) determined to have similar relative clinical effectiveness (i.e., similar efficacy, safety and tolerability) compared to similar agents on the UF and not excluded from the UF based on clinical issues alone. The updated list is included in Appendix D.

COMMITTEE ACTION: The P&T Committee voted (14 for, 0 against, 1 abstained 0 absent) to recommend that the list of non-formulary agents in Appendix D be evaluated for UF status when pre-established criteria are met.

Director, TMA, Decision:

Approved Disapproved

Approved, but modified as follows:



9) ITEMS FOR INFORMATION

TRICARE Management Activity (TMA), DoD PEC staff members, and PORT members briefed the P&T Committee on the following:

- A. **Beneficiary Advisory Panel (BAP) Briefing** – CDR Ellzy briefed the members of the P&T Committee regarding the July 2008 BAP meeting. The P&T Committee was briefed on the BAP comments regarding the DoD P&T Committee's Uniform Formulary (UF) and implementation guidelines.
- B. **Outcomes Research Reports – Fentanyl Patch Safety Program** – The PORT reported results of an analysis of the Fentanyl Patch Safety Program, which went into effect 1 Aug 2007. The program uses an automated prior authorization (PA) process to “look-back” at patients' pharmacy profiles; the dispensing process is stopped with a warning message if patients may not be opioid-tolerant based on prior dispensing of strong opioids. Pharmacists may override the warning using standard intervention and outcome codes after consulting with the prescriber or patient and/or taking into account information not available to the Pharmacy Data Transaction Service (PDTs) (i.e., prescriptions not paid for by DoD). Currently the program returns automated warning messages only at the retail network and mail order points of service.

In general, the program appeared to reduce the use of fentanyl patch among seemingly opioid-naïve patients, without placing an undue burden on patients who may have been wrongly identified as opioid-naïve. Results of the analysis will be presented to the MHS Clinical Quality Forum.

C. Implementation Status of UF Decisions – The PEC briefed the members of the P&T Committee on the progress of implementation of drug classes reviewed for UF status since February 2005.

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

10) CLASS OVERVIEWS

Class overviews for the Nasal Allergy Drugs (comprised of the nasal antihistamines and nasal corticosteroids) and the inhaled Short Acting Beta Agonists 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 during the November 2008 meeting.

11) ADJOURNMENT

The second day of the meeting adjourned at 1200 hours on 13 Aug 2008. The next meeting will be 18-19 Nov 2008.

Appendix A – Attendance

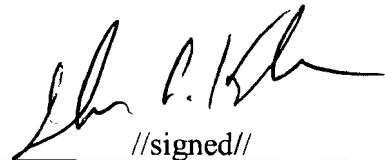
Appendix B – Table of Medical Necessity Criteria

Appendix C – Implementation Status of UF Recommendations/Decisions

Appendix D – Non-Formulary Agents for Re-evaluation

Appendix E – Table of Abbreviations

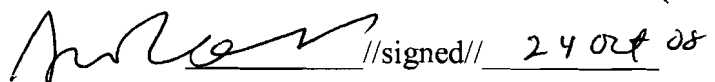
SUBMITTED BY:



Col John Kugler, MC
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.



S. Ward Casscells, III, M.D.

Appendix A – Attendance

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

Appendix A – Attendance – (continued)

Others Present	
CAPT Miles Rudd	USPHS/IHS
Cathy Kelly, PharmD	Dept of Veteran's Affairs, Pharmacy Benefits Management
Lt Col James McCrary, MC, USAF	DoD PEC
LTC Chris Conrad, MC, USA	DoD PEC
CDR Matthew Carlberg, MC, USN	DoD PEC
MAJ Misty Carlson, MC, USA	DoD PEC
Maj Josh Devine, BSC, USAF	DoD PEC
LCDR Joe Lawrence, MSC, USN	DoD PEC
Lt Dean Kang, MSC, USN	DoD PEC Pharmacy Resident
HM2 Trishonya McMihelk	DoD PEC
Angela Allerman, Pharm.D.	DoD PEC
David Meade, Pharm.D.	DoD PEC
Harsha Mistry, Pharm.D.	DoD PEC
Eugene Moore, Pharm.D.	DoD PEC
Shana Trice, Pharm.D.	DoD PEC
Jeremy Briggs, Pharm.D.	DoD PEC – Pharmacy Operations Center

Appendix B – Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Desvenlafaxine (Pristiq) (Antidepressant-1s)	<ul style="list-style-type: none"> The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.
Nisoldipine geomatrix (Sular geomatrix) (Dihydropyridine Calcium Channel Blockers)	<ul style="list-style-type: none"> The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.
Tolterodine IR (Detrol), Trospium (Sanctura) (Overactive Bladder Drugs)	<ul style="list-style-type: none"> 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.
One Touch Ultra TrueTrack Accu-chek Comfort Curve Accu-chek Compact Plus 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 Uniform Formulary (see BCF/ECF column in Appendix C) (Self-Monitoring Blood Glucose System (SMBGS) test strips)	<ul style="list-style-type: none"> Use of formulary alternatives is contraindicated The patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk.

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

Meeting	Drug Class	Non-Formulary Medications	BCF/ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	<ul style="list-style-type: none"> ▪ One Touch Ultra 2 strips (for One Touch 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 Uniform Formulary (see the BCF/ECF column) 	BCF	<ul style="list-style-type: none"> ▪ Precision Xtra strips (for Precision Xtra meter) <p>Uniform Formulary SMBGS test strips</p> <ul style="list-style-type: none"> ▪ Accu-chek Aviva (for Accu-chek Aviva meter) ▪ Ascensia Contour (for Ascensia Contour meter) ▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters) 	pending approval	pending approval
Aug 08 (re-review; Feb 06 original review)	Overactive Bladder (OAB) Agents	<ul style="list-style-type: none"> ▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura) 	BCF	<ul style="list-style-type: none"> ▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) <p>(Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)</p>	pending approval	pending approval
Aug 08 (update; reviewed Nov 05)	Antidepressants I	<p>Recommended for non-formulary status Aug 08</p> <ul style="list-style-type: none"> ▪ Desvenlafaxine (Pristiq) <p>To remain NF:</p> <ul style="list-style-type: none"> ▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg for weekly administration (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL) 	BCF	<p>No changes to BCF recommended Aug 08</p> <p>Currently BCF</p> <ul style="list-style-type: none"> ▪ citalopram ▪ fluoxetine (excluding weekly regimen and special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release 	pending approval	pending approval
					19 Jul 06	19 Jul 06 (180 days)

Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	Recommended for non-formulary status Aug 08 <ul style="list-style-type: none"> nisoldipine geomatrix (Sular geomatrix) 		No changes to BCF recommended Aug 08	pending approval	pending approval
		Previously non-formulary, recommended for UF status Nov 07 <ul style="list-style-type: none"> amlodipine besylate (Norvasc generic) 		Recommended for addition to BCF Nov 07 <ul style="list-style-type: none"> amlodipine besylate tablets 	13 Feb 08	13 Feb 08
		To Remain Non-Formulary <ul style="list-style-type: none"> isradipine IR (Dynacirc) isradipine ER (Dynacirc CR) nicardipine IR (Cardene, generics) nicardipine SR (Cardene SR) verapamil ER (Verelan) verapamil ER for bedtime dosing (Verelan PM, Covera HS) diltiazem ER for bedtime dosing (Cardizem LA) 	BCF	Currently BCF <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> calcitonin salmon nasal spray (Miacalcin) 	BCF	<ul style="list-style-type: none"> alendronate (Fosamax) ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (90 days)
Jun 08	Triptans	<ul style="list-style-type: none"> almotriptan (Axert) frovatriptan (Frova) naratriptan (Amerge) 	BCF	<ul style="list-style-type: none"> rizatriptan (Maxalt), immediate upon signing of the minutes sumatriptan oral and one injectable formulation, when multi-source generics are available 	27 Aug 08	26 Nov 08 (90 days)
Jun 08 (update; reviewed May 07)	Antilipidemic Agents II	No changes to NF recommended Jun 08	BCF	Recommended for addition to BCF Jun 08 <ul style="list-style-type: none"> fenofibrate melfdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	29 Oct 08 (60 days)
		To remain NF <ul style="list-style-type: none"> fenofibrate nanocrystallized (Tricor) fenofibrate micronized (Antara) omega-3 fatty acids (Omacor) colesevelam (Welchol) 		Currently BCF <ul style="list-style-type: none"> gemfibrozil 	24 July 07	21 Nov 07 (120 days)
Jun 08 (update; reviewed Nov 07)	Adrenergic Blocking Agents	Recommended for non-formulary status Jun 08 <ul style="list-style-type: none"> nebivolol (Bystolic) 	BCF	No change to BCF recommended Jun 08	27 Aug 08	29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		Currently BCF <ul style="list-style-type: none"> 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	29 Oct 08 (60 days)
		To remain NF ▪ desloratadine (Clarinet) ▪ desloratadine/pseudoephedrine (Clarinet 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	29 Oct 08 (60 days)
		To remain NF ▪ zileuton (Zyflo)		Currently BCF ▪ montelukast (Singulair)	17 Oct 07	16 Jan 08 (90 days)
Jun 08 (update) Original reviews ▪ ACE inhibitors: Aug 05 ▪ Miscellaneous antihypertensives, including ACE/CCB combos. Feb 06 ▪ ARBs: May 07 ▪ Renin inhibitors. Aug 07 ▪ CCB/ARB combos Nov 07 update	Renin Angiotensin Antihypertensives	Recommended for non-formulary status Jun 08 ▪ olmesartan/amlodipine (Azor)	BCF	No change to BCF recommended Jun 08	27 Aug 08	29 Oct 08 (60 days)
		To remain NF ▪ valsartan amlodipine (Exforge)		No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ moexipril (Univasc), ▪ moexipril / HCTZ (Uniretic) ▪ perindopril (Aceaon) ▪ ramipril (Altace) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan (Teveten) ▪ eprosartan HCTZ (Teveten HCT) ▪ irbesartan (Avapro) ▪ irbesartan HCTZ (Avalide) ▪ olmesartan (Benicar) ▪ olmesartan HCTZ (Benicar HCT) ▪ valsartan (Diovan) ▪ valsartan HCTZ (Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) ARBs ▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	ACE inhibitors ▪ 13 Oct 05 ACE/CCB combos ▪ 26 Apr 06 ARBs ▪ 24 July 07	ACE inhibitors ▪ 15 Feb 06 ACE/CCB combos ▪ 26 Jul 06 ARBs ▪ 21 Nov 07
Nov 07	Targeted Immunomodulatory Biologics	▪ etanercept (Enbrel) ▪ anakinra (Kineret)	ECF	▪ adalimumab (Humira) injection	13 Feb 08	18 Jun 08 (120 days)
Nov 07 re-review (Aug 05 original)	BPH Alpha Blockers	▪ tamsulosin (Flomax) Automated PA requiring trial of alfuzosin (Uroxatral) applies to new users of tamsulosin (no use of uroselective alpha blockers in last 180 days)	BCF	▪ terazosin tablets or capsules ▪ alfuzosin tablets (Uroxatral)	13 Feb 08	16 Apr 08 (60 days)
Nov 07 (update,	ADHD / Narcolepsy Agents	Recommended for non-formulary status Nov 07 ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)

original review Nov 06)		To remain NF <ul style="list-style-type: none"> dexmethylphenidate IR (Focalin) dexmethylphenidate SODAS (Focalin XR) methylphenidate transdermal system (Daytrana) 		Currently on the BCF <ul style="list-style-type: none"> methylphenidate OROS (Concerta) mixed amphetamine salts ER (Adderall XR) methylphenidate IR (Ritalin) 	17 Jan 07	18 Apr 07
Nov 07 (update, original review May 06)	Contraceptives	Recommended for non-formulary status Nov 07 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> EE 30 mcg / levonorgestrel 0.15 mg in special packaging for extended use (Seasonale) EE 25 mcg / norethindrone 0.4 mg (Ovcon 35) EE 50 mcg / norethindrone 1 mg (Ovcon 50) EE 20/30/35 mcg / norethindrone 1 mg (Estrostep Fe) 		Currently on the BCF <ul style="list-style-type: none"> 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
		<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> somatropin (Genotropin, Genotropin Miniquick) somatropin (Humatrope) somatropin (Omnitrope) somatropin (Saizen) 	ECF	<ul style="list-style-type: none"> somatropin (Norditropin) 	17 Oct 07	19 Dec 07 (60 days)
Aug 07 (new drug update, original review Nov 05)	Nasal Corticosteroids	Recommended for non-formulary status Aug 07 <ul style="list-style-type: none"> fluticasone furoate (Veramyst) 	BCF	No change to BCF recommended Aug 07	17 Oct 07	19 Apr 06 (90 days)
		<ul style="list-style-type: none"> beclomethasone dipropionate (Beconase AQ, Vancenase AQ) budesonide (Rhinocort Aqua) triamcinolone (Nasacort AQ) 		<ul style="list-style-type: none"> fluticasone propionate (Flonase) 	19 Jan 06	19 Dec 07 (60 days)
May 07 re-review (Feb 05 original)	PPIs	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> generic omeprazole 10 mg and 20 mg (excludes Prilosec 40 mg) esomeprazole (Nexium) 	24 July 07	24 Oct 07 (90 days)

May 07 re-review (Feb 05 original)	ARBs	<ul style="list-style-type: none"> • eprosartan (Teveten) • eprosartan HCTZ (Teveten HCT) • irbesartan (Avapro) • irbesartan HCTZ (Avalide) • olmesartan (Benicar) • olmesartan HCTZ (Benicar HCT) • valsartan (Diovan) • valsartan HCTZ (Diovan HCT) 	BCF	<ul style="list-style-type: none"> • telmisartan (Micardis) • telmisartan HCTZ (Micardis HCT) 	24 July 07	21 Nov 07 (120 days)
May 07	5-Alpha Reductase Inhibitors	<ul style="list-style-type: none"> • dutasteride (Avodart) 	BCF	<ul style="list-style-type: none"> • finasteride 	24 July 07	24 Oct 07 (90 days)
Feb 07	Newer Sedative Hypnotics	<ul style="list-style-type: none"> • zolpidem ER (Ambien CR) • zaleplon (Sonata) • ramelteon (Rozerem) <p>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)</p>	BCF	<ul style="list-style-type: none"> • zolpidem IR (Ambien) 	02 May 07	01 Aug 07 (90 days)
Feb 07	Monoamine Oxidase Inhibitors	<ul style="list-style-type: none"> • selegiline transdermal patch (Emsam) 	ECF	<ul style="list-style-type: none"> • phenelzine (Nardil) 	02 May 07	01 Aug 07 (90 days)
Feb 07	Narcotic Analgesics	<ul style="list-style-type: none"> • tramadol ER (Ultram ER) 	BCF	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • travoprost (Travatan, Travatan Z) • timolol maleate for once daily dosing (Istalol) • timolol hemihydrate (Betimol) • brinzolamide (Azopt) 	BCF	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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)

			<ul style="list-style-type: none"> econazole ciclopirox oxiconazole (Oxistat) sertaconazole (Ertaczo) sulconazole (Exelderm) 			<ul style="list-style-type: none"> nystatin clotrimazole 	17 Jan 07	18 Mar 07 (60 days)
Aug 06	H2 Antagonists / GI protectants		-	BCF	<ul style="list-style-type: none"> ranitidine (Zantac) – excludes gelcaps and effervescent tablets 		23 Oct 06	-
Aug 06	Antilipidemic Agents I		<ul style="list-style-type: none"> rosuvastatin (Crestor) atorvastatin / amlodipine (Caduet) 	BCF	<ul style="list-style-type: none"> simvastatin (Zocor) pravastatin simvastatin / ezetimibe (Vytorin) niacin extended release (Niaspan) 		23 Oct 06	1 Feb 07 (90 days)
May 06	Antiemetics		<ul style="list-style-type: none"> dolasetron (Anzemet) 	BCF	<ul style="list-style-type: none"> promethazine (oral and rectal) 		26 Jul 06	27 Sep 06 (60 days)
Feb 06 (re-classified Aug 07; and updated Jun 08; see above)	Misc Antihypertensive Agents (ACE/CCB combos now part of RAAAs class)		<ul style="list-style-type: none"> felodipine/enalapril (Lexxel) verapamil/trandolapril (Tarka) 	BCF	<ul style="list-style-type: none"> (ACE/CCB combos now part of RAAAs class) amlodipine/benazepril (Lotrel) hydralazine clonidine tablets 		26 Apr 06	26 Jul 06 (90 days)
Feb 06	GABA-analogs		<ul style="list-style-type: none"> pregabalin (Lyrica) 	BCF	<ul style="list-style-type: none"> gabapentin 		26 Apr 06	28 Jun 06 (60 days)
Nov 05	Alzheimer's Drugs		<ul style="list-style-type: none"> tacrine (Cognex) 	ECF	<ul style="list-style-type: none"> donepezil (Aricept) 		19 Jan 06	19 Apr 06 (90 days)
Nov 05	Macrolide/ Ketolide Antibiotics		<ul style="list-style-type: none"> azithromycin 2 gm (Zmax) telithromycin (Ketek) 	BCF	<ul style="list-style-type: none"> azithromycin (Z-Pak) erythromycin salts and bases 		19 Jan 06	22 Mar 06 (60 days)
May 05	PDE5 Inhibitors		<ul style="list-style-type: none"> sildenafil (Viagra) tadalafil (Cialis) 	ECF	<ul style="list-style-type: none"> vardeanafil (Levitra) 		14 Jul 05	12 Oct 05 (90 days)
May 05	MS-DMDs		-	ECF	<ul style="list-style-type: none"> interferon beta-1a intramuscular injection (Avonex) 		14 Jul 05	-

BCF = Basic Core Formulary; ECF = Extended Core Formulary; MN = Medical Necessity; TMOP = TRICARE Mail Order Pharmacy; TRRx = TRICARE Retail Pharmacy program; UF = Uniform Formulary

ER = extended release; IR = immediate release; SR = sustained release; IDD-P = insoluble drug delivery-microParticle
AD-1s: Antidepressant-1 Drugs; ADHD = Attention Deficit Hyperactivity Disorder; ARBs = Angiotensin Receptor Blockers; ACE Inhibitors = Angiotensin Converting Enzyme Inhibitors; BPH = Benign Prostatic Hyperplasia; CCBs = Calcium Channel Blockers; EE = ethinyl estradiol; GI = gastrointestinal; GABA = gamma-aminobutyric acid; H2 = Histamine-2 receptor; HCTZ = hydrochlorothiazide; LIP-1 = Antihypertensive-1 Drugs; LIP-2 = Antihypertensive-2 Drugs; MOAs = Monoamine Oxidase Inhibitor Drugs; MS-DMDs = Multiple Sclerosis Disease-Modifying Drugs; OABs = Overactive Bladder Medications; PDE5 Inhibitors = Phosphodiesterase- type 5 inhibitors; PPIs = Proton Pump Inhibitors; RAAAs = Renin Angiotensin Antihypertensives Drugs; 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 D – Non-Formulary Drugs for Re-Evaluation

Generic Name	Brand Name	UF Class	Generic Y/N
Ciclopirox	Loprox	Antifungal – Derm	Y
Econazole	Spectazole	Antifungal – Derm	Y
Oxiconazole	Oxistat, Oxizole	Antifungal – Derm	N
Sertaconazole	Ertaczo	Antifungal – Derm	N
Sulconazole	Exelderm	Antifungal – Derm	N
Moexipril + HCTZ	Univasc, Uniretic	RAAs – ACEs	Y
Perindopril	Aceon	RAAs – ACEs	N
Ramipril	Altace	RAAs – ACEs	Y
Diltiazem ER	Cardizem LA	CCBs	N
Isradipine / CR	DynaCirc, DynaCirc CR	CCBs	N
Nicardipine / SR	Cardene, Cardene SR	CCBs	Y
Verapamil ER/HS	Verelan, Verelan PM, Covera HS	CCBs	Y
Tamsulosin	Flomax	Alpha Blocker – BPH	N
Azithromycin	Zmax	Macrolide/Ketolide Abx	N
Telithromycin	Ketek	Macrolide/Ketolide Abx	N
Beclomethasone	Beconase AQ	Nasal corticosteroids	N
Budesonide	Rhinocort aqua	Nasal corticosteroids	N
Triamcinolone	Nasacort AQ	Nasal corticosteroids	N
Bupropion	Wellbutrin XL	Antidepressant – 1s	Y
Duloxetine	Cymbalta	Antidepressant – 1s	N
Escitalopram	Lexapro	Antidepressant – 1s	N
Fluoxetine	Prozac weekly	Antidepressant – 1s	N
Fluoxetine	Sarafem	Antidepressant – 1s	Y
Paroxetine CR	Paxil CR	Antidepressant – 1s	Y
Felodipine/ enalapril	Lexxel	RAAs – ACE/CCB combos	N
Verapamil/ trandolapril	Tarka	RAAs – ACE/CCB combos	N
Pregabalin	Lyrica	GABA Analogs	N
EE 30 mcg; 0.15mg levonorgestrel	Seasonale	Contraceptives (M30)	Y
EE 35 mcg; 0.4mg norethindrone	Ovcon 35	Contraceptives (M35)	Y
EE 50 mcg; 1 mg norethindrone	Ovcon 50	Contraceptives (M50)	N
EE 20/30/35 mcg; 1mg norethindrone	Estrostep Fe	Contraceptives (Triphasic)	Y
EE 30/10mcg; 0.15mg levonorgestrel	Seasonique	Contraceptives (Extended cycle)	N
EE 20mcg; 1mg norethindrone	Loestrin 24 Fe	Contraceptives (M20)	N
Dolasetron	Anzemet	Anti-emetics	N

Abx = antibiotics; CCB = Calcium Channel Blockers; EE = ethinyl estradiol; HCTZ = hydrochlorothiazide; M = monophasic; RAAs = Renin Angiotensin Antihypertensives

Appendix E – Table of Abbreviations

AD-1	Antidepressant-1 drug class
AE	adverse event
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
CC	coat core
CCB	calcium channel blocker
CEA	cost effectiveness analysis
CFR	Code of Federal Regulations
CI	confidence interval
CMA	cost minimization analysis
DHP	dihydropyridine
DoD	Department of Defense
DHP CCB	Dihydropyridine Calcium Channel Blocker drug class
ER	extended release
ESI	Express Scripts, Inc
FDA	Food and Drug Administration
FCP	Federal Ceiling Price
FY	fiscal year
GDH	glucose dehydrogenase
HA	Health Affairs
IR	immediate release
ISO	International Organization for Standardization
MHS	Military Health System
MN	medical necessity
MTF	military treatment facility
OAB	Over Active Bladder drug class
P&T	Pharmacy and Therapeutics
PA	prior authorization
PEC	Pharmacoeconomic Center
PORT	Pharmaceutical Outcomes Research Team
QD	once daily
QL	quantity limit
SMBGS	Self-Monitored Blood Glucose System drug class
SNRI	Serotonin Norepinephrine Re-Uptake Inhibitor
TMA	TRICARE Management Activity
TMOP	TRICARE Mail Order Pharmacy
TRRx	TRICARE Retail Pharmacy Network
µL	microliter