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. SELF-MONITORING BLOOD GLUCOSE SYSTEM TEST STRIPS (SMBGS)

P&T Comments

A. 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

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-chek 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 (μL) 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.

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

B. SMBGS Test Strips – 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).

Relative Cost Effectiveness Conclusion:

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 cost minimization analysis (CMA) and budget impact analysis (BIA) were conducted. Based on the results of the cost analyses and other clinical and cost considerations, the P&T Committee concluded:

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 True Track self SMBGS as non-formulary on the UF was more favorable to the MHS.

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

C. SMBGS Test Strips – Uniform Formulary Recommendation

In view of the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the SMBGS, and other relevant factors, the P&T Committee voted 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 Federal Ceiling Price (FCP) pricing.

D. SMBGS Test Strips – Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 120-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Network Pharmacy Program (TRRx). The implementation period will begin immediately following the approval by the Director, TMA.

III. SELF-MONITORING BLOOD GLUCOSE SYSTEM TEST STRIPS (SMBGS)

BAP Comments

A. SMBGS Test Strips – Uniform Formulary Recommendation: In view of 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 voted 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.

BAP Comment: □ Concur □ Non-concur

Additional Comments and Dissentions:

B. SMBGS Test Strips – Implementation Plan: The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 120-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Network Pharmacy Program (TRRx). The implementation period will begin immediately following the approval by the Director, TMA.

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

IV. OVERACTIVE BLADDER DRUGS (OABs)

P&T Comments

A. Overactive Bladder Drugs– 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). The clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1).

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).

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded that:

a) With regard to efficacy, 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 regard 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 regard 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 then 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 regard to tolerability and persistence rates, persistence rates for OAB medications reported in the medical literature are in general low (<10%). 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. When the analysis was updated for the August 2008 DoD P&T meeting, the reported 1-year persistence rate with OAB therapy was 14% overall. Generally higher persistence was seen 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.

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

B. Overactive Bladder Drugs– Relative Cost Effectiveness

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

Relative Cost Effectiveness Conclusion:

The 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 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.

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

C. Overactive Bladder Drugs – 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, based upon its collective professional judgment, voted 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).

D. Overactive Bladder Drugs – Implementation Plan - The P&T Committee recommended 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. The implementation period will begin immediately following the approval by the Director, TMA.

V. OVERACTIVE BLADDER DRUGS

BAP Comments

A. Overactive Bladder Drugs – Uniform Formulary Recommendation

Taking into consideration of the conclusions from the relative clinical effectiveness conclusions and cost effectiveness determinations of the Overactive Bladder Drugs, and other relevant factors, the P&T Committee, based on its professional judgment, voted to recommend that 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, and that tolterodine IR (Detrol) and trospium IR (Sanctura) be designated as non-formulary under the UF, based on cost effectiveness.

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

B. Overactive Bladder Drugs – Implementation Plan

The P&T Committee recommended 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. The implementation period will begin immediately following the approval by the Director, TMA.

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

VI. NEWLY APPROVED DRUGS – Desvenlafaxine (Pristiq)

P&T Comments

A. Pristiq – Relative Clinical Effectiveness - The desvenlafaxine clinical evaluation included, but was not limited to, the requirements stated in the UF rule, 32 CFR 199.21(e)(1). 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).

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.

Relative Clinical Effectiveness Conclusion: The P&T Committee concluded 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.

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

B. Pristiq – 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 that desvenlafaxine (Pristiq) is not cost effective relative to the other AD-1s included on the UF.

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

C. Pristiq – 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 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.

D. Pristiq – Implementation Plan - The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following approval by the Director, TMA.

VII. NEWLY APPROVED DRUGS – Desvenlafaxine (Pristiq)

BAP Comments

A. Pristiq – Uniform Formulary Recommendation

The P&T Committee, based on its professional judgment, voted to recommend that desvenlafaxine (Pristiq) be classified as non-formulary on the Uniform Formulary.

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

B. Pristiq – Implementation Plan - The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TMOP and TRRx. 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 – Nisoldipine geomatrix (Sular geomatrix)

P&T Comments

A. Sular geomatrix – Relative Clinical Effectiveness - 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 (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).

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.

Relative Clinical Effectiveness Conclusion - The P&T Committee concluded 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 DHP CCB agents currently included on the UF.

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

B. Sular geomatrix – Relative Cost Effectiveness The DoD 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 that nisoldipine geomatrix (Sular Geomatrix) is not cost effective relative to other UF DHP CCB agents.

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

C. Sular geomatrix – Uniform Formulary 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 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.

D. Sular geomatrix – Implementation Plan - The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following approval by the Director, TMA.

IX. NEWLY APPROVED DRUGS – Nisoldipine geomatrix (Sular geomatrix)

BAP Comments

A. Sular geomatrix – Uniform Formulary Recommendation – The P&T Committee, based on its professional judgment, voted to recommend that nisoldipine geomatrix (Sular geomatrix) be classified as non-formulary on the Uniform Formulary.

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

B. Sular geomatrix – Implementation Plan - The P&T Committee recommended an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TMOP and TRRx. The implementation period will begin immediately following approval by the Director, TMA.

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