DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS
August 2009

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 12, 2009 and August 13, 2009 at the DoD Pharmacoeconomic Center (PEC), Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is found in Appendix A.

A. Review Minutes of Last Meetings

1. Revisions to the minutes — Revisions to the May 2009 minutes will be reviewed at the November 2009 DoD P&T Committee meeting.
2. Approval of May minutes — The minutes from the DoD P&T Committee meeting held May 13, 2009 are still undergoing review.

III. REVIEW OF RECENTLY FDA-APPROVED AGENTS

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

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

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

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

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

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

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

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the multi-indication agents in the TIB class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2). A cost minimization analysis (CMA) was used to evaluate the cost-effectiveness of golimumab.

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

c) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee voted (11 for, 0 opposed, 1 abstained, 1 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at Military Treatment Facilities (MTFs) no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

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

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

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

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

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

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the multi-indication agents in the TIBs class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2). A cost minimization analysis (CMA) was used to evaluate the cost-effectiveness of certolizumab (Cimzia).

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

a) ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (12 for, 0 opposed, 0 abstained, 1 absent) that certolizumab

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

c) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee voted (12 for, 0 opposed, 0 abstained, 1 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at Military Treatment Facilities (MTFs) no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

ActingDirector, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

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

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

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

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the Alpha Blocker class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2). Cost minimization analysis (CMA) was used to evaluate the relative cost-effectiveness of silodosin capsules (Rapaflo) relative to other UF alpha blocking agents. Results from the CMA showed the projected weighted average cost per day for silodosin (Rapaflo) is higher than alfuzosin (Uroxatral). The CMA also revealed the projected weighted average cost per day for silodosin (Rapaflo) is lower than the non-formulary alpha blocking agent, tamsulosin (Flomax). Alfuzosin (Uroxatral) remains the most cost effective alpha blocking agents on the UF.

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

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

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

c) ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at Military Treatment Facilities (MTFs) no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

(1) Automated PA criteria:

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

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

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

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

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

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

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

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

Relative Cost-Effectiveness — The P&T Committee evaluated the costs of the agent in relation to the efficacy, safety, tolerability, and clinical outcomes of the Narcolepsy/ADHD class. Information considered by the P&T Committee included, but was not limited to, sources of information listed in 32 CFR 199.21(e)(2). A cost minimization analysis (CMA) was used to evaluate the cost-effectiveness of armodafinil tablets (Nuvigil).

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

a) ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (12 for, 0 opposed, 1 abstained, 0 absent) that armodafinil tablets (Nuvigil) be designated formulary on the UF.

Acting Director, TMA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Allen P. Dalbey

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

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

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Allen P. Dalbey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

IV. UNIFORM FORMULARY DRUG CLASS REVIEWS

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

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

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

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

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

1. With regard to efficacy, the following conclusions were made:
   a) ED: Sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra) are FDA-approved for the treatment of ED. There are no head-to-head trials comparing the three PDE-5 inhibitors.

      (1) There is insufficient evidence to conclude that there are clinically relevant differences in efficacy of PDE-5 inhibitors for ED. Although all PDE-5s are clinically superior to placebo, the variability in study design, demographics, and outcome measures

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) ***COMMITTEE ACTION: UF RECOMMENDATION*** — Taking into consideration the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors, the P&T Committee, based upon its collective professional judgment, recommended (13 for, 0 opposed, 0 abstained, 0 absent):

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows: Ellen P. Embrey

(5) ***COMMITTEE ACTION: UNIFORM FORMULARY (UF) IMPLEMENTATION PERIOD*** — The P&T Committee voted (13 for, 0 opposed, 0 abstained, 0 absent) to recommend 1) an effective date of the first Wednesday one week after the minutes are signed, following a 60-day implementation period in the TRICARE Mail Order Pharmacy (TMOP) and TRICARE Retail Pharmacy Network (TRRx), and at MTFs no later than a 60-day implementation period; and 2) TMA send a letter to beneficiaries affected by this UF decision. The implementation period will begin immediately following approval by the Director, TMA.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

(a) Automated PA criteria:

(i) The patient has received a prescription for sildenafil (Viagra), tadalafil (Cialis), or vardenafil (Levitra) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.

(ii) The patient is a male, aged 40 years or older (12 for, 1 opposed, 0 abstained, 0 absent)

(b) PA if automated criteria are not met:

(i) The patient has tried vardenafil (Levitra) and has had an inadequate response or was unable to tolerate treatment due to adverse effects.

(ii) Treatment with vardenafil (Levitra) is contraindicated.

(iii) Sildenafil (Viagra or Revatio) or tadalafil (Cialis or Adcirca) is for treatment of Pulmonary Artery Hypertension (PAH).

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

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

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

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

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

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

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

e) Myotonic dystrophy associated with excessive fatigue;

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

g) Idiopathic hypersomnia diagnosed by a sleep specialist;

h) Fatigue associated with mild traumatic brain injury.

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

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

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

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

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

Acting Director, TMA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Ellen P. Embrey

VII. ADJOURNMENT

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

Appendix A — Attendance

Appendix B — Table of Medical Necessity Criteria

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

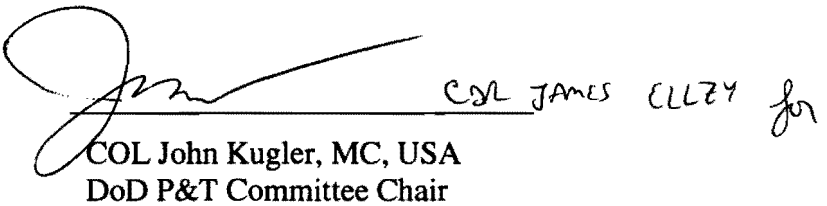
Appendix D — Table of Quantity Limits

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

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

Appendix G — Table of Abbreviations

SUBMITTED BY:



COL JAMES CLLZY for

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

DECISION ON RECOMMENDATIONS

Director, TMA, decisions are as annotated above.

Ellen P. Embrey
Acting Director

10/21/09
(Date)

Appendix A – Attendance

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

Appendix A – Attendance – (continued)

LCDR Joe Lawrence	DoD Pharmacoeconomic Center
Maj Joshua Devine, BSC	DoD Pharmacoeconomic Center
LCDR Marisol Martinez	DoD Pharmacoeconomic Center
CAPT Brian Haney	DoD Pharmacoeconomic Center
Dr. Shana Trice	DoD Pharmacoeconomic Center
Dr. Eugene Moore	DoD Pharmacoeconomic Center
Dr. Angela Allerman	DoD Pharmacoeconomic Center
Dr. David Meade	DoD Pharmacoeconomic Center
Dr. Teresa Anekwe	DoD Pharmacoeconomic Center
Dr. Jeremy Briggs	DoD Pharmacoeconomic Center
Mr. Stephen Yarger	DoD Pharmacy Outcomes Research Team contractor
Dr. Esmond Nwokeji	DoD Pharmacy Outcomes Research Team contractor
Ms. Deborah Garcia	DoD Pharmacy Outcomes Research Team contractor
Dr. Roger Potyk	DoD Pharmacy Outcomes Research Team contractor
Dr. Dean Valibhai	DoD Pharmacy Operations Center contractor
Dr. Elaine Furmaga	VA PBM
Mr. John Casciotti via teleconference	Office of General Counsel, TMA
Mr. David Hurt	Assistant General Counsel, TMA
Ms. Lisa McNair	DoD Pharmacy Operations Directorate

Appendix B — Medical Necessity Criteria

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

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

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

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

Appendix D — Quantity Limit Updates

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

Appendix E — National Defense Authorization Act (NDAA)

Section 703 Affected Medications

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

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

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

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

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

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

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

Appendix F — Implementation Status of UF Class Review Recommendations / Decisions

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (implementation period)
Aug 09 (update; original review Nov 2007)	Targeted Immunomodulatory Biologics	**Recommended for non-formulary status Aug 09; no change to non-formulary status from Nov 07** ▪ golimumab injection (Simponi) ▪ certolizumab injection (Cimzia)	ECF	**No changes to ECF recommendation Nov 07**	pending approval	pending approval
		▪ etanercept injection (Enbrel) ▪ anakinra injection (Kineret)	ECF	▪ adalimumab injection (Humira)	13 Feb 08	18 Jun 08 (120 days)
Aug 09 (update; original review May 05)	Phosphodiesterase Type-5 Inhibitors	**No change to non-formulary status from May 05** Automated PA requiring trial of vardenafil (Levitra) applies to new users of non-formulary PDE5s (no use of PDE5s in last 180 days)	Now BCF	Previously ECF Class ▪ vardenafil (Levitra)	pending approval	pending approval
		▪ sildenafil (Viagra) ▪ tadalafil (Cialis)	ECF	▪ vardenafil (Levitra)	14 Jul 05	12 Oct 05 (90 days)
Aug 09 (update; updated Nov 07; original review Aug 05)	Alpha Blockers for BPH	**Recommended for non-formulary status Aug 09; no change to non-formulary status from Nov 07 or Aug 05** ▪ silodosin (Rapaflo)	BCF	**No changes to BCF recommendation Nov 07**	pending approval	pending approval
		▪ tamsulosin (Flomax) Automated PA requiring trial of alfuzosin (Uroxatral) applies to new users of tamsulosin (no use of uroselective alpha blockers in last 180 days)	BCF	▪ terazosin tablets or capsules ▪ alfuzosin tablets (Uroxatral)	13 Feb 08	16 Apr 08 (60 days)
Aug 09 (update; updated Nov 07; original review Nov 06)	ADHD / Narcolepsy Agents	**No change to non-formulary status from Aug 05 or Nov 07**	BCF	**No changes to BCF recommendation from Aug 05**	pending approval	pending approval
		Recommended for non-formulary status Nov 07 ▪ lisdexamfetamine (Vyvanse)	BCF	No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
		To remain NF ▪ dexmethylphenidate IR (Focalin) ▪ dexmethylphenidate SODAS (Focalin XR) ▪ methylphenidate transdermal system (Daytrana)		Currently on the BCF ▪ methylphenidate OROS (Concerta) ▪ mixed amphetamine salts ER (Adderall XR) ▪ methylphenidate IR (Ritalin)	17 Jan 07	18 Apr 07
May 09 (update; reviewed Jun 08; original review May 07)	Antilipidemic Agents-II	**Recommended for non-formulary status May 09; no change to non-formulary status in Jun 08** ▪ fenofibrate acid (Trilipix)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		No changes to NF recommended Jun 08	BCF	**Recommended for addition to BCF Jun 08** ▪ fenofibrate meltdose (Fenoglide), to replace fenofibrate IDD-P (Triglide) (Note: fenofibrate IDD-P (Triglide) removed from BCF but still UF)	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ fenofibrate nanocrystallized (Tricor) ▪ fenofibrate micronized (Antara) ▪ omega-3 fatty acids (Omacor) ▪ colesevelam (Welchol)	BCF	Currently BCF ▪ gemfibrozil	24 July 07	21 Nov 07 (120 days)
May 09 update; reviewed Aug 08; Feb 06 original review)	Overactive Bladder Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Aug 08** ▪ fesoterodine (Toviaz)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		▪ tolterodine IR (Detrol) ▪ trospium IR (Sanctura)	BCF	▪ tolterodine ER (Detrol LA) ▪ oxybutynin ER (Ditropan XL, generics) (Note: oxybutynin IR [generic Ditropan] removed from BCF, but still UF)	24 Oct 08	4 Feb 09 (90 days)
May 09 (update; reviewed Nov 08) update to include nasal antihistamines; nasal steroids	Nasal Allergy Drugs	**Recommended for non-formulary status May 09; no change to non-formulary status in Nov 08** ▪ azelastine with sucralose (Astepro)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
reviewed Nov 05 & Aug 07 for Veramyst)		▪ olopatadine (Patanase) ▪ ciclesonide (Omnaris) ▪ fluticasone furoate (Veramyst) ▪ beclomethasone (Beconase AQ) ▪ budesonide (Rhinocort Aqua) ▪ triamcinolone (Nasacort AQ)	BCF	▪ Fluticasone propionate (generic Flonase) ▪ Azelastine (Astelin)	10 Feb 09	8 Apr 09 (60 days)
May 09 (update; reviewed May 07& Feb 05)	Proton Pump Inhibitors	**Recommended for non-formulary status May 09 no change to non-formulary status in May 07** ▪ Dexlansoprazole (Kapidex)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate (Zegerid) ▪ pantoprazole (Protonix) ▪ rabeprazole (Aciphex) Automated PA requiring trial of omeprazole OR esomeprazole (Nexium) applies to new users of non-formulary PPIs (no use of PPIs in last 180 days)	BCF	▪ generic omeprazole 10 mg and 20 mg (excludes Prilosec 40 mg) ▪ esomeprazole (Nexium)	24 July 07	24 Oct 07 (90 days)
May 09 (update; reviewed May 06)	Antiemetics	**Recommended for non-formulary status May 09; no change to non-formulary status in** ▪ granisetron transdermal system (Sancuso)	BCF	No changes to BCF recommendation May 09	17 Aug 09	28 Oct 09
		▪ dolasetron (Anzemet)	BCF	▪ promethazine (oral and rectal)	26 Jul 06	27 Sep 06 (60 days)
Feb 09	Inhaled Corticosteroids	▪ Beclomethasone HFA MDI (Qvar) ▪ Budesonide MFA MDI (Pulmicort Flexhaler) ▪ Ciclesonide HFA MDI (Alvesco) ▪ Flunisolide CFC MDI (Aerobid, Aerobid M) ▪ Triamcinolone CFC MDI (Azmacort)	BCF	▪ Fluticasone DPI (Flovent Diskus) ▪ Fluticasone HFA MDA (Flovent HFA) ▪ Mometasone DPI (Asmanex Twisthaler)	12 May 2009	16 Sep 09 (120 days)
Feb 09	Long-Acting Beta Agonists	▪ formoterol inhalation solution (Perforomist)	BCF	▪ Salmeterol DPI (Serevent Diskus)	12 May 2009	16 Sep 09 (120 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (implementation period)
Feb 09	Inhaled Corticosteroids / Long-Acting Beta Agonist Combinations	(No ICS/LABA combinations recommended for NF placement Feb 09)	BCF	▪ Fluticasone/salmeterol DPI (Advair Diskus) ▪ Fluticasone/salmeterol HFA MDI (Advair HFA)	12 May 2009	16 Sep 09 (120 days)
Nov 08	Short-Acting Beta Agonists	▪ albuterol chlorofluorocarbon (CFC) metered dose inhaler (MDI) (no longer manufactured) ▪ metaproterenol (Alupent) CFC MDI (no longer marketed) ▪ metaproterenol inhalation solution ▪ pirbuterol (Maxair) MDI	BCF	▪ Ventolin HFA (albuterol hydrofluoroalkane (HFA) MDI ▪ Albuterol inhalation solution; Note – does not include the following: Accuneb 0.021% [0.63 mg/mL] Accuneb 0.042% [1.25 mg/3mL] Albuterol 0.5% [2.5 mg/0.5 mL in 0.5 unit dose vial]	10 Feb 09	8 Apr 09 (60 days)
Nov 08 & Aug 08 (update; reviewed Nov 05)	Antidepressants I	**Recommended for non-formulary status Aug 08; no change to non-formulary status in Nov 08** ▪ desvenlafaxine (Pristiq)	BCF	No changes to BCF recommended Aug 08	10 Feb 09; original signing date 24 Oct 08	7 Jan 09 (60 days)
		To remain NF ▪ paroxetine HCl CR (Paxil) ▪ fluoxetine 90 mg weekly admin. (Prozac Weekly) ▪ fluoxetine in special packaging for PMDD (Sarafem) ▪ escitalopram (Lexapro) ▪ duloxetine (Cymbalta) ▪ bupropion extended release (Wellbutrin XL)	BCF	Currently BCF ▪ citalopram ▪ fluoxetine (excluding weekly regimen & special packaging for PMDD) ▪ sertraline (Zoloft) ▪ trazodone ▪ bupropion sustained release	19 Jan 06	19 Jul 06 (180 days)
Nov 08	ACE inhibitors – Renin Angiotensin Antihypertensives	Previously non-formulary, recommended for UF status Nov 08 ▪ ramipril (Altace generic)	BCF	▪ No changes recommended to BCF at Nov 08 meeting; ramipril removed from Non-formulary status and designated as Uniform Formulary immediately upon signing of the minutes	10 Feb 09	N/A
Oct 08 (interim teleconference meeting) & Jun 08	Triptans	▪ almotriptan (Axert) ▪ frovatriptan (Frova) ▪ naratriptan (Amerge)	BCF	▪ rizatriptan (Maxalt), immediate upon signing of the minutes ▪ sumatriptan oral and one injectable formulation, when multi-source generics are available	24 Oct 08;; original signing date: 27 Aug 08	26 Nov 08 (90 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Aug 08	Self-Monitoring Blood Glucose Systems (SMBGS) test strips	▪ OneTouch Ultra 2 strips (for OneTouch Ultra 2, Ultra Mini, and Ultra Smart meters) ▪ TrueTrack strips (for TrueTrack meter) ▪ Accu-chek Comfort Curve strips (for Accu-chek Advantage meter) ▪ Accu-chek Compact Plus drum (for Accu-check Compact Plus meter) ▪ Accu-chek Simplicity, Ascensia Autodisk, Ascensia Breeze 2, Ascensia Elite, Assure, Assure 3, Assure II, Assure Pro, Bd Test Strips, Chemstrip Bg, Control AST, Dextrostix Reagent, Easygluco, Easypro, Fast Take, Freestyle test strips (other than Freestyle Lite), Glucofilm, Glucolab, Glucometer Dex, Glucometer Elite, Glucose Test Strip, Glucostix, Optium, Precision Pcx, Precision Pcx Plus, Precision Q-I-D, Precision Sof-Tact, Prestige Smart System, Prodigy, Quicktek, Sidekick, Sof-Tact, Surestep, Surestep Pro, Test Strip, Relion Ultima, Uni-Check ▪ Plus all other store/private label brand strips not included on the UF (see BCF/ECF column)	BCF	**Basic Core Formulary SMBGS test strips** ▪ Precision Xtra strips (for Precision Xtra meter) **Uniform Formulary SMBGS test strips** ▪ Accu-chek Aviva (for Accu-chek Aviva meter) ▪ Ascensia Contour (for Ascensia Contour meter) ▪ Freestyle Lite (for Freestyle Freedom Lite and Freestyle Lite meters)	24 Oct 08	17 Mar 09 (120 days)
Aug 08 (update; reviewed Aug 05; also updated Nov 07)	Calcium Channel Blockers	**Recommended for non-formulary status Aug 08** ▪ nisoldipine geomatrix (Sular geomatrix)	BCF	No changes to BCF recommended Aug 08	24 Oct 08	7 Jan 09 (60 days)
		Previously non-formulary, recommended for UF status Nov 07 ▪ amlodipine besylate (Norvasc generic)		Recommended for addition to BCF Nov 07 ▪ amlodipine besylate tablets	13 Feb 08	13 Feb 08
		To Remain Non-Formulary ▪ isradipine IR, ER (Dynacirc; Dynacirc CR) ▪ nicardipine IR (Cardene, generics) ▪ nicardipine SR (Cardene SR) ▪ verapamil ER (Verelan) ▪ verapamil ER HS dosing (Verelan PM, Covera HS) ▪ diltiazem ER for bedtime dosing (Cardizem LA)		Currently BCF ▪ amlodipine besylate (Norvasc, generics) (Recommended at Nov 07 meeting) ▪ nifedipine ER (Adalat CC, generics) ▪ verapamil SR ▪ diltiazem ER (Tiazac, generics)	13 Oct 05	15 Mar 06 (150 days)
Jun 08	Osteoporosis Agents	▪ calcitonin salmon nasal spray (Miacalcin)	BCF	▪ alendronate (Fosamax) ▪ ibandronate (Boniva) (Note: raloxifene (Evista) removed from BCF, but still UF)	27 Aug 08	26 Nov 08 (90 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (implementation period)
Jun 08 (update; reviewed Nov 07)	Adrenergic Blocking Agents	**Recommended for non-formulary status Jun 08** ▪ nebivolol (Bystolic)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		(No ABAs selected for NF placement at Nov 07 meeting)		Currently BCF ▪ atenolol tablets ▪ metoprolol tartrate IR tablets ▪ carvedilol IR tablets ▪ metoprolol succinate ER tablets	13 Feb 08	-
Jun 08 (update; reviewed Aug 07	Newer Antihistamines	**Recommended for non-formulary status Jun 08** ▪ levocetirizine (Xyzal)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ desloratadine (Clarinex) ▪ desloratadine/pseudoephedrine (Clarinex D)		▪ MTFs required to carry at least one single ingredient agent from the newer antihistamine class (loratadine, cetirizine, or fexofenadine) on their local formulary, including at least one dosage form suitable for pediatric use	17 Oct 07	16 Jan 08 (90 days)
Jun 08 (update; reviewed Aug 07)	Leukotriene Modifiers	**Recommended for non-formulary status Jun 08** ▪ Zileuton ER (Zyflo CR)	BCF	No changes to BCF rec Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)
		To remain NF ▪ zileuton (Zyflo)		Currently BCF ▪ montelukast (Singulair)	17 Oct 07	16 Jan 08 (90 days)
Jun 08 (update) Original reviews ▪ ACE inhibitors: Aug 05 ▪ Miscellaneous antihypertensives,	Renin Angiotensin Antihypertensives	**Recommended for non-formulary status Jun 08** ▪ olmesartan/amlodipine (Azor)	BCF	No change to BCF recommended Jun 08	27 Aug 08	Revised implementation date: 26 Nov 08 original implementation date: 29 Oct 08 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (implementation period)
including ACE/CCB combos. Feb 06 ▪ ARBs: May 07 ▪ Renin inhibitors. Aug 07 ▪ CCB/ARB combos Nov 07 update		To remain NF ▪ valsartan amlodipine (Exforge)		No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ACE inhibitors ▪ Moexipril +/- HCTZ (Univasc; Uniretic) ▪ perindopril (Aceon) ▪ ramipril (Altace) ACE/CCB combos ▪ felodipine/enalapril (Lexxel) (D/C'd from market) ▪ verapamil/trandolapril (Tarka) ARBs ▪ eprosartan +/- HCTZ (Teveten; Teveten HCT) ▪ irbesartan+/- HCTZ (Avapro, Avalide) ▪ olmesartan +/- HCTZ (Benicar; Benicar HCT) ▪ valsartan +/- (Diovan; Diovan HCT)		Currently on the BCF ACE inhibitors ▪ captopril ▪ lisinopril ▪ lisinopril / HCTZ ACE/CCB combos ▪ amlodipine/benazepril (Lotrel, generics) ARBs ▪ telmisartan (Micardis) ▪ telmisartan HCTZ (Micardis HCT)	ACE inhibitors ▪ 13 Oct 05 ACE/CCB combos ▪ 26 Apr 06 ARBs ▪ 24 July 07	ACE inhibitors ▪ 15 Feb 06 ACE/CCB combos ▪ 26 Jul 06 ARBs ▪ 21 Nov 07
Nov 07 (update, original review May 06)	Contraceptives	**Recommended for non-formulary status Nov 07** ▪ EE 20 mcg/levonorgestrel 0.09 mg in special packaging for continuous use (Lybrel)	BCF	No change to BCF recommended Nov 07	13 Feb 08	16 Apr 08 (60 days)
		To remain NF ▪ EE 30 mcg / levonorgestrel 0.15 mg in special packaging for extended use (Seasonale) ▪ EE 25 mcg / norethindrone 0.4 mg (Ovcon 35) ▪ EE 50 mcg / norethindrone 1 mg (Ovcon 50) ▪ EE 20/30/35 mcg / noreth. 1 mg (Estrostep Fe)		Currently on the BCF ▪ EE 20 mcg / 3 mg drospirenone (Yaz) ▪ EE 20 mcg / 0.1 mg levonorgestrel (Lutera, Sronyx, or equivalent) ▪ EE 30 mcg / 3 mg drospirenone (Yasmin) ▪ EE 30 mcg / 0.15 mg levonorgestrel (Nordette or equivalent / excludes Seasonale) ▪ EE 35 mcg / 1 mg norethindrone (Ortho-Novum 1/35 or equivalent) ▪ EE 35 mcg / 0.25 mg norgestimate (Ortho-Cyclen or equivalent) ▪ EE 25 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo) ▪ EE 35 mcg / 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen or equivalent) ▪ 0.35 mg norethindrone (Nor-QD, Ortho Micronor, or equivalent)	26 Jul 06	24 Jan 07
		▪ EE 30/10 mcg / 0.15 mg levonorgestrel in special packaging for extended use (Seasonique) ▪ EE 20 mcg / 1 mg norethindrone (Loestrin 24 Fe)			17 Jan 07	18 Mar 07
Aug 07	Growth Stimulating Agents	▪ somatropin (Genotropin, Genotropin Miniquick) ▪ somatropin (Humatrope) ▪ somatropin (Omnitrope) ▪ somatropin (Saizen)	ECF	▪ somatropin (Norditropin)	17 Oct 07	19 Dec 07 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
May 07	5-Alpha Reductase Inhibitors	▪ dutasteride (Avodart)	BCF	▪ finasteride	24 July 07	24 Oct 07 (90 days)
Feb 07	Newer Sedative Hypnotics	▪ zolpidem ER (Ambien CR) ▪ zaleplon (Sonata) ▪ ramelteon (Rozerem) Automated PA requiring trial of zolpidem IR applies to new users of eszopiclone (Lunesta), ramelteon (Rozerem), zaleplon (Sonata), or zolpidem ER (Ambien CR) (new users = no use of newer sedative hypnotics in last 180 days)	BCF	▪ zolpidem IR (Ambien)	02 May 07	01 Aug 07 (90 days)
Feb 07	Monoamine Oxidase Inhibitors	▪ selegiline transdermal patch (Emsam)	ECF	▪ phenelzine (Nardil)	02 May 07	01 Aug 07 (90 days)
Feb 07	Narcotic Analgesics	▪ tramadol ER (Ultram ER)	BCF	▪ morphine sulfate IR 15 mg, 30 mg ▪ morphine sulfate 12-hour ER (MS Contin or equivalent) 15, 30, 60 mg ▪ oxycodone/APAP 5/325 mg ▪ hydrocodone/APAP 5/500 mg ▪ codeine/APAP 30/300 mg ▪ codeine/APAP elixir 12/120 mg/5 mL ▪ tramadol IR	02 May 07	01 Aug 07 (90 days)
Feb 07	Ophthalmic Glaucoma Agents	▪ travoprost (Travatan, Travatan Z) ▪ timolol maleate for once daily dosing (Istalol) ▪ timolol hemihydrate (Betimol) ▪ brinzolamide (Azopt)	BCF	▪ latanoprost (Xalatan) ▪ brimonidine (Alphagan P); excludes 0.1% ▪ timolol maleate ▪ timolol maleate gel-forming solution ▪ pilocarpine	02 May 07	01 Aug 07 (90 days)
Nov 06	Older Sedative Hypnotics	-	BCF	▪ temazepam 15 and 30 mg	17 Jan 07	-
Nov 06 (update; reviewed Nov 06)	Dermatologic Topical Antifungals*	**Recommended for non-formulary status Nov 06:** 0.25% miconazole / 15% zinc oxide / 81.35% white petrolatum ointment (Vusion)	BCF	No change to BCF recommended Nov 06	14 Jul 05	17 Aug 05 (30 days)
		▪ econazole ▪ ciclopirox ▪ oxiconazole (Oxistat) ▪ sertaconazole (Ertaczo) ▪ sulconazole (Exelderm)		▪ nystatin ▪ clotrimazole	17 Jan 07	18 Mar 07 (60 days)

Meeting	Drug Class	Non-Formulary Medications	BCF/ ECF Class	BCF/ECF Medications	Decision Date (DoD P&T minutes signed, effective date for BCF/ECF medications, NF to UF changes)	Effective Date for Non-Formulary Medications (Implementation period)
Aug 06	H2 Antagonists / GI protectants	-	BCF	▪ ranitidine (Zantac) – excludes gelcaps and effervescent tablets	23 Oct 06	-
Aug 06	Antilipidemic Agents I	▪ rosuvastatin (Crestor) ▪ atorvastatin / amlodipine (Caduet)	BCF	▪ simvastatin (Zocor) ▪ pravastatin ▪ simvastatin / ezetimibe (Vytorin) ▪ niacin extended release (Niaspan)	23 Oct 06	1 Feb 07 (90 days)
Feb 06	GABA-analogs	▪ pregabalin (Lyrica)	BCF	▪ gabapentin	26 Apr 06	28 Jun 06 (60 days)
Nov 05	Alzheimer's Drugs	▪ tacrine (Cognex)	ECF	▪ donepezil (Aricept)	19 Jan 06	19 Apr 06 (90 days)
Nov 05	Macrolide/ Ketolide Antibiotics	▪ azithromycin 2 gm (Zmax) ▪ telithromycin (Ketek)	BCF	▪ azithromycin (Z-Pak) ▪ erythromycin salts and bases	19 Jan 06	22 Mar 06 (60 days)
May 05	MS-DMDs	-	ECF	▪ interferon beta-1a intramuscular injection (Avonex)	14 Jul 05	-

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

Appendix G — Table of Abbreviations

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