DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

May 2014

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 14 and 15, 2014, at the Defense Health Agency (DHA) Pharmacoeconomic Branch, Fort Sam Houston, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes for the February 2014 DoD P&T Committee meeting on May 12, 2014.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations 199.21(e)(1). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

IV. REVIEW OF RECENTLY APPROVED U.S. FOOD AND DRUG ADMINISTRATION (FDA) AGENTS

A. Hepatitis C Virus Drugs: Sofosbuvir tablets (Sovaldi)

Background—Sofosbuvir (Sovaldi) is a new oral direct acting antiviral (DAA) indicated for the treatment of chronic hepatitis C virus (HCV) infection. The American Association for the Study of Liver Diseases and the Infectious Disease Society of America (AASLD/IDSA) released new HCV treatment guidelines in February 2014 (*www.hcvguidelines.org*). Several drugs are in the pipeline, including interferon-free regimens; consult the guidelines for updated recommendations.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 against, 0 abstained, 1 absent) the following:

- The AASLD/IDSA guidelines consider sofosbuvir as the standard of care for HCV infection. Sofosbuvir should be a component of a combination antiviral regimen (e.g., including ribavirin with or without peginterferon); it must not be used as monotherapy. Sustained virologic response (SVR) rates of 90% are achieved in HCV genotypes 1 through 6 when sofosbuvir is combined with ribavirin (dual therapy) and interferon (triple therapy).

- Advantages of sofosbuvir over the other DAAs [telaprevir (Incivek) and boceprevir (Victrelis)] include reduced frequency of administration, lower tablet burden, higher SVR rates, shorter treatment courses, fewer drug interactions, and improved tolerability profile.

- Telaprevir (Incivek) and boceprevir (Victrelis) are no longer recommended in the AASLD/IDSA guidelines as they are inferior to sofosbuvir and should not be used.

Relative Cost-Effectiveness Analysis and Conclusion—Initial cost minimization analysis (CMA) and cost-effectiveness analysis (CEA) were performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Cost minimization analysis showed that sofosbuvir (Sovaldi) is the most costly DAA currently available for treating HCV.

- CEA evaluated the potential benefit associated with improved efficacy data and improved tolerability associated with sofosbuvir (Sovaldi) compared to other HCV treatment regimens. Preliminary findings suggested that the cost per SVR achieved with sofosbuvir was comparable with previously prescribed DAAs for HCV infection.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:

    - Sofosbuvir (Sovaldi) be designated with formulary status on the UF, based on clinical and cost effectiveness. Patients are encouraged to fill Sovaldi prescriptions at Military Treatment Facilities (MTFs) or Mail Order Pharmacy points of service (POS), and

    - Sovaldi, and the other DAAs telaprevir (Incivek) and boceprevir (Victrelis), be added to the TRICARE Specialty Drug list to facilitate recapture from the Retail Network to the Mail Order Pharmacy.

2. ***COMMITTEE ACTION: REMOVAL OF TELAPREVIR (INCIVEK) FROM THE EXTENDED CORE FORMULARY (ECF)***—Telaprevir (Incivek) was designated as an ECF drug at the November 2012 P&T

Committee meeting. Telaprevir is no longer the standard of care as it has a higher incidence of adverse effects, a lower SVR rate, and requires multiple daily doses, compared to sofosbuvir. The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) removing telaprevir (Incivek) from the ECF upon signing of the minutes; it remains on the UF. As a result, no DAA is ECF at this time. PEG-Interferon alfa-2A (Pegasys) and ribavirin generic 200 mg capsules remain designated ECF.

3. ***COMMITTEE ACTION: SOFOSBUVIR (SOVALDI) PRIOR AUTHORIZATION (PA) CRITERIA***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) PA criteria for sofosbuvir (Sovaldi) for new users, consistent with AASLD/IDSA guidelines and FDA-approved labeling. Prior authorization will expire after 12 or 24 weeks for sofosbuvir (Sovaldi), as outlined in Appendix D. (See Appendix D for the full criteria.)

4. ***COMMITTEE ACTION: TELAPREVIR (INCIVEK) AND BOCEPREVIR (VICTRELIS) REVISED PA CRITERIA***
PA criteria for telaprevir (Incivek) and boceprevir (Victrelis) were recommended at the November 2012 P&T Committee meeting. Because of the new the AASLD/IDSA guidelines, the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) revised PA criteria for boceprevir (Victrelis) and telaprevir (Incivek) for new users. Current users of boceprevir or telaprevir are allowed to complete their course of therapy without interruption. (See Appendix D for the full criteria.)

5. ***COMMITTEE ACTION: SIMEPREVIR (OLYSIO) PA CRITERIA***
Simeprevir (Olysio) is a DAA approved by the FDA in December 2013. It will be reviewed as a new drug at an upcoming meeting. Simeprevir is indicated for use with ribavirin and PEG interferon, but the AASLD/IDSA guidelines recommend a non-FDA-approved regimen with sofosbuvir and ribavirin as an alternative treatment for genotype 1 patients who are interferon-ineligible. The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) PA criteria for new users of simeprevir (Olysio) consistent with AASLD/IDSA guidelines. (See Appendix D for the full criteria.) The PA will expire after 12 weeks.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of no later than the first Wednesday after a 30-day implementation period in all POS. Based on

the P&T Committee's recommendation, the effective date is October 15, 2014

Director, DHA, Decision: ☑ Approved □ Disapproved

Approved, but modified as follows:

B. Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)

Background—Mirabegron (Myrbetriq) is a beta-3 receptor agonist, which promotes urine storage by increasing bladder capacity. This mechanism of action is unique from the antimuscarinic OAB drugs [e.g., tolterodine (Detrol LA), oxybutynin, solifenacin (Vesicare), and trospium (Sanctura), etc.]. Compared to placebo, mirabegron produced statistically significant reductions in incontinence episodes, but the clinical effect is small and there is a high placebo response rate. An analysis of Military Health System (MHS) prescription data showed that the medication possession ratio was higher at six months with mirabegron than the OAB drugs (72% versus 61%).

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) that although there do not appear to be clinically relevant differences in efficacy between mirabegron and the antimuscarinic OAB drugs, it is well-tolerated and does not produce the anticholinergic effects of dry mouth and constipation seen with the other OAB drugs.

Relative Cost-Effectiveness Analysis and Conclusion—A CMA was performed to evaluate mirabegron (Myrbetriq), a new entrant in the OAB Drug Class. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic oxybutynin IR (Ditropan) was the most cost-effective agent, followed by oxybutynin ER (Ditropan XL, generic), trospium IR (Sanctura, generic), oxybutynin 10% gel (Gelnique), tolterodine ER (Detrol LA), tolterodine IR (Detrol; generic), solifenacin (Vesicare), mirabegron (Myrbetriq), oxybutynin transdermal system (Oxytrol), darifenacin (Enablex), trospium ER (Sanctura XR), fesoterodine (Toviaz), and oxybutynin pump (Gelnique Pump).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:
    - Mirabegron (Myrbetriq) be designated UF and non step-preferred ("behind the step"), due to the improved tolerability profile over the antimuscarinic OAB drugs. Step therapy will require that all new users

of mirabegron try Detrol LA or a preferred generic (oxybutynin IR, oxybutynin ER, or trospium IR) prior to the use of the other OAB drugs.

- Automated PA criteria (step therapy) and manual PA criteria for all new users of mirabegron were recommended at the February 2014 P&T Committee meeting and implemented on June 11, 2014. (See February 2014 DoD P&T Committee minutes.)

Director, DHA, Decision: ☐ Approved ☐ Disapproved

Approved, but modified as follows:

C. Oral Anticoagulants: Apixaban (Eliquis)

Background—Apixaban is a new oral anticoagulant (NOAC) and is the second oral factor Xa inhibitor to reach the market. Similar to the other NOACs, [(rivaroxaban (Xarelto) and dabigatran (Pradaxa)], apixaban has the advantages of predictable anticoagulant effect, fixed dosing, and fewer drug interactions compared to warfarin, and the convenience of no laboratory monitoring and no dietary restrictions. Apixaban was superior to poorly controlled warfarin at preventing stroke and systemic embolism in patients with atrial fibrillation (ARISTOTLE trial). Apixaban was non-inferior to enoxaparin when used for prevention of venous thromboembolism following hip or knee replacement surgery.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (12 for, 0 against, 0 abstained, 5 absent) the main benefit of apixaban and the other NOACs over warfarin is the reduced rate of intracranial hemorrhage when used for stroke prevention in patients with non-valvular atrial fibrillation. The NOACs and warfarin (Coumadin, generic) will be re-reviewed at an upcoming meeting for UF and BCF placement.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate apixaban (Eliquis) with other oral anticoagulants in the prevention of stroke and systemic embolism in atrial fibrillation and prevention of VTE in patients undergoing orthopedic surgery. The P&T Committee concluded (12 for, 0 opposed, 0 abstained, 5 absent) the following:

- CMA showed that warfarin (Coumadin, generic), including drug monitoring costs, remains the least costly agent in the class. Among NOACs, apixaban (Eliquis) was less costly than rivaroxaban (Xarelto) and more costly than dabigatran (Pradaxa).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (12 for, 0 against, 0 abstained, 5 absent) apixaban (Eliquis) be designated formulary on the UF, based on clinical and cost effectiveness.

Director, DHA, Decision: ☑ Approved □ Disapproved

Approved, but modified as follows:

D. Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors: Dapagliflozin (Farxiga)

Background—Dapagliflozin (Farxiga) is the second FDA-approved SGLT2 inhibitor. SGLT2 inhibitors are a relatively new subclass of the Non-Insulin Diabetes Drug Class and have a novel mechanism of action. Dapagliflozin is effective in lowering hemoglobin A1c (A1c) by about 0.4% to 1% when used as monotherapy, by about 0.5% to 2% as part of dual therapy, and about 0.3% to 1% as part of triple therapy. It is similar to canagliflozin (Invokana) in terms of decreasing triglycerides, increasing LDL cholesterol, increasing HDL cholesterol, and decreasing systolic blood pressure and body weight.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) dapagliflozin offers no clinically compelling advantages over the existing UF non-insulin diabetes drugs, given the modest decrease in A1c; risk of adverse reactions, including female genital mycotic infections and urinary tract infections; and unknown long-term cardiovascular safety profile.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate dapagliflozin (Farxiga) with other oral products on the Uniform Formulary used in the treatment of diabetes. The P&T Committee concluded (16 for, 0 opposed, 1abstained, 0 absent) the following:

- CMA results showed that dapagliflozin (Farxiga) was not cost-effective compared with existing formulary agents in the non-insulin diabetes class including metformin, sulfonylureas, thiazolidinediones, and dipeptidyl-dipeptidase-4 (DPP-4) inhibitors.
- Current costs for dapagliflozin (Farxiga) show it was comparable to canagliflozin (Invokana), the other product available in the SGLT2 subclass.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) dapagliflozin (Farxiga) be designated NF, due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcome, and cost disadvantage compared to UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 against, 1 abstained, 1 absent) MN criteria for dapagliflozin (Farxiga). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: PA CRITERIA***—Existing automated PA (step therapy) for the SGLT2 inhibitors requires a trial of metformin, or a sulfonylurea, and a DPP-4 inhibitor first, based on positive long-term outcomes data with metformin and the sulfonylureas.

   The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) a trial of metformin or a sulfonylurea and a DPP-4 inhibitor in all new and current users of dapagliflozin (Farxiga), due to the modest hemoglobin Alc lowering and safety concerns. (See Appendix C for full criteria.)

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
   The P&T Committee recommended (15 for, 0 against, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

E. Long-Acting Beta Adrenergic (LABA) Inhalers: Indacaterol (Arcapta Neohaler)

Background—Indacaterol (Arcapta) is a LABA that is dosed once daily. It is not available in a fixed-dose combination with an inhaled corticosteroid (ICS). The U.S. approved dose of 75 mcg QD was based on two trials showing indacaterol produced statistically and clinically significant improvement in forced expiratory volume in one second compared to placebo; there are no comparative trials available with this dose. The safety profile appears similar to the other LABAs, including a black box warning against use in patients with asthma.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 0 absent) that although indacaterol is the only LABA dosed once daily, other drug classes, including the ICS/LABA combinations and long-acting muscarinic agents, are more effective than LABAs at improving pulmonary function, and decreasing hospitalizations or exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate indacaterol (Arcapta) with other LABAs available on the UF that are used in the treatment of COPD. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that indacaterol (Arcapta) was not cost-effective compared to salmeterol (Serevent) and formoterol (Foradil).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—Despite the convenience of once daily dosing, the P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) indacaterol (Arcapta) be designated NF due to the lack of compelling advantages over the other LABAs and cost effectiveness. Additionally, the P&T Committee recommended reclassifying the LABAs to the Pulmonary II drug class, which includes other drug classes used for treating COPD.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) MN criteria for indacaterol (Arcapta). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014

Director, DHA Decision: ☑ Approved □ Disapproved

Approved, but modified as follows:

F. Gastrointestinal (GI-1s): GI steroid subclass—Budesonide Extended Release (ER) Tablets (Uceris)

Background—Budesonide ER tablets (Uceris) differs from the budesonide capsules (Entocort; generics) currently on the market in its delivery mechanism and FDA-approved indication. The Uceris tablet releases budesonide in the distal colon, making it effective for ulcerative colitis, while generic budesonide is released in the distal ileum and right colon and is only indicated for the treatment of Crohn's disease. There are no head-to-head studies comparing Uceris to the oral aminosalicylates, but an indirect comparison to mesalamine (Lialda) suggests reduced efficacy at inducing remission after eight weeks of treatment.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 against, 0 abstained, 0 absent) that although Uceris offers a locally-acting steroid option for patients

with mild to moderate ulcerative colitis, it failed to demonstrate clinically compelling advantages over existing UF agents for this indication.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate budesonide ER tablets (Uceris) with other oral GI steroids and mesalamine products on the UF for induction of remission in patients with mild to moderate ulcerative colitis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) budesonide ER (Uceris) was not cost-effective compared with other GI steroid alternatives and mesalamine products on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) budesonide ER tablets (Uceris) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) MN criteria for budesonide ER tablets (Uceris). (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 against, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

G. Non-Steroidal Anti-inflammatory Drugs (NSAIDs): Diclofenac Low Dose (Zorvolex)

Background—Zorvolex is a low dose formulation of diclofenac available in 18 mg and 35 mg capsules. The formulation is intended for faster dissolution and absorption compared to other diclofenac products (diclofenac potassium 50 mg and 100 mg; e.g., Cataflam). According to the FDA, the manufacturer failed to demonstrate these theoretical advantages, as there were no differences in the pharmacokinetic profile when Zorvolex was compared to diclofenac potassium. In the clinical trial used to obtain FDA approval, over 80% of patients received

rescue narcotics for pain control. The Zorvolex package insert contains usual black box warnings and precautions for NSAIDs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 against, 0 abstained, 4 absent) that there were no clinical compelling advantages between Zorvolex and the other UF NSAIDs.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate diclofenac (Zorvolex) with other oral NSAIDs available on the UF used in the treatment of mild to moderate pain. The P&T Committee concluded (13 for, 0 opposed, 0 abstained, 4 absent) the following:

- CMA results showed that diclofenac low dose 18 mg and 35 mg capsules (Zorvolex) were not cost-effective compared to generic formulations of meloxicam (Mobic), ibuprofen (Motrin), diclofenac sodium (Voltaren), and diclofenac potassium (Cataflam).

- Zorvolex was comparable in cost to celecoxib (Celebrex). However, generic formulations of celecoxib are expected later this year and should result in further cost reductions for celecoxib.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 0 against, 0 abstained, 4 absent) diclofenac low dose 18 mg and 35 mg capsules (Zorvolex) be designated NF, based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (13 for, 0 against, 0 abstained, 4 absent) MN criteria for Zorvolex. (See Appendix B for the full criteria.)

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (13 for, 0 against, 0 abstained, 4 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014

Director, DHA, Decision: ☑ Approved □ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Nasal Allergy Drugs

Background—The P&T Committee evaluated the clinical effectiveness of the Nasal Allergy Drugs, which includes the nasal corticosteroids, nasal antihistamines, and nasal anticholinergics. Three new drugs, ciclesonide hydrofluoroalkane (HFA), (Zetonna), beclomethasone HFA (QNASL), and fluticasone/azelastine (Dymista) have been marketed since the last UF review in May 2011. Triamcinolone (Nasacort OTC) is available over-the-counter (OTC) and is not included in the review.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) with the following conclusions:

1. There is no new evidence that substantively changes the conclusions of the class review completed in 2011. Nasal corticosteroids are first-line agents in reducing allergic rhinitis symptoms of, rhinorrhea, congestion, and itching.
2. Available data from placebo-controlled trials and head-to-head trials is not sufficient to clearly show superiority of one nasal allergy drug over another with regard to symptom relief or lower risk of harm.
3. Nasal steroid HFA aerosol formulations (ciclesonide [Zetonna] and beclomethasone [QNASL]) have advantages over aqueous formulations of no post nasal drip, longer retention in the nasal cavity, potentially better taste, once daily dosing, and inclusion of a dose counter. The disadvantages include a higher incidence of epistaxis and burning and FDA approval only for children older than 12 years.
4. Fluticasone/azelastine (Dymista) is the first combination nasal corticosteroid/nasal antihistamine. It has not been compared with individual components given separately or with concomitant use of another nasal steroid/oral antihistamine.
5. The nasal antihistamines are generally less effective than nasal corticosteroids for treating allergic rhinitis, but may be used as first-line therapy, and in non-allergic rhinitis. Nasal antihistamines have a quicker onset of effect than the nasal steroids. They are associated with a clinically significant effect on reducing nasal congestion. Somnolence is considered a class effect.

Relative Cost-Effectiveness Analysis and Conclusion—A pharmacoeconomic analysis and budget impact analysis (BIA) were performed to evaluate the Nasal Allergy Drugs. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed generic formulations of fluticasone propionate (Flonase), ipratropium (Atrovent), flunisolide (Nasarel), and azelastine 137 mcg (Astelin) were the most cost-effective agents in this class, followed by the branded agents mometasone (Nasonex), fluticasone furoate (Veramyst), azelastine 205 mcg

(Astepro), budesonide (Rhinocort Aqua), beclomethasone (QNASL), ciclesonide 50 mcg (Omnaris), olopatadine (Patanase), ciclesonide 37 mcg (Zetonna), beclomethasone (Beconase AQ), and fluticasone/azelastine (Dymista).

- A BIA was performed to evaluate the potential impact of scenarios with selected agents designated with formulary or NF status on the UF. BIA results showed that the scenario with azelastine 137 mcg, flunisolide, fluticasone propionate, and ipratropium all designated as formulary and step-preferred, and with all branded agents designated as NF and non step-preferred, was the most cost-effective for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following for the Nasal Allergy Drugs, based on the high degree of therapeutic interchangeability and on cost effectiveness:
    - UF and step-preferred ("in front of the step"): azelastine 137 mcg, flunisolide, fluticasone propionate, and ipratropium
    - NF and non-preferred ("behind the step"): azelastine 205 mcg (Astepro), beclomethasone (QNASL and Beconase AQ), ciclesonide (Omnaris and Zetonna), budesonide (Rhinocort Aqua), fluticasone furoate (Veramyst), fluticasone/azelastine (Dymista), mometasone (Nasonex), and olopatadine (Patanase)
    - This recommendation includes step therapy, which requires a trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium in all new and current users of the Nasal Allergy Drugs who are older than 4 years.
    - Generic formulations of mometasone (Nasonex) are expected later in 2014. When the generics to Nasonex become cost-effective relative to the step-preferred agents, the generic will become step-preferred without further action by the P&T Committee, Beneficiary Advisory Panel, or Director, DHA. A generic agent is cost-effective relative to step-preferred agents when its total weighted average cost per day of treatment is less than or equal to the total weighted average cost per day of treatment for the step-preferred agent.
    - If a shortage for generic fluticasone propionate occurs, the field will be quickly notified of the most appropriate action to take.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) that fluticasone propionate (Flonase, generic) remain on the BCF, due to cost effectiveness and existing high utilization in the MHS.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Astepro, QNASL, Beconase AQ, Omnaris, Zetonna, Rhinocort Aqua, Veramyst, Dymista, Nasonex, and Patanase. (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) automated (step therapy) and manual PA criteria in all new and current users of Astepro, QNASL, Beconase AQ, Omnaris, Zetonna, Rhinocort Aqua, Veramyst, Dymista, Nasonex, and Patanase who are older than 4 years of age. A trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is required before the non step-preferred drugs. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—QLs currently apply to the Nasal Allergy Drugs. The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for ciclesonide 50 mg HFA (Zetonna) of 1 inhaler/30 days in the Retail Network and 3 inhalers/90 days in the Mail Order Pharmacy. The P&T Committee also recommended maintaining the current QLs for the other Nasal Allergy Drugs.

6. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Inhaled Corticosteroids (ICS)

Background—The P&T Committee evaluated the clinical effectiveness of the ICS, which were last reviewed for UF status in February 2009. Mometasone (Asmanex HFA) metered dose inhaler was recently approved and has an August 2014 launch date; it will be reviewed at an upcoming meeting.

Relative Clinical Effectiveness Conclusion—The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 1 absent) with the following conclusions:

1. There is no new evidence that substantively changes the conclusions of the class review completed in 2009.
2. In patients with asthma, there is fair-to-moderate evidence that ICS agents do not differ with regard to symptom control, need for rescue medication, and exacerbations.
3. There is insufficient evidence to conclude there are clinically relevant differences in efficacy among the ICS products for treating COPD. The ICS products are not indicated for COPD treatment.
4. In terms of safety, there is insufficient evidence to determine whether there are clinically relevant differences among the ICS products in terms of minor adverse events or systemic adverse events.

Relative Cost-Effectiveness Analysis and Conclusion—A pharmacoeconomic analysis and BIA were performed to evaluate the ICS. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- The pharmacoeconomic analysis showed budesonide (Pulmicort Flexhaler) and fluticasone (Flovent Diskus and HFA) were the most cost-effective agents in this class, followed by beclomethasone (QVAR) and mometasone furoate (Asmanex Twisthaler), ciclesonide (Alvesco) and flunisolide (Aerospan).
- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and formulary or non-preferred and NF on the UF. BIA results showed that the scenario with Flovent Diskus and Flovent HFA designated as step-preferred and formulary on the UF, with Aerospan, Alvesco, Asmanex Twisthaler, Pulmicort Flexhaler and QVAR designated as non-preferred and NF on the UF, was the most cost-effective option for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following for the ICS, based on the high degree of therapeutic interchangeability and cost effectiveness:
    - UF and step-preferred ("in front of the step"): fluticasone (Flovent Diskus and Flovent HFA)
    - NF and non-preferred ("behind the step"): beclomethasone (QVAR), budesonide (Pulmicort Flexhaler), ciclesonide (Alvesco), flunisolide (Aerospan), and mometasone (Asmanex Twisthaler)
    - This recommendation includes step therapy, which requires a trial of Flovent Diskus or Flovent HFA in all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, or Asmanex Twisthaler who are older than 12 years.

- Budesonide nebulized solution (Pulmicort) was reviewed in 2009 and was not part of the class review for this meeting; it remains on the UF and is not subject to step therapy.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) that fluticasone (Flovent Diskus and Flovent HFA) remain on the BCF. As a result of this action, Asmanex Twisthaler is no longer on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) MN criteria for QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, and Asmanex Twisthaler. (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria in all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, or Asmanex Twisthaler who are older than 12 years of age. A trial of Flovent Diskus or Flovent HFA is required before the non-step preferred drugs. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014.

Director, DHA, Decision: ☑ Approved □ Disapproved

Approved, but modified as follows:

C. Osteoporosis Drugs: Oral Bisphosphonates Subclass

Background and Relative Clinical Effectiveness Conclusion—The oral bisphosphonates are a subclass of the Osteoporosis drugs, which were last reviewed for UF placement in June 2008. Generic formulations are available for alendronate (Fosamax) and ibandronate (Boniva). The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

1. There was no new significant efficacy data since the last review; however, there is substantial new safety information for the bisphosphonates.
2. Relative superiority of one agent versus another cannot be determined by bone mineral density data alone. For fracture prevention, available data from placebo-controlled trials and head-to-head trials is not sufficient to clearly establish superiority of one bisphosphonate versus another.
3. Clinical guidelines list ibandronate (Boniva, generics) as second-line therapy due to the lack of data for hip fracture prevention and lack of long-term data. However, ibandronate has the convenience of once monthly dosing and an MHS study showing improved persistence with the once monthly ibandronate formulation over the other once-weekly bisphosphonates.
4. The risedronate formulations of Atelvia (once weekly regimen) and Binosto (effervescent tablet) offer no clinically compelling advantages over the other bisphosphonate formulations.
5. Potential adverse events of osteonecrosis of the jaw, atrial fibrillation, esophageal cancer, and atypical femur fractures are considered a class effect by the FDA.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the bisphosphonate subclass. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed generic alendronate was the most cost-effective agent, followed by generic ibandronate, branded risedronate (Actonel), risedronate DR (Atelvia), alendronate/vitamin D (Fosamax Plus D), and alendronate effervescent tablet (Binosto).
- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and UF or non-preferred and NF on the UF. BIA results showed the scenario with generic alendronate designated as formulary and step-preferred, generic ibandronate as UF and non step-preferred for new users, and all branded agents (Actonel, Atelvia, Binosto, and Fosamax Plus D) designated as NF and non step-preferred for new and current users was the most cost-effective option for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) the following, based on the high degree of therapeutic interchangeability and cost-effectiveness:
    - UF and step-preferred (e.g., "in front of the step"): alendronate (Fosamax, generic)
    - UF and non step-preferred (e.g., "behind the step"): ibandronate (Boniva, generic)

- NF and non step-preferred: risedronate (Actonel), risedronate DR (Atelvia), alendronate effervescent (Binosto), and alendronate/Vitamin D (Fosamax Plus D)
- This recommendation includes step therapy, which requires a trial of alendronate prior to use of ibandronate only in new users, as the patient impact is less than if all current and new users were affected by the step. A trial of alendronate is required prior to use of risedronate (Actonel,), risedronate DR (Atelvia), alendronate effervescent (Binosto), and alendronate/Vitamin D (Fosamax Plus D) in all new and current users.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) retaining alendronate on the BCF. As a result of this action, Boniva Fosamax Plus D are no longer on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) MN criteria for Actonel, Atelvia, Binosto, and Fosamax Plus D. (See Appendix B for full criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria in all new users of ibandronate, and all new and current users of Actonel, Atelvia, Binosto, and Fosamax Plus D. A trial of alendronate is required before the non step-preferred drugs. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is December 17, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. BCF CHANGES

A. Renin Angiotensin Antihypertensives (RAAs): Telmisartan Deletion from the BCF

Telmisartan and telmisartan/HCTZ (Micardis, Micardis HCT, generics) have been BCF and step-preferred since January 2012. The manufacturer of the branded products has withdrawn the competitive pricing agreement for BCF placement. Generic formulations of telmisartan and telmisartan/HCTZ recently entered the market, but are not yet cost-effective. Other BCF, step-preferred RAAs drugs which are cost-effective include valsartan (Diovan) and generic formulations of losartan, losartan/HCTZ, and valsartan/HCTZ.

1. ***COMMITTEE ACTION: TELMISARTAN AND TELMISARTAN/HCTZ DELETION FROM THE BCF***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) removing telmisartan and telmisartan/HCTZ from the BCF upon signing of the minutes; the drugs remain UF and step-preferred.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PAs

1. **Cystic Fibrosis Drugs: Ivacaftor (Kalydeco)**—Ivacaftor (Kalydeco) is a potentiator of the cystic fibrosis transmembrane conductance regulator (CFTR). The drug initially targeted a specific subgroup of patients with cystic fibrosis (CF) who had a G551D gene mutation. The FDA has expanded Kalydeco's approved indication to include additional mutations in the CFTR gene. PA criteria were recommended by the P&T Committee for Kalydeco in February 2012 and were implemented in July 2012. There are several FDA-approved in-vitro molecular diagnostic tests designed to simultaneously detect and identify mutations in the CFTR gene.

    a) ***COMMITTEE ACTION: IVACAFTOR (KALYDECO) PA CRITERIA*** The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) updating the existing PA criteria to include the expanded FDA-approved indication.

(1) Coverage will be approved for the treatment of CF patients aged 6 years and older who have a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene, detected by an FDA-approved test.

(2) Coverage is not approved for patients who are homozygous for the F508del mutation in the CFTR gene.

(3) The approved PA limits coverage of the drug to its labeled use. DHA will expedite review of the required test to determine its coverage under 32 CFR 199.4(g)(15). Providers and beneficiaries will be advised to retain receipts for the test to submit for reimbursement following the coverage determination.

2. **Targeted Immunomodulatory Biologics (TIBSs): Tofacitinib (Xeljanz) and Apremilast (Otezla)**—PA criteria currently apply to the TIBs. Tofacitinib (Xeljanz) is a janus kinase inhibitor approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had inadequate response or intolerance to methotrexate. Xeljanz is the first oral TIB to reach the market. Apremilast (Otezla) is an oral phosphodiesterase-4 inhibitor approved for the treatment of psoriatic arthritis. PA criteria were proposed for Xeljanz and Otezla, consistent with FDA-approved product labeling.

   a) ***COMMITTEE ACTION: TOFACITINIB (XELJANZ) AND APREMILSAST (OTEZLA) PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) PA criteria for tofacitinib (Xeljanz) and apremilast (Otezla), consistent with the product's labeling. (See Appendix C for full criteria.)

B. QLs

1. **Hepatitis C Drugs: Simeprevir (Olysio)**—Simeprevir (Olysio) is a new direct acting agent for hepatitis C approved in December 2013. QLs currently apply to the hepatitis C drugs, including the DAAs. (See Section IV, Review of Recently Approved U.S. FDA Agents, Hepatitis C Virus Drugs on page three, for Olysio PA criteria recommendations.)

   a) ***COMMITTEE ACTION: SIMEPREVIR (OLYSIO) QLs***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for simeprevir of 28 tablets per 28 days in all POS (MTFs, Retail Network, and Mail Order Pharmacy), consistent with the FDA-approved product dosing of one tablet given once daily. There are no multiple fills for multiple co-pays.

2. **TIBSs: Tofacitinib (Xeljanz) and Apremilast (Otezla)**—QLs currently apply to the TIBs.

   a) ***COMMITTEE ACTION: TOFACITINIB (XELJANZ) AND APREMILSAST (OTEZLA) QLs***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) the following QLs, consistent with the products' packaging and labeling.

      (1) Tofacitinib (Xeljanz): a maximum allowable quantity at the retail network POS of 60 tablets (30-day supply) and 120 tablets at the Mail Order Pharmacy (60-day supply).

      (2) Apremilast (Otezla): a maximum allowable quantity at the retail network POS of 60 tablets (30-day supply) and 120 tablets at the Mail Order Pharmacy (60-day supply).

Director, DHA, Decision: ☑ Approved □ Disapproved

Approved, but modified as follows:

C. Generic to Brand Changes: PA Criteria for the Retail Network

1. **Niacin ER (Niaspan)**—AB-rated generic formulations for niacin ER (Niaspan) were launched in August 2013; however, pricing for the branded product is lower than the generic formulations. The manufacturer of Niaspan offered a Voluntary Agreement for Retail Refunds, and the Tier 1 (generic) copayment was assigned to the branded product at the November 2013 P&T Committee meeting.

   The mandatory generic drug policy is in place at the Retail Network; however, brand Niaspan is the preferred product for the MHS. PA criteria allowing for a patient to receive generic niacin ER instead of branded Niaspan is needed as a result of the generic to brand change (i.e., the reverse of the current brand to generic policy).

   a) ***COMMITTEE ACTION: NIACIN ER (NIASPAN) GENERIC TO BRAND PA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) manual PA criteria for generic niacin ER in the Retail Network. The prescriber will provide patient-specific justification as to why the brand Niaspan product cannot be used. Acceptable reasons include the following, which have occurred or are likely to occur with the branded Niaspan product: allergy to the branded Niaspan; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues.

2. **Esomeprazole (Nexium)**—Esomeprazole (Nexium) and omeprazole (generic Prilosec) are BCF and step-preferred in the Proton Pump Inhibitor (PPI) drug class. The patent for Nexium expired in May 2014; however, the launch date for generic formulations is unknown, due to manufacturing issues with the company granted exclusivity by the FDA. Market research indicates generic esomeprazole entrants will be less cost-effective than the branded formulation, leaving branded Nexium as the preferred product in the MHS. Therefore, PA criteria are needed to allow a patient to receive the generic esomeprazole instead of branded Nexium (i.e., the reverse of the current brand to generic policy).

   a) ***COMMITTEE ACTION: ESOMEPRAZOLE (NEXIUM) GENERIC TO BRAND PA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) manual PA criteria for generic esomeprazole in the Retail Network. The prescriber will provide patient-specific justification as to why the branded Nexium product cannot be used. Acceptable reasons include the following, which have occurred or are likely to occur with the branded Nexium product: allergy to branded Nexium; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues. Implementation will occur when generic esomeprazole products reach the market.

Director, DHA, Decision: ☒ Approved □ Disapproved

Approved, but modified as follows:

VIII. SECTION 716 OF THE NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FISCAL YEAR 2013 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM

A. **Medication Drug List for the Pilot Program: Updates**—The Medication Drug list for the Pilot Program for TRICARE for Life beneficiaries was recommended at the November 2013 P&T Committee meeting. An update to the drug list is required, due to recent UF changes and to ensure consistency within the drug classes. (See the November 2013 P&T Committee meeting minutes, Appendix F, found at *http://pec.ha.osd.mil/PT_min_charter.php?submenuheader=5* or the TRICARE Formulary Search Tool at *http://pec.ha.osd.mil/TFL_maintenance_drug_list.php* for the full medication drug list.)

1. ***COMMITTEE ACTION: MAINTENANCE MEDICATION PROGRAM DRUG LIST UPDATE***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) the following changes to the list of covered maintenance medications for the Section 716 pilot program. Implementation will occur upon signing of the minutes.

   Add: anticoagulants: rivaroxaban (Xarelto) and apixaban (Eliquis); antimuscarinics/antispasmodics: aclidinium (Tudorza PressAir); beta-adrenergic agonists: formoterol (Foradil); and DPP-4 inhibitors: linagliptin (Tradjenta)

   Remove: 5-alpha-reductase inhibitors for benign prostatic hyperplasia: dutasteride/tamsulosin (Jalyn); GI-1s: mesalamine (Asacol HD and Pentasa); beta agonists: indacaterol (Arcapta); corticosteroids for respiratory disease: mometasone (Asmanex), budesonide (Pulmicort Flexhaler), budesonide/formoterol (Symbicort), and mometasone/formoterol (Dulera); disease-modifying antirheumatic drugs: anakinra (Kineret); and statins: lovastatin ER (Altoprev), lovastatin/niacin (Advicor), and fluvastatin XL (Lescol XL)

   Not part of pilot program: PPIs omeprazole/sodium bicarbonate (Zegerid OTC)

   ~~Director, DHA, Decision~~: ☑ Approved ☐ Disapproved

   Approved, but modified as follows:

IX. LINE EXTENSIONS

A. Formulary Status Clarification—The P&T Committee clarified the formulary status for five product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug. The products include new dosage strengths (Horizant, Butrans patch); new packaging (Androgen 1.62% gel packets); a new dosage formulation (Pregabalin); and a new drug concentration (Pennsaid).

1. ***COMMITTEE ACTION: LINE EXTENSIONS FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) clarifying the formulary status of the following five products to reflect the current formulary status and step therapy/PA criteria of the parent compound. Implementation will occur upon signing of the minutes.

   - gabapentin enacarbil (Horizant) 300 mg tablets: NF and non step-preferred, similar to Horizant 600 mg tablets

- buprenorphine (Butrans patch) 15 mcg/hour patch: UF with PA, similar to Butrans patch 5, 10, and 20 mcg/hour
- testosterone (Androgel) 1.62% gel packets: NF and non step-preferred, similar to Androgel 1.62% gel pump
- pregabalin (Lyrica) 20 mg/mL solution: NF and non step-preferred, similar to Lyrica capsules (all dosages)
- diclofenac 2% solution (Pennsaid): NF, similar to Pennsaid 1.5% solution

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

X. FISCAL YEAR 2008 NDAA, Section 703

The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not in compliance with the Fiscal Year 2008 National Defense Authorization Act, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in the MTFs. These NF drugs will remain available in the Mail Order POS without preauthorization.

1. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) that the following products be designated NF on the UF:

CorePharma:	dextroamphetamine sulfate capsules
Lupin:	fenofibrate capsules; Wymzya Fe tablets
Royal:	Derma-Smoothe/FS Body Oil topical oil; DermOtic Oil otic drops
Savient:	Oxandrin tablets

2. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) the following pre-authorization criteria for the drugs recommended NF above: 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the

patient. These pre-authorization criteria do not apply to any POS other than retail network pharmacies.

3. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by these decisions. Based on the P&T Committee's recommendation, the effective date is December 17, 2014.

4. ***COMMITTEE ACTION: DRUG DESIGNATED FORMULARY***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) retaining tedglutide recombinant injection (GATTEX) manufactured by NPS Pharma on the UF and maintaining availability at all POS, due to its unique clinical niche in treating adults with short bowel syndrome who are dependent on parenteral support.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

XI. OVERVIEWS

Overviews of the Targeted Immunomodulatory Biologics (self-injectable and oral products) and Multiple Sclerosis (injectable and oral products) drug classes were presented to the P&T Committee. The P&T Committee provided expert opinion regarding those clinical outcomes considered most important for use in contract solicitation and for completing the clinical effectiveness review and developing the appropriate cost-effectiveness modes. The clinical and economic analyses of these classes will be presented at an upcoming meeting.

XII. ITEMS FOR INFORMATION

A. Self-Monitoring Blood Glucose System (SMBGS) Test Strips—The SMGBS test strips cost-effectiveness analysis and UF decision occurred at the August 2013 P&T Committee meeting. All steps necessary for implementation of the SMBGS test strips decision have been delayed pending a protest filed at the U.S. Court of Claims.

B. BCF Clean Up—The BCF drug listing periodically requires review for any obsolete or unnecessary products. The P&T Committee tabled a discussion of the BCF clean up for a future meeting.

C. **Review of Recently Approved U.S. FDA Agent for Attention Deficit Hyperactivity Disorder—Methylphenidate ER Suspension (Quillivant XR)**: The new drug review and recommendation for Quillivant XR was tabled until the next meeting.

XIII. ADJOURNMENT

The meeting adjourned at 1200 hours on May 15, 2014. The next meeting will be in August 2014.

Appendix A—Attendance: May 2014 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D— Table of Prior Authorization Criteria for Hepatitis C Drugs

Appendix E—Table of Implementation Status of UF Recommendations/Decisions Summary

Appendix F—Table of Abbreviations

SUBMITTED BY:

John P. Kugler, M.D., MPH
DoD P&T Committee Chair

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

Douglas J. Robb, DO, MPH
Lieutenant General, USAF, MC, CFS
Director

12 Sept 2014
Date

Appendix A—Attendance: May 2014 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
LTC Robert Conrad, MS	Chief, DHA Pharmacoeconomic Branch (Recorder)
CAPT Nita Sood	Chief of Staff, DHA Pharmacy Operations Division
COL Thirsa Martinez for COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Derrik Clay for CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
MAJ John Poulin for COL Ted Cieslak, MC	Army, Physician at Large
Col Michael Wynn, MC	Army, Family Practice Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Physician
Col Lowell Sensintaffer, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
COL Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Voting Members Absent	
Col Michael Spilker, BSC	DHA Deputy Chief, Pharmacy Operations Division
Nonvoting Members Present	
Mr. Bryan Wheeler for David Hurt	Deputy General Counsel, DHA
CDR Brandon Hardin by phone	Medical Logistics Division, DLA

Appendix A—Attendance (continued)

Guests	
Mr. Bill Davies via DCO	Defense Health Agency, Pharmacy Operations Division
Capt Richard Caballero via DCO	Defense Logistics Agency Troop Support
Mr. Alexander Quinones	Defense Logistics Agency Troop Support
CDR Matthew Baker	Indian Health Service
Maj Michele Sampayan	Air Force, Pharmacy Officer
Capt Brandy Renner	Air Force, Pharmacy Officer
Others Present	
CAPT Walter Downs, MC	DHA Pharmacoeconomic Branch
LCDR Marisol Martinez, USPHS	DHA Pharmacoeconomic Branch
LCDR Joshua Devine, USPHS	DHA Pharmacoeconomic Branch
LCDR Linh Quach, MSC	DHA Pharmacoeconomic Branch
Maj David Folmar, BSC	DHA Pharmacoeconomic Branch
MAJ Misty Cowan, MC	DHA Pharmacoeconomic Branch
Maj Ronald Khoury, MC	DHA Pharmacoeconomic Branch
Dr. David Meade	DHA Pharmacoeconomic Branch
Dr. Angela Allerman	DHA Pharmacoeconomic Branch
Dr. Shana Trice	DHA Pharmacoeconomic Branch
Dr. Eugene Moore	DHA Pharmacoeconomic Branch
Dr. Brian Beck	DHA Pharmacoeconomic Branch
Dr. Amy Lugo via DCO	DHA Pharmacoeconomic Branch
Dr. Teresa Anekwe via DCO	DHA Pharmacy Operations Division
Ms. Deborah Garcia	DHA Pharmacoeconomic Branch contractor
Dr. Esmond Nwokeji	DHA Pharmacoeconomic Branch contractor
Mr. Kirk Stocker	DHA Pharmacoeconomic Branch contractor
Maj Ellen Roska	University of Texas PhD Student

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Beclomethasone (Beconase AQ) • Beclomethasone HFA (QNASL) • Budesonide (Rhinocort Aqua) • Ciclesonide (Omnaris) • Ciclesonide (Zetonna) • Fluticasone furoate (Veramyst) • Mometasone (Nasonex) **Nasal Corticosteroids — Nasal Allergy Drugs**	• Use of **at least two** of the formulary agents is contraindicated • The patient has experienced significant adverse effects (persistent epistaxis, pharyngitis, significant nasal irritation) from **at least two** formulary drugs that is not expected to occur with the nonformulary Nasal Allergy Drug medication. • **At least two** formulary agents have resulted in therapeutic failure. • There is no alternative formulary agent for the following: 1. Rhinocort: The patient is pregnant 2. Beconase AQ and Nasonex: the patient has nasal polyps and cannot be treated with the formulary product **Formulary alternatives:** azelastine 137 mcg, flunisolide, fluticasone propionate, ipratropium
• Azelastine 205 mcg (Astepro) • Fluticasone/azelastine (Dymista) • Olopatadine (Patanase) • **Nasal Antihistamines/combinations — Nasal Allergy Drugs**	• The patient has experienced significant adverse effects (persistent epistaxis, pharyngitis, significant nasal irritation) from **at least two** formulary drugs that is not expected to occur with the nonformulary Nasal Allergy Drug medication. • **At least two, including one nasal antihistamine**, formulary agents have resulted in therapeutic failure. **Formulary alternatives:** azelastine 137 mcg, flunisolide, fluticasone propionate, ipratropium
• Beclomethasone (QVAR) • Budesonide (Pulmicort Flexhaler) • Ciclesonide (Alvesco) • Flunisolide (Aerospan) • Mometasone (Asmanex Twisthaler) **Inhaled Corticosteroids (ICS)**	• Use of Flovent Diskus or Flovent HFA is contraindicated • The patient has experienced significant adverse effects from Flovent Diskus or Flovent HFA, which is not expected to occur with the nonformulary ICS. • The patient has had an inadequate response to Flovent Diskus or Flovent HFA. • The patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk. • No alternative formulary agent: the patient is pregnant and requires Pulmicort Flexhaler **Formulary alternatives**: Flovent Diskus, Flovent HFA, Pulmicort Respules
• Risedronate (Actonel) • Risedronate delayed release (Atelvia) **Oral Bisphosphonates**	• Patient has experienced significant adverse effects from formulary agents.
• Risedronate effervescent tablet (Binosto) • **Oral Bisphosphonates**	• No alternative formulary agent and patient has swallowing difficulties and cannot consume 8 ounces of water and has no sodium restrictions

Drug / Drug Class	Medical Necessity Criteria
• Alendronate with vitamin D (Fosamax Plus D) • **Oral Bisphosphonates**	• No alternative formulary agent and patient cannot take alendronate and Vitamin D separately
• Dapagliflozin (Farxiga) **Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors**	• Use of the formulary agent is contraindicated
• Indacaterol (Arcapta) **Long-Acting Beta Agonists (LABAs)**	• Patient has experienced significant adverse effects from formulary agents.
• Budesonide ER Tablets (Uceris) **Gastrointestinal Steroid Gastrointestinal-1 Drug Class**	• Use of the formulary agents is contraindicated • The patient has experienced or is likely to experience significant adverse effects from formulary agents. • The formulary agents resulted or are likely to result in therapeutic failure. **Formulary alternatives:** budesonide enteric coated capsules (Entocort, generics), sulfasalazine, mesalamine (Lialda, Delzicol, Apriso), balsalazide, olsalazine
• Diclofenac low dose 18 and 25 mg capsules (Zorvolex) **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**	• Patient has experienced or is likely to experience significant adverse effects from formulary NSAIDs.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Azelastine 205 mcg (Astepro) • Beclomethasone (QNASL and Beconase AQ) • Ciclesonide (Omnaris and Zetonna) • Budesonide (Rhinocort Aqua) • Fluticasone furoate (Veramyst) • Fluticasone/azelastine (Dymista) • Mometasone (Nasonex) • Olopatadine (Patanase) **Nasal Allergy Drugs**	PA criteria apply to all new and current users of Astepro, Beconase AQ, QNASL, Rhinocort Aqua, Zetonna, Omnaris, Veramyst, Dymista, Nasonex, and Patanase who are older than 4 years of age. Automated PA criteria: The patient has filled a prescription for azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Astepro, Beconase AQ, QNASL, Rhinocort Aqua, Zetonna, Omnaris, Veramyst, Dymista, Nasonex, or Patanase is approved (e.g., trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is NOT required) if: • Patient has experienced any of the following issues with **at least one** of the following step-preferred Nasal Allergy Drugs (fluticasone propionate, flunisolide, azelastine, or ipratropium), which is not expected to occur with the non-preferred Nasal Allergy drug: o inadequate response to the step-preferred drugs o intolerable adverse effects (persistent epistaxis, significant nasal irritation, pharyngitis) o contraindication o no formulary alternative for the following » for budesonide (Rhinocort Aqua): patient is pregnant (pregnancy category B) » for beclomethasone (Beconase AQ) and mometasone (Nasonex): patient has nasal polyps and cannot be treated with one of the step-preferred products
• Beclomethasone (QVAR) • Budesonide (Pulmicort Flexhaler) • Ciclesonide (Alvesco) • Flunisolide (Aerospan) • Mometasone (Asmanex Twisthaler) **Inhaled Corticosteroids (ICS)**	PA criteria apply to all new users of QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, and Asmanex Twisthaler who are older than 12 years of age. Automated PA criteria: The patient has filled a prescription for Flovent Diskus or Flovent HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: QVAR, Pulmicort Flexhaler, Alvesco, Aerospan, and Asmanex Twisthaler is approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if: • Patient has experienced any of the following issues with Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred ICS: o inadequate response to the step preferred drugs o intolerable adverse effects (patient has a history of adrenal suppression and the request is for Alvesco) o contraindication o patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk o No formulary alternative for the following: Pulmicort Flexhaler: patient is pregnant

Drug / Drug Class	Prior Authorization Criteria

• Ibandronate (Boniva, generics)
• Risedronate (Actonel)
• Risedronate delayed release (Atelvia)
• Risedronate effervescent tablet (Binosto)
• Alendronate with Vitamin D (Fosamax Plus D)
 	
Oral Bisphosphonates
	PA criteria apply to all new users of ibandronate, and all new and current users of Actonel, Atelvia, Binosto, and Fosamax Plus D.
	
	Automated PA criteria: The patient has filled a prescription for alendronate at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.
	
	AND
	
	Manual PA criteria—ibandronate, Actonel, Atelvia, Binosto, and Fosamax Plus D is approved (e.g., trial of alendronate is NOT required) if:
	
	• Patient has experienced any of the following issues with alendronate, which is not expected to occur with the non-preferred oral bisphosphonates:
	  ○ Intolerable adverse effects
	  » Patient requires once monthly ibandronate or Actonel 150 mg due to gastrointestinal adverse events from alendronate weekly dosing
	  » Patient has experienced significant adverse effects from formulary agents
	  » For Binosto: No alternative formulary agent and patient has swallowing difficulties and cannot consume 8 oz of water and has no sodium restrictions
	  » For Fosamax Plus D: No alternative formulary agent and patient cannot take alendronate and vitamin D separately
	  ○ Contraindication

• Dapagliflozin (Farxiga)
 	
Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors
	All new and current users of dapagliflozin (Farxiga) are required to try metformin, a sulfonylurea (SU), and a dipeptidyl-dipeptidase-4 (DPP-4) inhibitor before dapagliflozin (Farxiga).
	
	Automated PA criteria: The patient has filled a prescription for metformin, a SU, AND a DPP-4 inhibitor at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.
	
	AND
	
	Manual PA criteria: If automated criteria are not met, dapagliflozin (Farxiga) is approved (e.g., trial of metformin or SU AND a DPP-4 inhibitor is NOT required) if:
	
	• The patient has experienced any of the following issues on metformin:
	  ○ impaired renal function precluding treatment with metformin
	  ○ history of lactic acidosis
	• The patient has experienced any of the following issues on a sulfonylurea:
	  ○ hypoglycemia requiring medical treatment
	• The patient has had inadequate response to metformin or a SU or a DPP-4 inhibitor
	• The patient has a contraindication to metformin or a SU or DPP-4 inhibitor

Drug / Drug Class	Prior Authorization Criteria
• Tofacitinib (Xeljanz) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with: • Moderate to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. • Not approved for use in combination with other biologics or potent immunosuppressants (aziathioprine and cyclosporine).
• Apremilast (Otezla) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis • Coverage not approved for use in combination with other biologics

Appendix D—Table of Prior Authorization (PA) Criteria for Hepatitis C Drugs

Prior Authorization Criteria

Sofosbuvir (Sovaldi)
Direct Acting Antiviral Subclass

- New users of sofosbuvir are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- Patients are encouraged to use the Mail Order Pharmacy or MTFs to fill their Sovaldi prescriptions.
- Consult the AASLD/IDSA HCV guidelines (www.hcvguidelines.org) for the most up-to-date and comprehensive treatment for HCV. Unique patient populations are also addressed, and treatment recommendations may differ from those for the general population.

Manual PA Criteria:

- Age ≥18
- Has laboratory evidence of chronic HCV infection
- Has laboratory evidence of HCV genotype 1, 2, 3, or 4 HCV infection
    1. State the HCV genotype on the PA form.
- Sofosbuvir (Sovaldi) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.
- The patient is not co-infected with Hepatitis B virus (HBV).
- Sofosbuvir (Sovaldi) is not prescribed as monotherapy; ribavirin with or without PEG-interferon is also prescribed. (Exception: sofosbuvir may be used with simeprevir (Olysio) in genotype 1 HCV patients who are ineligible for interferon; see below.)

Treatment Regimens and Duration of Therapy

- Treatment and duration of therapy are approved for one of the following regimens outlined below, based on HCV genotype or unique population.
- Prior authorization will expire after 12 weeks or 24 weeks, based on the treatment regimen selected.

Genotype 1

- Approved in patients who meet ONE of the following criteria: (1 or 2)
    1. Interferon eligible: sofosbuvir + interferon + ribavirin for 12 weeks
    2. Interferon ineligible: sofosbuvir + simeprevir for 12 weeks
        - Interferon ineligible is defined as ONE of the following:
            - intolerance to interferon (patient has previously taken interferon)
            - autoimmune hepatitis or other autoimmune disorders
            - hypersensitivity to peginterferon or any of its components
            - decompensated hepatic disease
            - history of depression or clinical features consistent with depression
            - baseline CBC: neutrophil count < 1,500/μ or PLTs < 90,000/μ or Hgb<10 g/dl
            - history of preexisting cardiac disease
- NOTE: Sofosbuvir + ribavirin for 24 weeks is an alternative regimen recommended by the AASLD/IDSA but is not as effective at the sofosbuvir + simeprevir in interferon-ineligible patients. If utilizing this treatment regimen, consider future highly effective pan-genotypic direct acting antiviral (DAA) combination that are interferon-free.

Prior Authorization Criteria

Genotype 2

- Sofosbuvir + ribavirin approved for 12 weeks

Genotype 3

- Approved in patients who meet ONE of the following criteria: (1 or 2):
  1. Sofosbuvir + ribavirin approved for 24 weeks
  2. Sofosbuvir + ribavirin + interferon approved for 12 weeks as an alternative in cirrhotic individuals or treatment experienced

Genotype 4

- Sofosbuvir + ribavirin+ interferon approved for 12 weeks
- NOTE: Sofosbuvir + ribavirin for 24 weeks is an interferon-ineligible alternative regimen recommended by the AASLD/IDSA, but is not as effective as sofosbuvir + interferon for 12 weeks. If utilizing this treatment regimen, consider future highly effective pan-genotypic DAA combinations that are interferon-free.

Regimen other than those listed above:

- Explain the rationale for treatment and duration of therapy. Consult the AASLD/IDSA HCV guidelines for new updates and guidelines.

Table of recommended treatment regimens and duration of therapy for sofosbuvir (Sovaldi)

HCV genotype	Treatment	Duration	SVR / Cure Rate
Genotype 1 IFN eligible	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks	90%
Genotype 1 IFN ineligible	*SOFOSBUVIR + SIMEPREVIR +/- ribavirin (not FDA-Approved)*	12 weeks	93%–96%
Genotype 2	SOFOSBUVIR + ribavirin	12 weeks	95%
Genotype 3	SOFOSBUVIR + ribavirin	24 weeks	Treatment naïve: 93% Treatment experienced: 77%
Genotype 4	SOFOSBUVIR + peginterferon alfa + ribavirin	12 weeks	96%
Hepatocellular carcinoma awaiting transplant	SOFOSBUVIR + ribavirin	up to 48 weeks or at transplant	64%

Prior Authorization Criteria

Boceprevir (Victrelis) and Telaprevir (Incivek)
Direct Acting Antiviral Subclass

- The revised PA will apply to new users of boceprevir or telaprevir.
- Current users of boceprevir or telaprevir are allowed to complete the course of therapy without interruption.

Manual PA Criteria:

Telaprevir and Boceprevir are NO LONGER RECOMMENDED for ANY HCV treatment by the (AASLD/IDSA). See www.hcvguidelines.org.

- Although regimens of PEG-interferon and ribavirin plus telaprevir or boceprevir for 24 to 48 weeks using response-guided therapy are also FDA-approved; they are **markedly inferior** to the currently available regimens.
- Telaprevir and boceprevir regimens are associated with higher rates of serious adverse events than recommended current regimens with sofosbuvir (Sovaldi).
- Consider treatment with sofosbuvir-containing regimens OR future highly effective pan-genotypic direct acting antiviral combination regimens that are interferon-free.
- The justification and dosing/duration for boceprevir or telaprevir must be documented (e.g., allergic to all other known regimens; inability to wait for treatment).

Prior authorization will expire after 12 weeks for telaprevir and 44 weeks for boceprevir.

Prior Authorization Criteria

Simeprevir (Olysio)
Direct Acting Agent Subclass

- New users of simeprevir for HCV are required to undergo the PA process.
- The FDA-approved indication of simeprevir + PEG-interferon + ribavirin for 24 to 48 weeks is no longer recommended for HCV treatment by the AASLD/IDSA. See www.hcvguidelines.org.
- The current AASLD/IDSA recommendation for simeprevir is for patients with HCV genotype 1 who are ineligible for interferon; simeprevir is given with sofosbuvir and either with or without ribavirin for 12 weeks.

Manual PA Criteria:

- Age ≥18
- Has laboratory evidence of chronic HCV (quantified viral load above undetectable)
- Has laboratory evidence of genotype 1 HCV infection
- If HCV genotype 1a, the patient is negative for NS3 Q80K polymorphism at baseline
- Is not co-infected with HIV or HBV
- The patient has not previously used HCV protease inhibitor (boceprevir, telaprevir, or simeprevir)
- Simeprevir is not approved for monotherapy
    - AASLD/IDSA guidelines recommend a regimen of simeprevir plus sofosbuvir either with or without ribavirin for 12 weeks.
- The patient is interferon ineligible. Interferon ineligible is defined as ONE of the following:
    - Intolerance to interferon (patient has previously taken interferon)
    - Autoimmune hepatitis or other autoimmune disorders
    - Hypersensitivity to peginterferon or any of its components
    - Decompensated hepatic disease
    - History of depression or clinical features consistent with depression
    - A baseline CBC: neutrophil count < 1,500/μ or PLTs < 90,000/μ or HgB <10 g/dl
    - History of preexisting cardiac disease

Prior authorization will expire after 12 weeks.

Table of recommended treatment regimens and duration of therapy for simeprevir (Olysio)

HCV genotype	Treatment	Duration	SVR / Cure Rate
Genotype 1 IFN ineligible	*SOFOSBUVIR + SIMEPREVIR +/- ribavirin (not FDA-Approved)*	12 weeks	93%–96%

Appendix E—Table of Implementation Status of UF Recommendations/Decisions Summary

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2014	**Nasal Allergy Drugs**	UF class review Previously reviewed	▪ Fluticasone propionate (Flonase generic)	▪ Azelastine 137 mcg (Astelin, generic) ▪ Flunisolide (Nasalide, generic) ▪ Ipratropium (Atrovent, generic)	▪ Azelastine 205 mcg (Astepro) ▪ Beclomethasone (Beconase AQ & QNASL) ▪ Budesonide (Rhinocort Aqua) ▪ Ciclesonide (Zetonna and Omnaris) ▪ Fluticasone furoate (Veramyst) ▪ Fluticasone/azelastine (Dymista) ▪ Mometasone (Nasonex) ▪ Olopatadine (Patanase)	Pending singing of the minutes / 90 days	▪Step therapy required; see comments ▪Quantity Limits apply; see Minutes	▪ Must try the generics first before the branded products in all current and new users older than 4 years. (See Appendix C)
May 2014	**Inhaled Corticosteroids** **Metered Dose Inhalers and Dry Powder Inhalers**	UF Class review Previously reviewed	▪ Flovent HFA ▪ Flovent Diskus	▪ N/A (Flovent is on the BCF)	▪ Beclomethasone (QVAR) ▪ Budesonide (Pulmicort Flexhaler) ▪ Ciclesonide (Alvesco) ▪ Flunisolide (Aerospan) ▪ Mometasone (Asmanex Twisthaler)	Pending signing of the minutes / 90 days	▪Step therapy required; see comments ▪Quantity Limits apply; see Minutes	▪ Must try Flovent Diskus or Flovent HFA before the non-preferred products in all new users older than age 12. (See Appendix C)

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2014	**Oral Bisphosphonates (Osteoporosis Drugs)**	UF Class review Previously reviewed	▪ alendronate	▪ ibandronate	▪ risedronate (Actonel) ▪ risedronate delayed release (Atelvia) ▪ risedronate effervescent tablet (Binosto) ▪ alendronate with vitamin D ▪ (Fosamax Plus D)	Pending signing of the minutes / 90 days	▪ Step therapy required; see comments ▪ Quantity Limits apply; see Minutes	▪ Must try alendronate before the non-preferred products (See Appendix C)
May 2014	**Hepatitis C Drugs Direct Acting Antiviral Subclass**	New Drug	Extended Core Formulary (ECF): ▪ PEG-interferon alfa-2a (Pegasys) ▪ ribavirin 200 mg capsules (generics); excludes Ribapak formulation	▪ **sofosbuvir (Sovaldi) designated UF at May 2014 meeting** ▪ boceprevir (Victrelis) ▪ **telaprevir (Incivek) – no longer ECF** ▪ interferon alfa-2b (Intron A) ▪ PEG-interferon alfa-2b (PEG-Intron) ▪ ribavirin (Copegus, Rebetol, Ribasphere)	▪ interferon alfacon-1 (Infergen) ▪ ribavirin Ribapak formulation	Pending signing of the minutes / no later than 30 days	▪ PA recommended for sofosbuvir and simeprevir; revised PA for boceprevir and telaprevir (See Appendix D) ▪ QL recommended for simeprevir (Olysio)	▪ May 2014: telaprevir (Incivek) removed from the ECF ▪ QL recommendation for simeprevir: 28-day supply in MTFs, Mail Order, and Retail; no multiple fills for multiple co-pays

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2014	**Overactive Bladder Drugs (OABs)**	New Drug	▪ Tolterodine ER (Detrol LA)* ▪ Oxybutynin ER (Ditropan XL, generics)* *step-preferred	▪ **mirabegron (Myrbetriq)** ▪ oxybutynin IR (Ditropan, generics)* ▪ solifenacin (Vesicare) ▪ trospium IR (Sanctura, generics) ▪ trospium ER (Sanctura ER, generics) ▪ tolterodine IR (Detrol IR, generics) *step-preferred	▪ fesoterodine (Toviaz) ▪ darifenacin (Enablex) ▪ oxybutynin transdermal delivery system (Oxytrol) ▪ oxybutynin 10% gel (Gelnique)	N/A	▪ Step therapy (Automated PA); requires trial of Detrol LA, trospium IR (Sanctura), oxybutynin IR, or oxybutynin ER (step-preferred drugs) prior to another OAB drug.	▪ Mirabegron (Myrbetriq) designated UF and non step-preferred. ▪ See Feb 2014 DoD P&T Committee meeting minutes for step therapy criteria.
May 2014	**Oral Anticoagulants**	New Drug Review	▪ warfarin	▪ **apixaban (Eliquis) May 2014** ▪ dabigatran (Pradaxa) ▪ rivaroxaban (Xarelto)	▪ None	N/A	N/A	N/A
May 2014	**Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	New Drug	▪ None	▪ None	▪ **Dapagliflozin (Farxiga) May 2014** ▪ Canagliflozin (Invokana)	Pending signing of the minutes / 90 days	▪ Step therapy (automated PA); requires a trial of metformin, or a SU, and a DPP-4 inhibitor in all new and current users of a SGLT2 inhibitor.	▪ BCF, UF, and NF drugs are designated for the non-insulin diabetes drugs for metformin, SUs, DPP-4 inhibitors, glucagon-like peptide-1 receptor agonists, thiazolidinediones, meglitinides, and alpha glucosidase inhibitors. See DoD P&T Minutes for Nov 2010, Aug 2012, and Nov 2012.

Date	DoD PEC Drug Class	Type of Action*	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2014	**Long-Acting Beta Agonists**	New Drug	▪ Salmeterol (Serevent)	▪ Formoterol (Foradil) ▪ Arformoterol (Brovana)	▪ **Indacaterol (Arcapta) May 2014** ▪ Formoterol (Perforomist)	Pending signing of the minutes / 90 days	▪QL apply	▪ Arcapta designated NF
May 2014	**GI-Steroid Subclass** **GI-1 Drug Class**	New Drug	▪ None (sulfasalazine and Lialda are BCF)	▪ Orals: Entocort EC and generics ▪ Rectals: Cortenema and generics ▪ Cortifoam and generics	▪ **Budesonide extended release (Uceris) May 2014**	Pending signing of the minutes / 90 days	N/A	▪ Uceris designated NF
May 2014	**NSAIDs**	New Drugs	▪ ibuprofen 400 mg, 600 mg & 800 mg ▪ indomethacin 25 mg & 50 mg (generic) ▪ meloxicam 7.5 mg & 15 mg (generic) ▪ naproxen 250 mg & 500 mg (generic) & 125 mg/5 mL susp (generic)	▪ celecoxib (Celebrex) ▪ diclofenac/misoprostol (Arthrotec) ▪ diclofenac potassium tablets (Cataflam generic) ▪ diclofenac sodium tablets (Voltaren generic) ▪ diflunisal ▪ etodolac ▪ fenoprofen ▪ flurbiprofen ▪ ketoprofen ▪ ketorolac ▪ meclofenamate ▪ nabumetone ▪ naproxen sodium 275 mg & 550 mg (Anaprox, generic) ▪ oxaprozin ▪ piroxicam ▪ sulindac ▪ tolmetin ▪ naproxen/esomeprazole (Vimovo)	▪ **Diclofenac low dose 18 and 35 mg capsules (Zorvolvex) May 2014** ▪ diclofenac potassium liquid filled capsules (Zipsor) 25 mg ▪ diclofenac potassium powder packets 50 mg (Cambia) ▪ naproxen sodium ER (Naprelan CR, generic) 375 mg, 500 mg, & 750 mg ER tabs, dosing card ▪ mefenamic acid (Ponstel, generic) 250 mg	Pending signing of the minutes / 90 days	N/A	▪ Zorvolex designated NF

TRICARE Formulary Search tool: *http://www.pec.ha.osd.mil/formulary_search.php*

Appendix F—Table of Abbreviations

A1c	hemoglobin A1c
AASLD/IDSA	The American Association for the Study of Liver Diseases and the Infectious Disease Society of America
BCF	Basic Core Formulary
BIA	budget impact analysis
CEA	cost-effectiveness analysis
CF	cystic fibrosis
CFTR	cystic fibrosis transmembrane conductance regulator
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
DAA	direct acting antiviral
DCO	Defense Connect Online
DHA	Defense Health Agency
DoD	Department of Defense
DPP-4	dipeptidyl-dipeptidase-4 inhibitors
DR	delayed release
ER	extended release
ECF	Extended Core Formulary
FDA	U.S. Food and Drug Administration
GI-1s	Gastrointestinal-1 Drug Class
HCV	hepatitis C virus
HFA	hydrofluoroalkane
ICS	inhaled corticosteroids
IR	immediate release
LABA	long-acting beta adrenergic inhalers
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NF	nonformulary
NDAA	National Defense Authorization Act
NOAC	new oral anticoagulant
NSAIDs	non-steroidal anti-inflammatory drugs
OTC	over-the-counter
OAB	overactive bladder
P&T	Pharmacy and Therapeutics
PA	prior authorization
POS	points of service
PPIs	proton pump inhibitors
QLs	quantity limits
SGLT2	sodium-glucose cotransporter 2 inhibitor
SMBGS	self-monitoring blood glucose system
SU	sulfonylurea
SVR	sustained virologic response
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary