DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

November 2016

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 16 and 17, 2016, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August 2016 Minutes—**VADM R.C. Bono, MC, USN, Director, DHA, approved the minutes from the August 2016 DoD P&T Committee meeting on November 8, 2016.

2. **Clarification of August 2016 Minutes**

   a) **Topical Acne and Rosacea Agents Prior Authorization (PA) Expiration Date—**Step therapy and manual PAs for the topical acne and rosacea agents will expire after 365 days rather than 180 days, due to operational issues.

   b) **Topical Acne and Rosacea Agents Basic Core Formulary (BCF) Clarification—**The BCF recommendation listed that sodium sulfacetamide/sulfur 10% would remain on the BCF. The current listing is actually for the sulfacetamide sodium 10% ophthalmic drops. Therefore, the topical sulfacetamide sodium/sulfur 10% formulation was not added to the BCF. The BCF products for the subclass are the generic formulations of Duac, Metrogel, Cleocin T, and Retin-A 0.025% and 0.05% cream.

   c) **Implementation for All "upon signing" Items—**All "upon signing" implementations (quantity limits, BCF recommendations, Innovator nonformulary drugs, and Innovator PAs) will move to November 9, 2016, from November 8, 2016, due to the large number of decisions implementing on November 2, 2016 from the May 2016 P&T Committee meeting.

3. **Correction to the August 2016 Minutes**

   a) **Lidocaine 5% Transdermal (Lidoderm; generic) Quantity Limits (QLs)** The QLs for Lidoderm were corrected to a maximum of 90 patches per 30 days in the Retail Network and 270 patches per 90 days at the MTFs and Mail Order Pharmacy.

   b) **Section 703, National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2008—**Tacrolimus ER (Envarsus XR; Veloxis Pharma) was designated nonformulary at the August 2016 meeting due to noncompliance with FY08

NDAA, Section 703. Following the August 2016 meeting, the manufacturer became compliant. Envarsus XR will retain UF status and letters to affected patients are not required.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including innovator drugs, and full drug class reviews included, but were not limited to, the requirements stated in 32 Code of Federal Regulations (CFR) 199.21(e)(1) and (g)(5). 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.

Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

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

A. Long-Acting Muscarinic Antagonist (LAMA) Agents: Tiotropium Soft Mist Inhaler (Spiriva Respimat)

Spiriva Respimat contains tiotropium, the same active ingredient, as found in the Spiriva HandiHaler, but in a new soft mist inhaler device. Spiriva HandiHaler was launched in 2004 and added to the BCF in May 2013, while Spiriva Respimat entered the market in 2014. Both formulations are FDA-approved for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations. Spiriva Respimat is also approved for treating asthma in patients older than 12 years of age. Improvements in forced expiratory volume in one second (FEV_1) were similar between Spiriva Respimat and Spiriva HandiHaler. The safety profile is similar to the other LAMAs.

Spiriva HandiHaler was not associated with an increased risk of mortality in the placebo-controlled UPLIFT trial. However, initial concerns of increased mortality with Spiriva Respimat were raised in meta-analyses of placebo-controlled trials. These concerns were allayed in the prospective TIOSPIR clinical trial, where Spiriva Respimat was non-inferior to Spiriva HandiHaler with regard to overall mortality and cardiovascular mortality.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that Spiriva Respimat, as with Spiriva HandiHaler, has advantages over the other LAMAs in terms of the reductions in COPD exacerbations and once daily dosing. Patients with dexterity issues may find initial assembly of the Respimat device difficult.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) the following rankings from most-to-least cost effective: tiotropium soft mist inhaler (Spiriva Respimat), tiotropium bromide inhalation powder (Spiriva HandiHaler), aclidinium (Tudorza Pressair), umeclidinium (Incruse Ellipta), and glycopyrrolate (Seebri Neohaler).

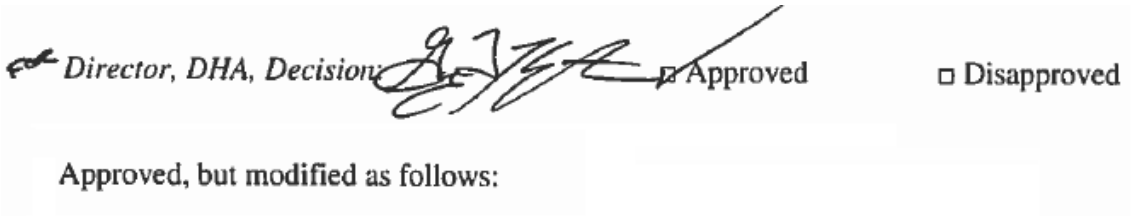
1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) tiotropium soft mist inhaler (Spiriva Respimat) be designated as formulary on the UF, based on clinical and cost effectiveness.

   Note that Spiriva Respimat will continue to remain as part of the Expanded Military Treatment Facility/Mail Pharmacy Initiative (EMMPI).

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) adding tiotropium soft mist inhaler (Spiriva Respimat) to the BCF and maintaining tiotropium bromide inhalation powder (Spiriva HandiHaler) on the BCF.

3. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QLs for tiotropium soft mist inhaler (Spiriva Respimat), consistent with the FDA-approved package labeling. See Appendix D.

4. ***COMMITTEE ACTION: UF AND BCF IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) the UF and BCF implementation become effective upon signing of the minutes.



V. UF DRUG CLASS REVIEWS

A. Oral Anticoagulants

Background—The P&T Committee previously reviewed the oral anticoagulants at the May 2015 DoD P&T Committee meeting. The class is comprised of the vitamin K antagonist warfarin (Coumadin, generic) and the newer direct-acting oral anticoagulants (DOACs). "DOACs" is now the preferred terminology for apixaban (Eliquis), dabigatran (Pradaxa), edoxaban (Savaysa) and rivaroxaban (Xarelto). The majority of DOAC usage in the Military

Health System (MHS) is for stroke prevention in patients with non-valvular atrial fibrillation (NVAF)—the clinical review focused on this indication.

Since the May 2015 review, dabigatran gained approval for venous thromboembolism (VTE) prophylaxis following hip replacement surgery in November 2015. Additionally idarucizumab (Praxbind) is now available as a reversal agent for the direct thrombin inhibitor dabigatran. However, Praxbind is not part of the TRICARE pharmacy benefit as it an IV infusion. A reversal agent for the factor Xa inhibitors (apixaban, edoxaban, rivaroxaban) is in the FDA drug approval pipeline.

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

- There are no head-to-head trials to determine if one DOAC is more efficacious or safe than another.
- With respect to NVAF, the following conclusions were made:
    - Dabigatran and apixaban were superior to not optimally controlled warfarin, while edoxaban and rivaroxaban were non-inferior at preventing stroke and systemic embolism.
    - Intracranial bleeding was lower with all four DOACs compared with warfarin in the major trials used to obtain FDA approval.
    - Edoxaban advantages include once daily dosing and an overall lower rate of bleeding versus warfarin. Disadvantages include a higher rate of gastrointestinal (GI) bleeding, and a higher risk of stroke in patients with normal renal function (creatinine clearance greater than 95 mL/min).
    - Dabigatran was the only DOAC to show superior ischemic stroke reduction, but it has a higher incidence of GI bleeding than warfarin, causes dyspepsia, and is highly dependent on renal clearance.
    - Rivaroxaban advantages include once daily dosing, but it has an increased incidence of GI bleeding and major bleeding compared to warfarin. The patient population studied with rivaroxaban had more comorbidities than the other three DOACs.
    - Apixaban showed significantly less major bleeding than warfarin, and was the only DOAC to show a reduction in mortality, but the confidence interval approached one. The point estimates and confidence intervals for all the DOACs are similar for mortality.
- In terms of clinical coverage, warfarin is required on the BCF due to its wide number of FDA indications and long history of use. For the DOACs, apixaban and rivaroxaban are the most appropriate candidates for preferred formulary status due to the number of FDA-approved indications, pharmacokinetic profile, dosing regimen, and Military Treatment Facility (MTF) provider opinions, compared with dabigatran and edoxaban.

Relative Cost-Effectiveness Analysis and Conclusion—CMA, cost-effectiveness analysis (CEA), and budget impact analysis (BIA) were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA and CEA results found that generic warfarin was the most cost-effective oral anticoagulant, followed by apixaban, dabigatran, rivaroxaban, and edoxaban, in order from most cost effective to least cost effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating warfarin, apixaban, rivaroxaban, and dabigatran as formulary on the UF, with edoxaban designated as NF, demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATIONS—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following:

    - **UF:**
        - Warfarin (Coumadin; generic)
        - Apixaban (Eliquis)
        - Dabigatran (Pradaxa)
        - Rivaroxaban (Xarelto)
    - **NF:** Edoxaban (Savaysa)

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) adding Eliquis to the BCF, and maintaining generic warfarin on the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Savaysa. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation; and, 2) DHA send letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is May 10, 2017.

Director, DHA, Decision: ☐ Approved ☐ Disapproved

Approved, but modified as follows:

B. Antilipidemics-1 (LIP-1s) Agents: Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor Subclass

Background—The P&T Committee evaluated the PCSK9 inhibitors. Alirocumab (Praluent) and evolocumab (Repatha) are a new class of biologic drugs that reduce low-density lipoprotein (LDL) cholesterol. They are injectable monoclonal antibodies requiring biweekly or monthly administration. Prior authorization criteria and quantity limits were recommended for the PCSK9 inhibitors in November 2015, due to the lack of data on cardiovascular (CV) morbidity and mortality, unknown long-term safety profile, and high cost. Evolocumab was reviewed as an innovator drug and is currently NF.

Both products are indicated as an adjunct to diet and maximally-tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL cholesterol. Evolocumab has an additional indication for treatment of homozygous familial hypercholesterolemia (HoFH) in patients 13 years and older.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following for the PCSK9 Inhibitor Subclass:

- Dyslipidemia treatment guidelines have been in flux, with an overall shift from LDL lowering targets to a focus on addressing risk reduction. However, clinical practice guidelines from several professional organizations consistently support the use of statins to reduce cardiovascular risk.
- The PCSK9 inhibitors significantly reduce LDL by 50% to 60% when added on to maximum tolerated statin therapy in patients with HeFH or ASCVD.
- At this time, there are no direct head-to-head trials between alirocumab and evolocumab. Meta-analyses suggest that both drugs effectively lower LDL whether used as monotherapy, when compared to ezetimibe, or when used as add-on therapy to standard care.
- CV outcomes trials are still pending to determine whether the LDL-lowering benefit of the PCSK9 inhibitor agents will produce significant improvements in mortality beyond that established with statins. The results of outcome trials are anticipated in 2017 to 2018.
- Both agents appear safe and well-tolerated during the short-term periods when they have been studied. The most commonly reported adverse events include injection site and hypersensitivity reactions. Long-term safety concerns have yet to be resolved, including neurocognitive effects and immunogenicity risk.
- The PCSK9 inhibitors are highly therapeutically interchangeable. There is extremely limited data to support switching between evolocumab and alirocumab once an initial product has been selected.

- The most appropriate place in therapy for the PCSK9 inhibitors is in high-risk patients with ASCVD, HeFH, or HoFH who require additional CV risk reduction through LDL-lowering despite maximally-tolerated statin and lipid-lowering therapy, including ezetimibe.
- Provider input solicited from cardiologists and endocrinologists slightly favored evolocumab. Of note, there was limited clinical experience of these products with most providers.
- For clinical coverage, at least one PCSK9 inhibitor is required on the UF to serve the needs of the majority of MHS patients who would most likely benefit from these products.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed alirocumab (Praluent) and evolocumab (Repatha) had comparable cost effectiveness.

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. All modeled scenarios show cost avoidance against current MHS expenditures. BIA results showed that designating evolocumab as formulary and step-preferred, with alirocumab as formulary and non step-preferred, demonstrated a cost-effective option for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

    - UF and step-preferred: evolocumab (Repatha)
    - UF and non step-preferred: alirocumab (Praluent)

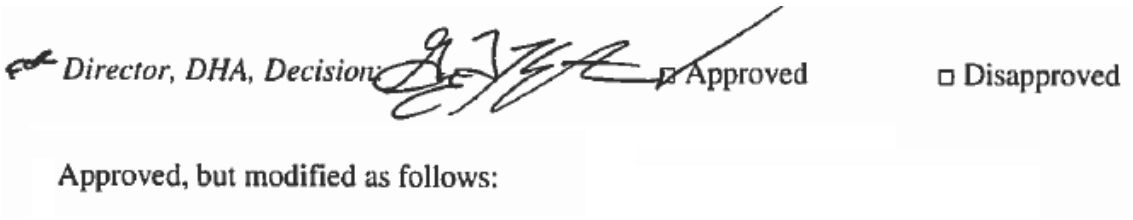
    Note that as part of this recommendation, all new users of alirocumab are required to try evolocumab first. Additionally, a PCSK9 inhibitor was not selected for BCF placement. The LIP-1 BCF products include the statins atorvastatin, pravastatin, and simvastatin; and niacin extended release (non-statin therapy).

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Manual PA criteria for both PCSK9 inhibitors were recommended at the August 2015 P&T Committee meeting and implemented on October 30, 2015. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) maintaining the current manual PA criteria for alirocumab and evolocumab. The renewal PA criteria were updated to include prescriptions written by a primary care provider in consultation with a specialist who initially prescribed the agent. The step therapy

requirement for a trial of evolocumab prior to use of alirocumab in new users is included in the manual PA criteria. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for alirocumab and evolocumab. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose or to use the Pushtronex device (420mg/3.5 mL). See Appendix D for the QLs.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period. Based on the P&T Committee's recommendation, the effective date is April 5, 2017.



VI. INNOVATOR DRUGS

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (14 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the innovator drugs. For the complete list of innovator drugs reviewed at the November 2016 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, see Appendix E. For information on the innovators and the EMMPI Program and NF to Mail Order Pharmacy requirements, see Section XII on pages 16-17.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) the following:

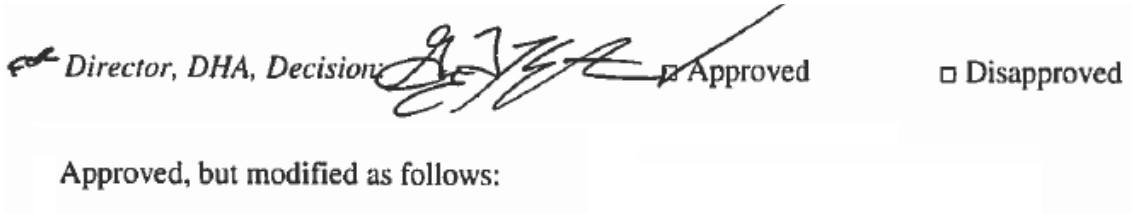
   - **UF**:
     - Antiemetics: aprepitant oral suspension (Emend)
     - Antihemophilic Factors: von Willebrand factor (Vonvendi)
     - Ophthalmic Anti-Inflammatory Immunomodulatory Agents: lifitegrast ophthalmic solution (Xiidra)
     - Topical Otic Antibiotic/Steroid Combinations: ciprofloxacin/ fluocinolone acetonide otic solution (Otovel)

- **NF:**
    - Antigout Agents: lesinurad (Zurampic)
    - Antiplatelet Agents: aspirin/omeprazole (Yosprala)
    - Beta Blocker Combination Antihypertensive Agents: nebivolol/valsartan (Byvalson)
    - LAMA/Long-Acting Beta Agonists (LABA) combinations: glycopyrrolate/formoterol oral inhaler (Bevespi Aerosphere)
    - Miscellaneous Cardiovascular Agents: nitroglycerin sublingual (SL) powder (GoNitro)
    - Multiple Sclerosis Drugs: daclizumab (Zinbryta)
    - Opioid-Induced Constipation Drugs: methylnaltrexone tablets (Relistor)
    - Oral Contraceptives: norethindrone/ethinyl estradiol/iron (Taytulla)
    - Renin-Angiotensin Antihypertensive Agents (RAAs): lisinopril oral solution (Qbrelis)

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) MN criteria for aspirin/omeprazole (Yosprala), daclizumab (Zinbryta), glycopyrrolate/formoterol (Bevespi Aerosphere), lesinurad (Zurampic), lisinopril oral solution (Qbrelis), methylnaltrexone tablets (Relistor), nebivolol/valsartan (Byvalson), nitroglycerin SL powder (GoNitro), and norethindrone/ethinyl estradiol/iron (Taytulla). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users of the ophthalmic agent lifitegrast ophthalmic solution (Xiidra); for new users of the multiple sclerosis agent daclizumab (Zinbryta); and, for new and current users of the antigout drug lesinurad (Zurampic). See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date upon signing of the minutes in all points of service (POS).



VII. UTILIZATION MANAGEMENT

A. PA Criteria

1. **Basal Insulins: Insulin Degludec (Tresiba) Manual PA Criteria**—Tresiba is a new basal insulin indicated for glycemic control in adults with diabetes mellitus. Tresiba was reviewed in February 2016 as an innovator product and designated NF. The basal insulins will be reviewed for formulary status at an upcoming meeting.

    a) ***COMMITTEE ACTION: INSULIN DEGLUDEC (TRESIBA) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Tresiba in new and current users. Despite its ultra-long duration of action and steady-state profile, Tresiba offers no clinically compelling advantages over existing basal insulins used to treat Type I or Type II diabetes. Patients will be required to try insulin glargine before using Tresiba. See Appendix C for the full criteria.

2. **Analgesics and Combinations: Butalbital/Acetaminophen Tablets (Allzital) Manual PA Criteria**—Allzital is an oral tablet formulation containing butalbital and acetaminophen that is approved for tension or muscle headaches.

    a) ***COMMITTEE ACTION: BUTALBITAL/ACETAMINOPHEN (ALLZITAL) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Allzital in new and current users, due to cost disadvantages compared to generic butalbital/ acetaminophen combinations. See Appendix C for the full criteria.

3. **Targeted Immunomodulatory Biologic (TIBs): Adalimumab (Humira) and Ustekinumab (Stelara) Manual PA Criteria**—The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Adalimumab (Humira) was selected as the UF step-preferred agent. In June 2016, adalimumab (Humira) received FDA approval for treatment of non-infectious intermediate, posterior and panuveitis in adult patients. The PA criteria were updated for Humira to reflect its new FDA indication. Clinical data supporting several off-label uses for Humira were reviewed; these will be considered for coverage.

    Ustekinumab (Stelara) is UF and non step-preferred; it is currently approved for rheumatoid arthritis and plaque psoriasis. In September 2016, Stelara received FDA approval for the treatment of adult patients with moderate to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators, corticosteroids, or tumor necrosis factor (TNF) blockers. The existing manual PA criteria were updated to include these new indications.

a) ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA) AND USTEKINUMAB (STELARA) PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) updating the manual PA criteria for Humira and Stelara to include their respective new indications. See Appendix C for the full criteria.

4. **Ophthalmic Anti-Inflammatory/Immunomodulatory Agents: Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis) Updated Manual PA Criteria**—Restasis was reviewed in February 2016, with manual PA criteria recommended. Based on feedback from MTF providers and supporting literature, updates were made to the criteria to include treatment of atopic keratoconjunctivitis and vernal keratoconjunctivitis in pediatric patients; and in adults following LASIK surgery.

    a) ***COMMITTEE ACTION: CYCLOSPORINE 0.05% OPHTHALMIC EMULSION (RESTASIS) UPDATED MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) updating the Restasis manual PA criteria. See Appendix C for the full criteria.

5. **Oral Oncology Agents: Crizotinib (Xalkori) Updated Manual PA Criteria**
Xalkori is an oral oncologic agent used for the treatment of non-small cell lung cancer (NSCLC). Xalkori inhibits tyrosine kinases including anaplastic lymphoma kinase (ALK) and c-ros oncogene 1 (ROS). Manual PA criteria have been in place since February 2012. The criteria were updated to add additional indications.

    a) ***COMMITTEE ACTION: CRIZOTINIB (XALKORI) UPDATED MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) updating the manual PA criteria. See Appendix C for the full criteria.

B. Quantity Limits

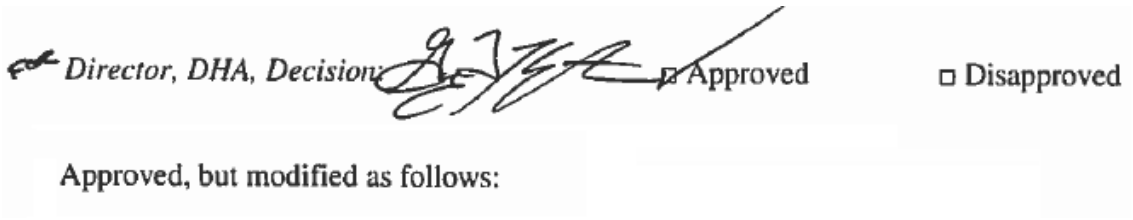
1. **QLs**—Quantity limits were reviewed for three drugs: aprepitant oral suspension (Emend) for nausea and vomiting associated with moderate and highly emetogenic chemotherapy regimens, glycopyrrolate/formoterol (Bevespi Aerosphere) for COPD, and butalbital/acetaminophen tablets (Allzital) for tension headaches.

    a) ***COMMITTEE ACTIONS: QLs—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) QLs for Emend, Bevespi Aerosphere, and Allzital. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

1. ***COMMITTEE ACTION: PA AND QLs IMPLEMENTATION PERIODS***
   The P&T Committee recommended the following implementation periods:

   - 14 for, 0 opposed, 0 abstained, 1 absent—The manual PAs for butalbital/ acetaminophen tablets (Allzital) and insulin degludec (Tresiba) become effective on the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is May 10, 2017.
   - 14 for, 0 opposed, 0 abstained, 1 absent—The updated manual PAs for adalimumab (Humira), ustekinumab (Stelara), cyclosporine ophthalmic (Restasis), and crizotinib (Xalkori) become effective upon signing of the minutes.
   - 14 for, 0 opposed, 0 abstained, 1 absent—The QLs for Emend, Bevespi Aerosphere, and Allzital become effective upon signing of the minutes.



VIII. NF DRUGS AND AVAILABILITY AT THE MTFs: MEDICAL NECESSITY FORM

The Service Pharmacy Consultants requested revisions to the current wording on the MN forms regarding prescribing of NF drugs by non-MTF providers, in order to support "recapture" efforts to bring prescriptions from the Retail Network back to local MTFs.

Background—According to Health Affairs Policy 04-032 from December 22, 2004:

> Non-formulary pharmaceutical agents are excluded from MTF formularies. MTFs may make non-formulary agents available to covered beneficiaries only for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary agent in lieu of a pharmaceutical agent that is on the MTF formulary. The non-formulary special order process may only be used for prescriptions written by MTF providers or for prescriptions written by a civilian provider to whom the patient was referred by the MTF.

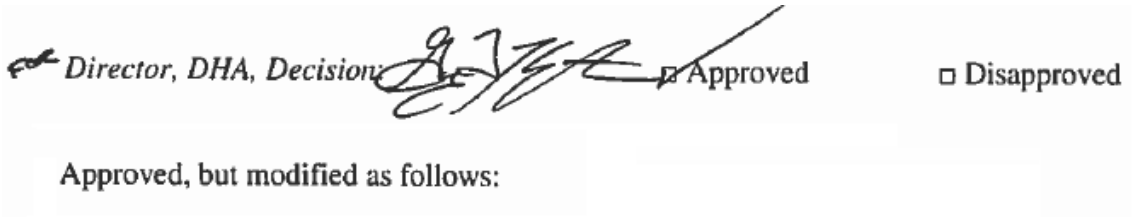
The wording currently on the MN form reflects the HA policy, as it states prescriptions for NF medications may be filled at the MTFs only if two conditions are met: 1) the prescription is written by a military provider, or at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF; and, 2) the NF medication is determined to be medically necessary.

However, in 32 CFR 199.21 (7-1-11 Edition) regarding the availability of NF pharmaceutical agents at MTFs, there is no provision that the patient for whom the NF drug is prescribed must be referred to a civilian provider. The CFR states,

> Although not a beneficiary entitlement, non-formulary pharmaceutical agents may be made available to eligible covered beneficiaries through the MTF pharmacies for prescriptions approved through the non-formulary special order process that validates the medical necessity for use of the non-formulary pharmaceutical agent.

This language is available at https://www.gpo.gov/fdsys/pkg/CFR-2011-title32-vol2/pdf/CFR-2011-title32-vol2-sec199-21.pdf.

1. ***COMMITTEE ACTION: MEDICAL NECESSITY FORM UPDATE***
   The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) changing the current MN wording to the following: 1) the prescription is written by a military provider, or at the discretion of the MTF, a network provider and, 2) the nonformulary prescription is determined to be medically necessary.



Note: The Director, DHA, will forward a recommendation to the Assistant Secretary of Defense to update 2004 HA Policy 04-032, to align the HA policy with encouraging prescription dispensing at the most cost effective point of service.

IX. LINE EXTENSIONS

A. Definition—Line extensions retain the same formulary and copayment status as the "parent" drug. Requirements for medical necessity, manual prior authorization, and step therapy apply to the line extension product. The P&T Committee recommended updating the current line extension definition from the May 2014 meeting.

1. ***COMMITTEE ACTION: LINE EXTENSION DEFINITION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) that the line extension definition may include changes in the release properties of parent drug; for example, an immediate release preparation now available in a sustained or extended release formulation by the same manufacturer.

B. Formulary Status Clarification—The P&T Committee clarified the formulary status for three product line extensions ("follow-on products") by the original manufacturer. The line

extensions have the same FDA indications and pricing as the "parent" drug.

- Hepatitis C Virus (HCV) Direct-Acting Antiviral (DAA) Agents Subclass—Dasabuvir/ombitasvir/paritaprevir/ritonavir (Viekira XR) is approved for treatment of HCV and provides an extended-release (ER) formulation of the co-packaged product with the same active ingredient, Viekira Pak.
- Anticonvulsant and Anti-Mania Drug Class—Perampanel 0.5 mg/mL oral suspension (Fycompa) provides a liquid formulation of Fycompa tablets. The oral suspension and tablets are approved for partial-onset seizures and primary generalized tonic-clonic seizures in patients 12 years of age and older.
- Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors Subclass—Canagliflozin/metformin ER (Invokamet XR) is a SGLT2 inhibitor containing an ER formulation of metformin. Invokamet contains an immediate release (IR) metformin component.

1. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following three products to reflect the current formulary status, step therapy/PA criteria, and QLs of the parent compound. Implementation will occur upon signing of the minutes.

    - dasabuvir/ombitasvir/paritaprevir/ritonavir (Viekira XR):
        - UF, with the same manual PA and QLs as co-packaged dasabuvir/ombitasvir/paritaprevir/ritonavir (Viekira Pak)
    - perampanel 0.5 mg/mL oral suspension (Fycompa):
        - UF, similar to Fycompa tablets
    - canagliflozin/metformin ER (Invokamet XR):
        - NF and non step-preferred, with the same PA and MN criteria as Invokamet

for Director, DHA, Decision: ☒ Approved ☐ Disapproved

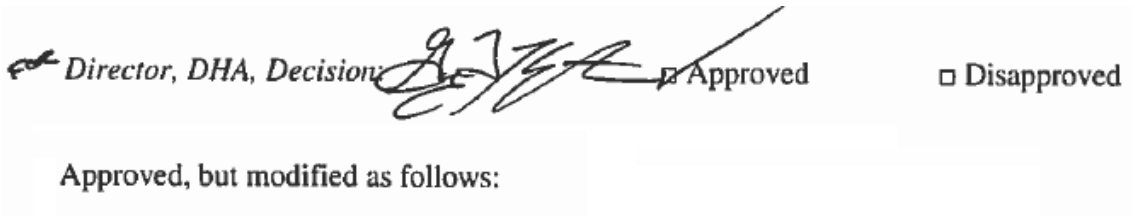
Approved, but modified as follows:

X. FORMULARY STATUS UPDATE: NON-INSULIN DIABETES DRUGS DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS

Linagliptin/metformin ER (Jentadueto XR) was reviewed as an innovator drug in August 2016 and designated NF and non step-preferred, with MN criteria. Linagliptin/metformin IR

(Jentadueto) is UF and non step-preferred. Price parity now exists between Jentadueto and Jentadueto XR.

A. ***COMMITTEE ACTION: LINAGLIPTIN/METFORMIN ER (JENTADUETO XR) FORMULARY STATUS UPDATE***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) designating Jentadueto XR as UF and non step-preferred, and removing the MN criteria, with implementation upon signing of the minutes.



XI. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail POS and medical necessity at MTFs. These NF drugs will remain available in the mail order POS without pre-authorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) the following products be designated NF on the UF:

- New Haven Pharma: aspirin ER (Durlaza) 162.5 mg oral capsules
- Tris Pharma: amphetamine (Dyanavel XR) 2.5mg/mL oral suspension

Note that both Durlaza and Dyanavel XR were previously recommended for NF placement as innovator drugs at the February 2016 P&T Committee meeting. The Director, DHA, approved the recommendation and implementation became effective in all POS on May 5, 2016.

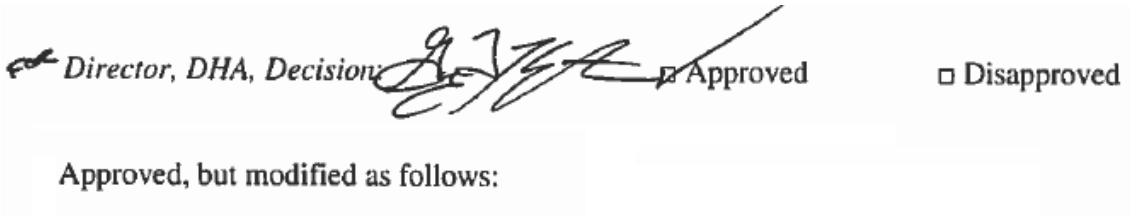
B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for Durlaza and Dyanavel XR:

1. Obtaining the product by home delivery would be detrimental to the patient; and,
2. For branded products with products with AB-rated generic availability, use of the generic product would be detrimental to the patient.

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

Dyanavel XR is a Schedule II controlled substance, but is not typically used as first line therapy for attention deficit hyperactivity disorder, or used for acute therapy. If the home delivery requirement for Dyanavel XR impacts availability through the Mail Order Pharmacy, the P&T Committee will allow an exception to the Section 703 rule, and allow dispensing at the Retail Pharmacy Network.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Durlaza and Dyanavel XR; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is May 90, 2017.



XII. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EMMPI)

For more information about the Expanded MTF/Mail Pharmacy Initiative (EMMPI) and the statutory and regulatory mandate that NF pharmaceutical agents are generally not available at MTFs or the Retail Network, but are available in the Mail Order program, refer to the August 2015 DoD P&T Committee meeting minutes, available at http://www.health.mil/PandT.

A. Innovator Drugs

1. **Innovator Drugs Recommended for UF Status:** The P&T Committee noted Emend oral suspension, Otovel otic suspension, and Vonvendi injection were not suitable for addition to the EMMPI program based on acute use or other factors. Lifitegrast ophthalmic solution (Xiidra) was suitable for addition to the EMMPI program.

2. **Innovator Drugs Recommended for NF Status***:* The P&T Committee noted/recommended:

   a) The previously established exceptions apply to daclizumab (Zinbryta) injection for multiple sclerosis (limited distribution requirements); nitroglycerin SL powder (GoNitro) (acute use); and, norethindrone/ethinyl

estradiol/iron (Taytulla) (previously established exception for contraceptive medications).

b) Delaying implementation of the mail order requirement for methylnaltrexone 150 mg tablets (Relistor) due to uncertainty about the suitability of requiring mail order dispensing, pending future review of agents in this drug class.

c) Aspirin/omeprazole (Yosprala), glycopyrrolate/formoterol (Bevespi Aerosphere), and lesinurad (Zurampic) fall into classes that are already defined as automatic additions to the EMMPI program. The P&T Committee found no reason to exempt lisinopril 1 mg/mL oral solution (Qbrelis) or nebivolol/valsartan (Byvalson) from the mail order requirement.

B. Topical Acne and Rosacea Agents

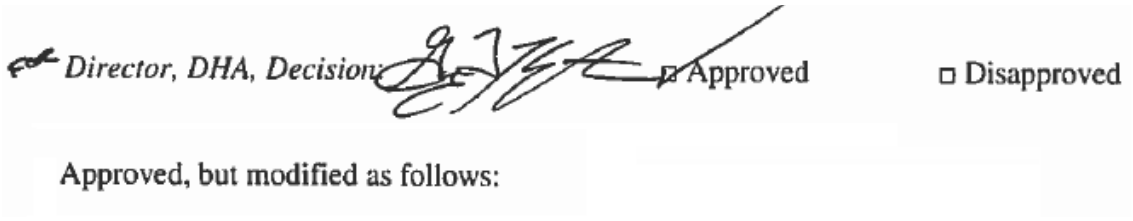
Several Topical Acne and Rosacea agents were recommended for NF status during the subclass review at the August 2016 meeting. At the time, the P&T Committee saw no reason to exempt these NF agents from the mail order requirement, given that the designated NF agents are specifically used for the chronic treatment of acne or rosacea.

As a follow-up, the P&T Committee agreed that all acne and rosacea agents, whether formulary or NF, were suitable for and should be added to the EMMPI program, with the exception of products requiring mixing immediately prior to dispensing (e.g., clindamycin/benzoyl peroxide gel [Benzaclin, generics]) or also indicated for acute indications, such as seborrheic dermatitis (e.g., sulfacetamide sodium/sulfur 10% lotion [Plexion, generics]).

1. ***COMMITTEE ACTION: TOPICAL ACNE AND ROSACEA AGENTS NF TO MAIL ORDER REQUIREMENT***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) establishing a class definition for acne rosacea products to specify that all "branded, legend products in GC3s L5G, L5H, L9B, L9H, or Q5W that are intended for the chronic treatment of acne or rosacea be added to the EMMPI list, with the exception of medications requiring mixing or also used for acute indications."

C. Mail Order Status of Medications Designated as NF During P&T Committee Meetings from November 2015 to August 2016

The Committee reviewed drugs that have been designated with NF status since the November 2015 P&T Committee meeting, and determined which NF products can be exempted from the requirement to limit their availability to the Mail Order Pharmacy. See Appendix F for the table of drugs designated NF during the past four meetings and their mail order status.



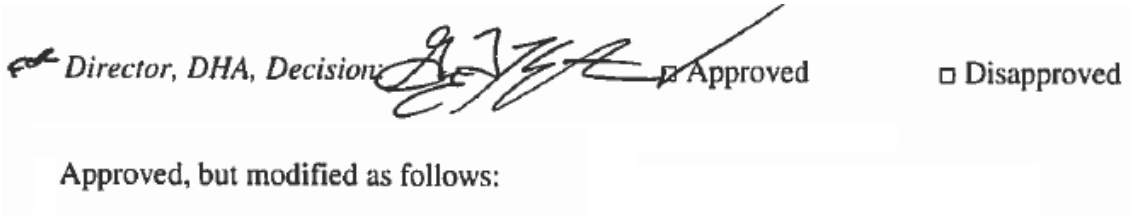
XIII. SPECIALTY CARE DRUG LIST (CLINICAL SERVICES DRUG LIST)

At the November 2014 meeting, the P&T Committee reviewed the Clinical Services Drug List (now known as the Specialty Care Drug List), which identifies drugs for which Express Scripts provides additional clinical services at the Mail Order Pharmacy under the TRICARE pharmacy contract, which started in May 2015. Medications on this list must be filled either through mail order, at an MTF, or at a retail network pharmacy in the Specialty Drug Network. Information about pharmacies in the Specialty Network is available at http://www.tricare.mil/CoveredServices/Pharmacy/Drugs/SpecialtyMeds.

Services proved at Mail Order included dedicated call lines for patient support, refill reminders, outgoing clinical calls to encourage adherence and provide patient education, and expedited delivery. At the November 2014 meeting, the P&T Committee recommended that additions or deletions to the list be made administratively, in order to accommodate new product approvals or product discontinuations, with any additions or deletions reported at the next scheduled P&T Committee meeting. However, potential expansion of the program to include new drugs or drug classes has not routinely occurred.

Based on requests from network providers, the P&T Committee discussed the potential addition of five oral oncology agents for renal cell carcinoma to the Specialty Care Drug List. Addition of this drug class may assist analyzing the potential benefits of the program.

1. ***COMMITTEE ACTION: SPECIALTY CARE DRUG LIST***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) addition of oral oncology agents for renal cell carcinoma to the Specialty Care Drug List, to include: axitinib (Inlyta), everolimus (Afinitor), pazopanib (Votrient), sorafenib (Nexavar), and sunitinib (Sutent).



XIV. ITEMS FOR INFORMATION

A. Proton Pump Inhibitor (PPI) Safety Update

Recently published literature regarding PPI long-term safety concerns prompted a review of MHS prescribing patterns. In the MHS, PPI utilization is rising, while the total number of eligible TRICARE beneficiaries is declining. There have been no significant clinical efficacy updates since the previous PPI class review in May 2007. However, three FDA drug safety communications issued since 2011 report concerns of hypomagnesemia, increased risk of bone fracture, and increased risk of *Clostridium difficile*-associated diarrhea. Additional adverse effects associated with PPIs include cyanocobalamin (vitamin B12) deficiency, chronic kidney disease, and stroke. Causation of these adverse events with PPI use has not been definitively determined. Recent guidelines recommend treating patients with the lowest effective PPI dose, and routinely re-evaluating the need for continued therapy. The P&T Committee will conduct further analyses and provide education to assist prescribers in selecting the most appropriate patients and optimal duration of therapy.

B. Annual Pharmacy Utilization and Cost Review for FY 2016

The P&T Committee reviewed current pharmacy trends, including shifts in utilization associated with the EMMPI Program, changes in cost and utilization in top drug classes, and ongoing increases in use of specialty drugs.

XV. ADJOURNMENT

The meeting adjourned at 1215 hours on November 17, 2016. The next meeting will be in February 2017.

Appendix A—Attendance: November 2016 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Appendix F—Mail Order Status of Medications Designated Nonformulary During DoD P&T Committee Meetings from November 2015 to August 2016

Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

Appendix H—Table of Abbreviations

SUBMITTED BY:

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

DECISION ON RECOMMENDATIONS

For Director, DHA, decisions are as annotated above.

For R.C. Bono
VADM, MC, USN
Director
Mr. Guy Kiyokawa, Deputy Director, DHA

2FEB17
Date

Appendix A—Attendance: November 2016 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood for George Jones, PharmD, MS	Chief, DHA Operations Management Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
Col James Jablonski, MC	Air Force, Physician at Large
CDR Karl Kronmann, MC for CDR Brian King, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore	Army, Internal Medicine Physician
CAPT Shaun Carstairs, MC	Navy, Physician at Large
MAJ John Poulin, MC	Army, Physician at Large
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Ms. Jennifer Zacher for Mr. Joe Canzolino	Department of Veterans Affairs
Voting Members Absent	
Maj Jeffrey Colburn, MC for Col William Hannah, MC	Air Force, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
MAJ Dausen Harker, MC	Army, Family Practice Physician
Nonvoting Members Present	
Mr. Bryan Wheeler	Acting General Counsel, DHA
Guests	
COL Alfonso S. Alarcon, MD	Director, TRICARE Area Office Latin America & Canada
LCDR John Dischert	Defense Logistics Agency Troop Support
Mr. Jason Wray	Defense Logistics Agency Troop Support
Mr. Bruce Mitterer	DHA Contract Operations Division
Mr. Keith Boulware	DHA Contract Operations Division
CDR Ryan Schupbach	Indian Health Service

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
Ms. Deborah Garcia via telephone	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Mr. Bill Davies via telephone	Chief, DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Dean Valibhai, PharmD, MBA via telephone	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Maj Gregory Palmrose	University of Texas PhD student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
▪ edoxaban (Savaysa) **Oral Anticoagulants**	• The patient has experienced, or is likely to experience significant adverse effects from the formulary agents. • Patient previously responded to the nonformulary agent and changing to the formulary agent would incur unacceptable risk. • No alternative formulary agent: patient has experienced a pulmonary embolism with significant right ventricular dysfunction **Formulary Alternatives:** warfarin, apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto)
▪ Aspirin/omeprazole (Yosprala) **Antiplatelet Agents**	• No alternative formulary agent – Patient cannot take aspirin and omeprazole separately **Formulary alternatives:** aspirin, omeprazole OTC
▪ Daclizumab (Zinbryta) **Multiple Sclerosis Drugs**	• The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • Patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** Betaseron, Rebif, Rebidose, Avonex, Betaseron, Extavia, Copaxone, Ampyra, Aubagio, Gilenya, Tecfidera
▪ Glycopyrrolate/formoterol (Bevespi Aerosphere) **Long-Acting Muscarinic Antagonists (LAMA)/Long-Acting Beta Agonists (LABA) Combinations**	• No alternative formulary agent; patient cannot use a dry-powder inhaler (DPI) and requires a pressurized metered-dose inhaler (pMDI) **Formulary Alternatives**—LAMAs: tiotropium (Spiriva), aclidinium (Tudorza), umeclidinium (Incruse Ellipta); LABA/LAMA: vilanterol/umeclidinium (Anoro Ellipta), olodaterol (Incruse Ellipta) used with tiotropium (Spiriva); LAMA/LABA Combo: olodaterol/tiotropium (Stiolto Respimat)
▪ Lesinurad (Zurampic) **Antigout Drugs**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** Probenecid
▪ Lisinopril oral solution (Qbrelis) **Renin-Angiotensin Antihypertensive Agents (RAAs)**	• No alternative formulary agent – Patient cannot swallow tablets or tolerate a formulary liquid (e.g., enalapril) **Formulary Alternatives:** lisinopril tablets and all other generic angiotensin-converting enzyme (ACE) inhibitors, generic angiotensin receptor blockers (ARBs); amlodipine
▪ methylnaltrexone tab (Relistor) **Opioid-Induced Constipation Drugs**	• No alternative formulary agent – Patient cannot use methylnaltrexone injectable agents **Formulary alternatives**: methylnaltrexone syringe and vials

Drug / Drug Class	Medical Necessity Criteria
▪ Nebivolol/valsartan (Byvalson) **Beta-Blocker Combination Antihypertensive Agents**	• No alternative formulary agent – Patient cannot take a generic beta blocker and a ARB separately **Formulary alternatives:** all generic beta blockers and all generic ARBs
▪ Nitroglycerin sublingual (SL) powder (GoNitro) **Cardiovascular – Miscellaneous Agents**	• No alternative formulary agent – patient cannot use generic sublingual spray or sublingual tablets **Formulary alternatives:** generic SL tablets and spray, paste, patch
▪ Norethindrone/EE/iron (Taytulla) **Oral Contraceptives**	• Provider must explain why the patient cannot be treated with formulary oral contraceptives. **Formulary alternatives:** Loestrin Fe, generics (21/7 cycle) tablets; other monophasic oral contraceptives with 20 mcg ethinyl estradiol (EE)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Alirocumab (Praluent) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	**Changes from November 2016 meeting are in BOLD** **All new users of alirocumab (Praluent) are required to try evolocumab (Repatha) first.** Manual PA criteria—Alirocumab is approved if: • A cardiologist, lipidologist, or endocrinologist initially prescribes the drug. • The patient is at least 18 years of age. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximally-tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR o If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. o Contraindication to statin ▪ The contraindication must be defined. • Praluent is not approved for any indication other than HeFH or clinical ASCVD. • Praluent is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 75 mg every 2 weeks, or o 150 mg every 2 weeks. • PA expires in one year. • **PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, or lipidologist.** Continued use of Praluent will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.

Drug / Drug Class	Prior Authorization Criteria
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	**Changes from November 2016 meeting are in BOLD** Manual PA criteria apply to all new users of evolocumab (Repatha). Manual PA criteria—Evolocumab is approved if: • A cardiologist, lipidologist, or endocrinologist initially prescribes the drug. • The patient is at least 18 years of age for HeFH and clinical ASCVD. For HoFH, patients as young as 13 years of age can receive the drug. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR o If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. o Contraindication to statin ▪ The contraindication must be defined. • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 140 mg every 2 weeks, or o 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. • PA expires in one year. • **PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, or lipidologist.** Continued use of Repatha will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.

Drug / Drug Class	Prior Authorization Criteria
• Adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs)**	Prior Authorization criteria originally approved August 2014 and implemented February 18, 2015. **November 2016 changes to PA criteria in BOLD.** **Manual PA criteria for non-infectious intermediate, posterior and panuveitis in adults applies to new patients.** Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate • Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade • Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants • Moderate to severe hidradenitis suppurativa (November 2015) • **Non-infectious intermediate, posterior and panuveitis in adults patients (November 2016)** Coverage approved for pediatric patients (age 4-17 years) with: • Moderate to severe active polyarticular juvenile idiopathic arthritis • Moderate to severely active Crohn's disease (≥ 6 years) who have had an inadequate response to corticosteroids, azathioprine, 6-mercaptopurine, or methotrexate. **Coverage for off-label uses not listed above. Please provide diagnosis and rationale for treatment. Supportive evidence will be considered.** PA does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan).
• Butalbital/ acetaminophen tablets (Allzital) **Analgesics and Combinations**	All new and current users of butalbital/acetaminophen are required to undergo manual prior authorization. Manual PA criteria—Coverage will be approved if: • Patient cannot tolerate generic oral tablet or capsule formulations of butalbital/acetaminophen or butalbital/acetaminophen/caffeine. • Off-label uses are not approved • PA does not expire
• Crizotinib (Xalkori) **Oral Oncologic Agents**	Manual PA criteria apply to all new and current users of crizotinib. Manual PA criteria—Xalkori is approved if: a. Patient has a documented diagnosis of ALK-positive NSCLC OR **b. Patient has a documented diagnosis of ROS-1 positive NSCLC (November 2016)** • PA does not expire • Non-FDA approved uses are not approved

Drug / Drug Class	Prior Authorization Criteria
• Cyclosporine 0.05% ophthalmic emulsion (Restasis) **Ophthalmic Anti-Inflammatory/ Immunomodulatory Agents—Ophthalmic Immunomodulatory Agents Subclass**	**November 2016 updates are in BOLD** PA criteria apply to all new users of Restasis. • Current User is defined as a patient who has had Restasis dispensed during the previous 365 days at a Military Treatment Facility (MTF), a retail network pharmacy, or the Mail Order Pharmacy. o If there is a Restasis prescription in the past 365 days (automated lookback with Restasis as the qualifying drug), the claim goes through and no manual PA is required. • New User is defined as a patient who has no had Restasis dispensed in the past 365 days. o If there is no Restasis prescription in the past 365 days, a manual PA is required. Manual PA Criteria: • Coverage is approved if one of the following is fulfilled: o Patient has diagnosis of keratoconjunctivitis sicca (KCS), **dry eye disease or dry eye syndrome** with lack of therapeutic response to at least 2 OTC artificial tears agents o Patient has ocular graft versus host disease o Patient has corneal transplant rejection o Patient has experienced documented corneal surface damage while using frequent artificial tears o **Restasis is prescribed by an ophthalmology/corneal specialist for a pediatric patient with a diagnosis of atopic keratoconjunctivitis (AKC) or vernal keratoconjunctivitis (VKC)** o **Patient has had LASIK surgery not more than 3 months previously. Note that therapy is limited to a maximum of 3 months of therapy after the procedure.** • **The combination of Xiidra and Restasis is not allowed.** • **For all indications, the patient must have had a trial of artificial tears.** • Coverage is not approved for off-label uses such as, but not limited to: o Pterygia o Blepharitis o Ocular rosacea o Contact lens intolerance Prior Authorization expires in one year. • If there is a break in therapy, the patient will be subject to the PA again.
• Daclizumab (Zinbryta) **Multiple Sclerosis Drugs**	Manual PA criteria apply to all new users of daclizumab. Manual PA criteria—Coverage will be approved if: 1. Age ≥ 18 AND 2. Has documented diagnosis of relapsing multiple sclerosis AND 3. Has tried and had an inadequate response to 2 or more multiple sclerosis drugs • Off-label uses are not approved • PA does not expire
• Insulin degludec (Tresiba) **Basal Insulins**	Manual PA criteria apply to all new and current users of insulin degludec. Manual PA criteria—Tresiba is approved if: 1. Patient is age ≥ 18 AND 2. Patient has tried and failed or is intolerant to insulin glargine. • Non-FDA approved uses are not approved • PA does not expire

Drug / Drug Class	Prior Authorization Criteria
• Lesinurad (Zurampic) **Antigout Drugs**	Manual PA criteria apply to all new and current users of lesinurad. Manual PA criteria: Coverage will be approved if: 1. Age ≥ 18 2. The patient has chronic or tophaceous gout 3. The patient has a creatinine clearance (CrCl) >45 mL/min 4. The gout patient has not achieved target serum uric acid level despite maximally- tolerated therapy with a xanthine oxidase inhibitor • Off-label uses are not approved • PA does not expire
• Lifitegrast ophthalmic solution (Xiidra) **Ophthalmic Anti-Inflammatory / Immunomodulatory Agents**	Manual PA criteria apply to all new users of lifitegrast ophthalmic solution. Manual PA criteria: Coverage will be approved if: 1. Age ≥ 18 AND 2. Has documented diagnosis of moderate to severe inflammatory Dry Eye Disease AND 3. Drug is prescribed by an ophthalmologist or optometrist AND 4. Patient has failed to respond to an adequate trial of artificial tears • Combination use of Xiidra and Restasis not allowed • Off-label uses are NOT approved • PA does not expire
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	**November 2016 changes to PA criteria in bold.** **Manual PA criteria for moderate to severe active Crohn's disease in adults applies to new patients.** Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) 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, coverage is approved for Stelara if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Adverse reactions to Humira not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy • **Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids, or TNF blockers. (November 2016)** • Prior Authorization does not expire. • Non-FDA approved uses are not approved. • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), apremilast (Otezla), or rituximab (Rituxan).

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Alirocumab (Praluent) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	▪ Retail Network: 2 syringes or pens per 30 days ▪ MTF and Mail Order Pharmacy: 6 syringes or pens per 90 days ▪ Note: No change to QLs from August 2015
• Aprepitant oral solution (Emend) **Antiemetic Antivertigo Agents**	▪ Retail: 6 packets/30 days ▪ MTF and Mail Order: 18 packets/90 days
• Butalbital /acetaminophen tablets (Allzital) **Analgesics and Combinations**	▪ Retail: 60 tablets / 30 days ▪ MTF and Mail Order: 180 tablets / 90 days
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors**	▪ HeFH and ASCVD o Retail Pharmacy Network: 2 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 6 of the 140 mg syringes per 90 days. Repatha Pushtronex not allowed for HeFH and ASCVD ▪ HoFH o Retail Pharmacy Network: 3 of the 140 mg syringes per 30 days; 1 Pushtronex device (420mg/3.5 mL) / 30 days o MTF and Mail Order Pharmacy: 9 of the 140 mg syringes per 90 days; 3 Pushtronex devices / 90 days
• Glycopyrrolate/formoterol (Bevespi Aerosphere) **Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMA)/Long-Acting Beta Agonist Combinations**	▪ Retail: 1 inhaler / 30 days ▪ MTF and Mail Order: 3 inhalers / 90 days ▪ No refills allowed on institutional packs
• Tiotropium soft mist inhaler (Spiriva Respimat) **Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)**	▪ Retail: 1 inhaler / 30 days ▪ MTF and Mail Order: 3 inhalers / 90 days Note: No change to QLs from February 2016

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
aprepitant 125 mg oral suspension (Emend)	Antiemetic Substance P /NK1 Receptor Antagonist	• Aprepitant capsules (Emend) • Rolapitant (Varubi)	Patients ≥ 6 months old for the prevention of N/V from highly emetogenic chemotherapy (HEC) and moderately emetogenic chemotherapy (MEC)	• The only Substance P/NK1 Receptor Antagonist in an oral liquid form • For patients who are unable to take aprepitant capsules • Must be used concomitantly with dexamethasone and a $5HT_3$ antagonist • Approved for prevention and delayed onset CINV • Approved for ages ≥ 6 years • Emend capsules are UF	• UF
aspirin delayed release / omeprazole IR tablets 81/40mg, 325/40mg (Yosprala)	Antiplatelet with PPI	• Aspirin 81mg, 325mg • Omeprazole 40mg • Durlaza	For pts who require ASA for 2^0 prevention of CV & cerebrovascular events & who are at risk of developing ASA associated gastric ulcer	• Guidelines recommend a proton pump inhibitor (PPI) with aspirin for secondary prevention for patients at risk of gastric ulcer (≥55 years or history of gastric ulcer) • 2 clinical trials; N=524 Yosprala & N=525 EC ASA 325 mg; 6 month incidence of gastric ulcers reduced • Has not been shown to ↓ risk of GI bleeding with aspirin • Convenient but costly	• NF • Add to mail list
ciprofloxacin 0.75%/ fluocinolone acetonide 0.0625% otic solution (Otovel)	Topical Otic Antibiotic/ Steroid Combination	• Ciprodex • Ciproflox/HC • Ofloxacin Otic	Acute Otitis Media (AOM) in peds ≥6 mo with tympanic tubes	• Topical quinolone antibiotics are the treatment of choice for otorrhea in patients with tympanostomy tubes • Current formulary options include ciprodex and ofloxacin • The addition of a steroid to quinolone otic drops reduces time to cessation of otorrhea by 59% • There are no head-to-head studies with Otovel and Ciprodex at this time • There is no clinically compelling advantages over existing quinolone/steroid otic preparations in the tx of otorrhea	• UF
daclizumab (Zinbryta)	Immunosuppressant/ Monoclonal Antibody	• Copaxone • Betaseron • Tecfidera	Multiple sclerosis, relapsing; reserve for pts with inadequate response to ≥2 MS drugs	• Reserve daclizumab for patients who have had an inadequate response to 2 or more MS drugs (Package insert) • Once monthly self-injection • REMS program due to hepatic injury	• NF • Exempt from mail
formoterol; glycopyrrolate (Bevespi Aerosphere)	Pulmonary II LAMA/LABA Combination Pulmonary II	• Anoro Ellipta • Utibron Neohaler • Stiolto Respimat • Incruse Ellipta	Long-term, maintenance treatment of airflow obstruction in COPD	• 4th available LABA/LAMA combination for COPD • No evidence to suggest Bevespi is superior in efficacy or safety to LABA/LAMA combinations currently available • Least studied LAMA/LABA combination • 1st LAMA/LABA available in a pressurized MDI (Aerosphere device) • Bevespi offers no clinically compelling advantages over existing UF agents used in the long-term maintenance treatment of COPD	• NF • Add to mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
lesinurad (Zurampic)	Antigout Agent Uric Acid Transporter 1 (URAT-1) Inhibitor	• Probenecid	Hyperuricemia associated with gout	• Lesinurad is a URAT-1 & organic anion transporter 4 (OAT4) inhibitor that must be used in combination with a xanthine oxidase inhibitor (XOI) • First line therapy is a XOI • No clinically significant differences between lesinurad, allopurinol, and febuxostat (Uloric) in tophi reduction or gout flare rate reduction • No clinically compelling advantages over existing antigout treatments • Step therapy exists: must try allopurinol before febuxostat	• NF • Add to mail
Lifitegrast ophthalmic solution (Xiidra)	Ophthalmic Anti-inflammatory / Immunomodulatory Agents Lymphocyte Fxn-Associated Antigen-1 (LFA-1) Antagonist	• Restasis	For the signs and symptoms of dry eye disease	• Restasis is UF with PA criteria • First in class lymphocyte function-associated antigen-1 (LFA-1) antagonist • 2nd drug indicated for dry eye disease • Faster onset compared to Restasis	• UF • Add to mail
lisinopril 1mg/mL oral solution (Qbrelis)	Renin-Angiotensin Anti-Hypertensive Agent (RAA)	HF, MI, HTN: • Captopril • Lisinopril • Ramipril CAD, HTN: • Amlodipine	• HTN in pts ≥ 6 years • Acute MI • Heart Failure	• The only commercially available liquid ACE inhibitor • All available ACE inhibitor tablets can be split or crushed • Captopril can be compounded as a suspension • Marketed toward pediatric use; adult use would require new bottle every 4 days (typical 40 mg dose) • No clinically compelling advantages over existing ACEIs	• NF • Add to mail
methylnaltrexone oral tablet (Relistor)	Peripherally Acting mu Opioid Receptor Antagonist (PAMORA) Alcohol Deterrents Narcotic Antagonists	• Relistor vial (OIC in palliative care setting) • Relistor prefilled syringe (OIC in non-cancer pts) • Movantik	Opioid-induced constipation (OIC) in patients with chronic non-cancer pain	• Tablet formulation of Relistor, which was previously available in prefilled syringe for OIC • Reserve for use after failure of osmotic agents (Miralax) or stimulant laxatives • Other oral products for OIC are less expensive (Movantik, Amitiza) • Relistor, Movantik and Amitiza are 2nd-line therapy after laxatives, lifestyle changes (incr. fluid intake, dietary fiber, exercise), or opioid rotation	• NF • Exempt from mail
nebivolol 5 mg/ valsartan 80 mg (Byvalson)	Beta Blocker Combination Anti-hypertensive Agent	• Beta Blockers • ARBs	• Treatment of HTN (adults); w/wo other drugs • ↓ BP reduces the risk of fatal & nonfatal CV events, primarily strokes & MI	• 1st beta blocker/ARB combo • Diuretics first line for HTN • Currently several HTN fixed dose combinations with diuretics are available on UF • Only one dosage approved; lowest nebivolol dose/lowest valsartan dose produced similar BP↓ as higher doses, but fewer AEs • Bystolic is currently NF and has PA criteria • No clinically compelling evidence over current UF antihypertensive therapies	• NF • Add to mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
nitroglycerin SL powder 400mcg (GoNitro)	Misc Cardiovascular Agents	Nitroglycerin (NTG) SL 400mcg tablets and spray	Acute relief of an attack or prophylaxis of angina pectoris due to CAD	• NTG sublingual (SL) tablets and oral spray are BCF (from 1998) • No clinically compelling advantages over generic SL spray or SL tablets	• NF • Exempt from mail
norethindrone/ EE/iron (Taytulla)	Contraceptives	• UF: Loestrin Fe, generics (21/7 cycle) tablets • NF: Loestrin 24 Fe, generics (24/4 cycle) tablets • NF: Minastrin 24 Fe chewable (24/4 cycle) tablets	For use by females of reproductive age to prevent pregnancy	• No clinically compelling evidence over existing combined oral contraceptives already available on the BCF and UF	• NF • Exempt from mail
von Willebrand factor (Vonvendi)	Antihemophilic Factors	• vWF/FVIII • (Humate P) • vWF/FVII • (Alphanate)	On demand and control of bleeding episodes in adults with von Willebrand disease	• 1st recombinant pure von Willebrand factor. • Requires addition of FVIII in those who are deficient. • As a recombinant product, potentially reduces risk of blood borne pathogens.	• UF

Appendix F—Mail Order Status of Medications Designated Nonformulary During DoD P&T Committee Meetings from November 2015 to August 2016

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
Nov 2015	**Alzheimer's** NAMENDA XR (memantine ER) NAMZARIC (memantine/donepezil) **Antirheumatics, Injectable Methotrexate** OTREXUP, RASUVO (methotrexate) auto-injectors	**ADHD, Stimulants** DAYTRANA (methylphenidate) transdermal system *Focalin XR* (dexmethylphenidate ER) VYVANSE (lisdexamfetamine) – specific exception for C-II agents **Acne Drugs, Oral Isotretinoins** ABSORICA (isotretinoin) – not available at mail due to REMS requirements
Feb 2016	**Antifungals, Topical Lacquers** JUBLIA (efinaconazole)10% topical solution KERYDIN (tavaborole) 5% topical solution **Innovators** DURLAZA (aspirin ER) 162.5 mg SEEBRI NEOHALER (glycopyrrolate) oral inhaler TRESIBA (insulin degludec) UTIBRON NEOHALER (indacaterol/glycopyrrolate) oral inhaler VIVLODEX (meloxicam low dose)	**Newly-Approved** AFREZZA (inhaled insulin) – specific exception PAZEO (olopatadine) 0.7% ophth solution – acute use TIVORBEX (indomethacin low dose) – acute use **Contraceptives** – all NF contraceptives (multiple) – specific exception for contraceptives **Innovators** DYANAVEL XR (amphetamine ER) oral susp – C-II exception VARUBI (rolapitant) – acute use
May 2016	**Newly-Approved** VIBERZI (eluxadoline) **Innovators** TALTZ (ixekizumab) injection	**Atypical Antipsychotics** SAPHRIS (asenapine) REXULTI (brexpiprazole) VRAYLAR (cariprazine) FANAPT (iloperidone) – specific exception for antipsychotics **Innovators** ADZENYS XR ODT (amphetamine) – C-II exception BELBUCA (buprenorphine) buccal – acute use QUILLICHEW ER (methylphenidate ER) chewable tab – C-II exception
Aug 2016	**Topical Acne/Rosacea** ACZONE (dapsone) 5% and 7.5% gel CLINDACIN ETZ, CLINDACIN PAC (clindamycin) 1% cleansing kits CLINDAGEL (clindamycin) 1% gel EPIDUO (adapalene/benzoyl peroxide) 0.1%/2.5% gel EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%/2.5% gel FABIOR (tazarotene) 0.1% foam MIRVASO (brimonidine) 0.33% gel NEUAC KIT (clindamycin/benzoyl peroxide)1.2%/5% gel/cream kit NORITATE (metronidazole) 1% cream ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75% gel *Retin-A Micro; Retin-A Micro Pump* (tretinoin microsphere) 0.04%, 0.08% , 0.1% gel ROSADAN CREAM KIT (metronidazole) 0.75% cream/cleanser ROSADAN GEL KIT (metronidazole) 0.75% gel/cleanser kit SOOLANTRA (ivermectin) 1% cream *Veltin, Ziana* (clindamycin/tretinoin) 1.2%/0.025% gel **Innovators** BRIVIACT (brivaracetam) tablets and oral solution JENTADUETO XR (linagliptin/metformin) SERVIVO (betamethasone dipropionate) 0.05% spray TOLAK (fluorouracil) 4% cream ULTRAVATE (halobetasol propionate) 0.05% lotion	**Triptans** *Axert* (almotriptan) Frova (frovatriptan); ONZETRA XSAIL (sumatriptan) nasal powder SUMAVEL DOSEPRO (sumatriptan) needle-free injection TREXIMET (sumatriptan/naproxen) ZECUITY (sumatriptan) transdermal, if reintroduced to the market ZEMBRACE SYMTOUCH (sumatriptan) 3 mg autoinjector – acute use **Alcohol Deterrents, Narcotic Antagonists** EVZIO (naloxone) autoinjector – acute use **Innovators** NUPLAZID (pimavanserin) – antipsychotic exception FERRIPROX (deferiprone) oral solution – specific exception (intermittent use) XTAMPZA ER (oxycodone ER) – C-II exception
Nov 2016	**Oral Anticoagulants** SAYVASA (edoxaban) tablets	**See Section XII pages 16-17**

Appendix G—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
Nov 2016	**Antilipidemics–1 (LIP-1s) Agents PCSK9 Inhibitors Subclass**	UF subclass review; not previously reviewed	**BCF LIP-1s:** ▪atorvastatin ▪pravastatin ▪simvastatin ▪niacin ER	**UF – Step-Preferred:** ▪evolocumab (Repatha) **UF – Non Step-Preferred:** ▪alirocumab (Praluent)	None	Pending signing of the minutes / 60 days The effective date is April 5, 2017.	▪Manual PA applies to evolocumab and alirocumab. See Appendix C	▪Note: No PCSK9 inhibitors were added to the BCF ▪Evolocumab is the preferred PSCK9 inhibitor
Nov 2016	**Oral Anticoagulants**	UF class previously reviewed May 2015	▪warfarin generic ▪apixaban (Eliquis)	▪ dabigatran (Pradaxa) ▪ rivaroxaban (Xarelto)	▪ edoxaban (Savaysa)	Pending signing of the minutes / 90 days The effective date is May 10, 2017.		▪Note: apixaban added to the BCF; edoxaban made NF
Nov 2016	**Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)**	UF class review; subclass not previously reviewed; Pulmonary II drugs reviewed May 2013	▪**tiotropium soft mist inhaler (Spiriva Respimat)** ▪tiotropium bromide inhalation powder (Spiriva HandiHaler)	▪ aclidinium (Tudorza Pressair) ▪ umeclidinium (Incruse Ellipta)	▪ glycopyrrolate (Seebri Neohaler)	Pending signing of the minutes The effective date is Feb 2, 2017.	▪QLs from Feb 2016 apply See Appendix D	▪Note: Spiriva Respimat added to the BCF; Spiriva HandiHaler remains on the BCF

TRICARE Formulary Search tool: http://www.express-scripts.com/tricareformulary

Appendix H—Table of Abbreviations

ACE	angiotensin-converting enzyme inhibitor
AE	adverse events
ARB	angiotensin receptor blocker
ALK	anaplastic lymphoma kinase
ASCVD	atherosclerotic cardiovascular disease
AKC	atopic keratoconjunctivitis
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BP	blood pressure
CAD	coronary artery disease
CD	controlled delivery
CEA	cost-effectiveness analysis
CFR	Code of Federal Regulations
CHF	congestive heart failure
CINV	chemotherapy induced nausea and vomiting
CK	creatine kinase
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
CrCl	creatinine clearance
CV	cardiovascular
DAA	direct acting antiviral agent
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DOAC	Direct-Acting Oral Anticoagulants
DoD	Department of Defense
DPP-4	dipeptidyl peptidase-4 inhibitors
DPI	dry powder inhaler
DR	delayed release
EC ASA	enteric coated aspirin
ECF	Extended Core Formulary
EE	ethinyl estradiol
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FEV_1	forced expiratory volume in one second
FY	fiscal year
GCN	generic code number
GI	gastrointestinal
GU	gastro urinary
HCV	hepatitis C virus
HEC	highly emetogenic chemotherapy
HeFH	heterozygous familial hypercholesterolemia
HoFH	homozygous familial hypercholesterolemia
HTN	hypertension

IR	immediate release
KCS	keratoconjunctivitis sicca
LABA	long-acting beta agonists
LAMA	Long-Acting Muscarinic Antagonists Subclass
LDL	low-density lipoprotein cholesterol
MEC	moderately emetogenic chemotherapy
MHS	Military Health System
MI	myocardial infarction
MN	medical necessity
MTF	Military Treatment Facility
NDA	New Drug Application
NDAA	National Defense Authorization Act
NF	nonformulary
NSAIDs	non-steroidal anti-inflammatory drugs
NSCLC	non-small cell lung cancer
NTG	nitroglycerin
NVAF	non-valvular atrial fibrillation
ODT	orally dissolving tablet
OIC	opioid-induced constipation
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
pMDI	pressurized metered dose inhaler
P/NK1	substance P/neurokinin 1 (NK1) receptor antagonist
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPI	proton pump inhibitor
PCSK9	proprotein convertase subtilisin/kexin type 9 inhibitors
QD	once daily
QLs	quantity limits
RAAs	renin-angiotensin antihypertensive agents
REMS	Risk Evaluation and Mitigation Strategy
ROS1	c-ros oncogene 1
SGLT2	sodium-glucose co-transporter 2 inhibitor
SL	sublingual
TAA	Trade Agreements Act
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
UF	Uniform Formulary
ULN	upper limit of normal
VA	U.S. Department of Veterans Affairs
VKC	vernal keratoconjunctivitis
VTE	venous thromboembolism
XOI	xanthine oxidase inhibitor
XR	extended release