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).

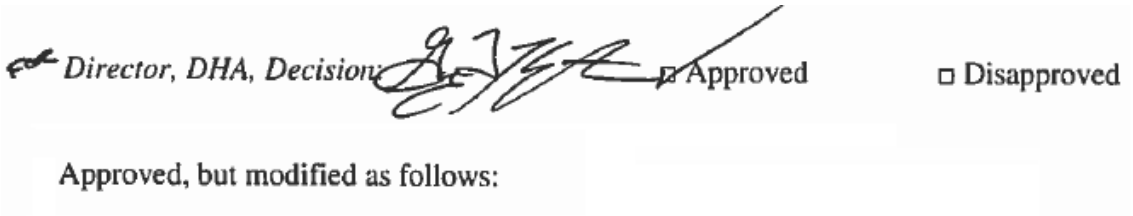
1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) tiotropium soft mist inhaler (Spiriva Respimat) be designated as formulary on the UF, based on clinical and cost effectiveness.

   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)

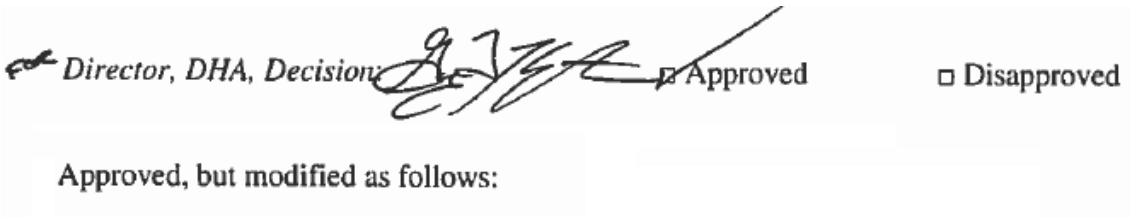
    Note that as part of this recommendation, all new users of alirocumab are required to try evolocumab first. Additionally, a PCSK9 inhibitor was not selected for BCF placement. The LIP-1 BCF products include the statins atorvastatin, pravastatin, and simvastatin; and niacin extended release (non-statin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

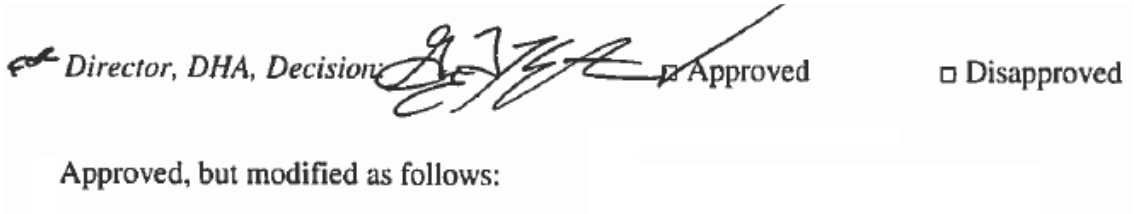
   - **UF**:
     - Antiemetics: aprepitant oral suspension (Emend)
     - Antihemophilic Factors: von Willebrand factor (Vonvendi)
     - Ophthalmic Anti-Inflammatory Immunomodulatory Agents: lifitegrast ophthalmic solution (Xiidra)
     - Topical Otic Antibiotic/Steroid Combinations: ciprofloxacin/ fluocinolone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

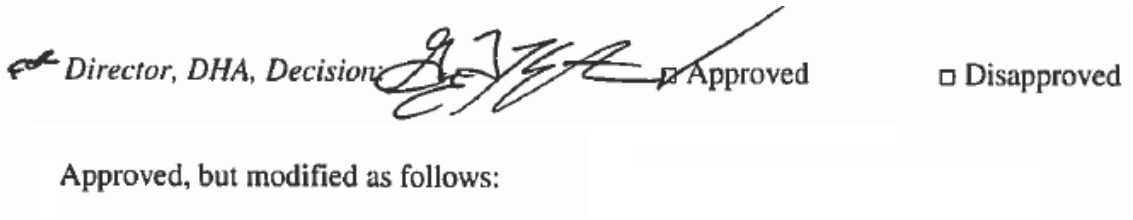
1. **QLs**—Quantity limits were reviewed for three drugs: aprepitant oral suspension (Emend) for nausea and vomiting associated with moderate and highly emetogenic chemotherapy regimens, glycopyrrolate/formoterol (Bevespi Aerosphere) for COPD, and butalbital/acetaminophen tablets (Allzital) for tension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

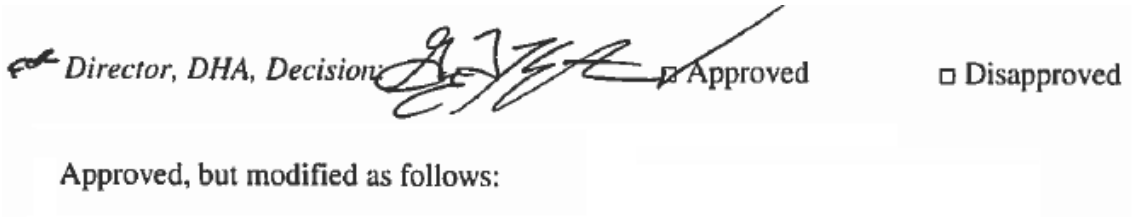
The wording currently on the MN form reflects the HA policy, as it states prescriptions for NF medications may be filled at the MTFs only if two conditions are met: 1) the prescription is written by a military provider, or at the discretion of the MTF, a civilian provider to whom the patient was referred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

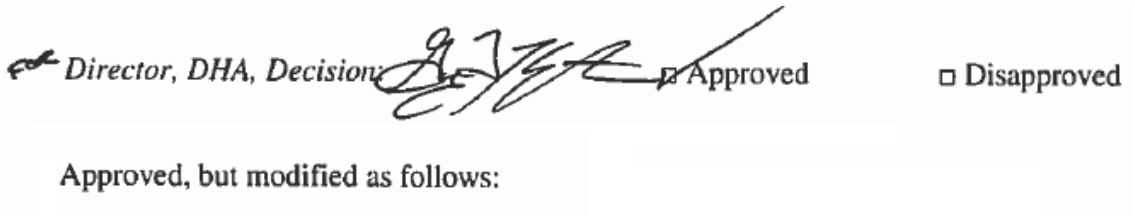
Approved, but modified as follows:

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.

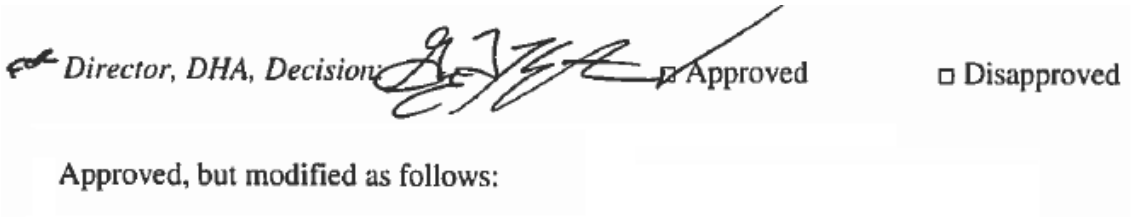
B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for Durlaza and Dyanavel XR:

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

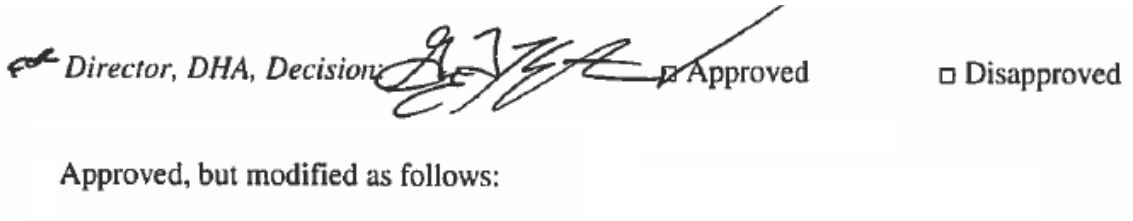
Several Topical Acne and Rosacea agents were recommended for NF status during the subclass review at the August 2016 meeting. At the time, the P&T Committee saw no reason to exempt these NF agents from the mail order requirement, given that the designated NF agents are specifically used for the chronic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



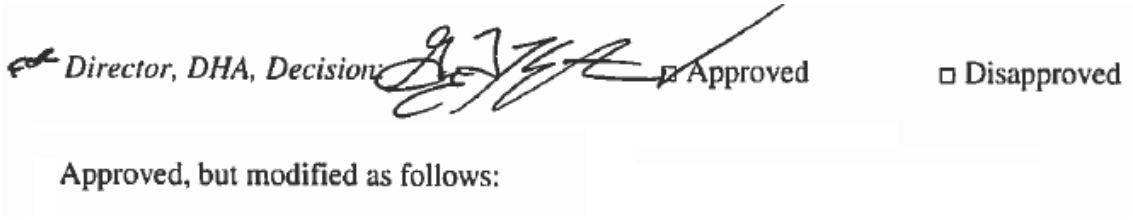
XIII. SPECIALTY CARE DRUG LIST (CLINICAL SERVICES DRUG LIST)

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

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2016

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 10 and 11, 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 May 2016 Minutes—**VADM R.C. Bono, MC, USN, Director, DHA, approved the minutes from the May 2016 DoD P&T Committee meeting on July 28, 2016.

2. **Clarification of May 2016 Minutes**

   a) **Basic Core Formulary (BCF) Clarification for Emergency Contraceptives—**The emergency contraceptives were reviewed at the May 2016 DoD P&T Committee meeting, and levonorgestrel 1.5 mg (Plan B One-Step) was added to the BCF. The sole product added to the BCF is the Plan B One-Step branded product for clinic use with the NDC #5128-146-10; generic formulations of levonorgestrel 1.5 mg are designated with Uniform Formulary status, but were not added to the BCF.

   b) **Uniform Formulary (UF) Clarification for Proton Pump Inhibitors—**At the May 2016 DoD P&T Committee meeting, rabeprazole delayed release tablets (Aciphex, generics) were designated as formulary and step-preferred on the UF. There is no change to the current formulary status of rabeprazole sprinkles (Aciphex sprinkles); they remain designated as formulary on the UF and non step-preferred.

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. UF DRUG CLASS REVIEWS

A. Acne Agents: Topical Acne and Rosacea Agents Subclass

Background—The P&T Committee evaluated the Topical Acne and Rosacea Subclass, which has not been previously reviewed for UF placement. The reviewed products were further categorized based on mechanism of action, and included the topical antibiotics and combinations with benzoyl peroxide, topical retinoids, azelaic acid, dapsone, sodium sulfacetamide/sulfur products, ivermectin, and brimonidine.

There are over 35 products in the subclass, several with respective generics or therapeutic alternatives available in multiple strengths and formulations. The clinical effectiveness review focused on the new branded entrants to the market, and the place in therapy for the products. Meta-analyses and professional treatment guidelines were also reviewed. Military Health System (MHS) provider opinions were solicited and considered in the UF recommendations.

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

- Benzoyl peroxide used in combination with the clindamycin 1% gel or solution is a first-line choice for treatment of mild to moderate acne. Monotherapy with clindamycin is not recommended, due to the risk of bacterial resistance.
- The topical retinoids (tretinoin, adapalene, and tazarotene) are effective when used as monotherapy in patients with comedonal or mild acne, or in combination with other products in patients with inflammatory acne lesions. Tazarotene (Fabior) has a limited role, due to its pregnancy category X rating.
- The 2015 Cochrane Review of rosacea agents reported that there is high quality evidence for use of topical azelaic acid for decreasing inflammatory lesions and erythema; for brimonidine for decreasing facial erythema; and, ivermectin for decreasing inflammatory lesions. There is moderate quality evidence for topical metronidazole for decreasing inflammatory lesions and erythema, but topical metronidazole is widely used as a first line therapy.
- The available clinical data for the newer products, including dapsone 7.5% gel (Aczone) (an innovator drug), brimonidine 0.33% gel (Mirvaso), and ivermectin 1% cream (Soolantra), is limited by the lack of active controls, use of subjective rating scale, and non-rigorous study designs.
    - The acne treatment guidelines recommend topical dapsone for inflammatory acne, particularly in adult females.
    - Brimonidine 0.33% gel has a clinical niche for treatment of persistent facial erythema in rosacea, but will not change the underlying course of the disease. A recent FDA safety alert warned of the risk of hypotension, bradycardia, and

dizziness, particularly in patients with pre-existing cardiovascular disease due to its mechanism as an alpha-2 adrenergic agonist.

- Ivermectin 1% cream has a clinical niche for treating papulopustular rosacea associated with proliferation of Demodex mites.

- Safety profiles for acne and rosacea agents are primarily dermatological in nature with some unique differences, including hypopigmentation with azelaic acid, photosensitivity with retinoids, the potential to induce bacterial resistance with the topical antibiotics, and the rare potential for methemoglobinemia with dapsone 5% gel.

- A variety of agents in different dosage formulations (e.g., cream, gel, etc.) are required on the UF to meet the needs of patients. Additionally, azelaic acid is required on the formulary due to its pregnancy category rating (Category B) and tolerability.

Relative Cost-Effectiveness Analysis and Conclusion—A cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed for the topical acne products that generic formulations in the class were the most cost-effective agents, followed by branded formulations of clindamycin/benzoyl peroxide 1.2%/2.5% gel (Acanya), clindamycin/benzoyl peroxide 1.2%/5% gel kit (Neuac), adapalene/benzoyl peroxide 0.1%/2.5% gel (Epiduo), clindamycin/tretinoin (Veltin), adapalene/benzoyl peroxide 0.3%/2.5% gel (Epiduo Forte), dapsone 5% gel and 7.5% gel (Aczone), azelaic acid 20% cream (Azelex), clindamycin cleansing kit (Clindacin ETZ), tazarotene 0.1% foam (Fabior), clindamycin/benzoyl peroxide 1.2%/3.75% gel (Onexton), clindamycin/tretinoin (Ziana), clindamycin cleansing kit (Clindacin PAC), and brand clindamycin 1% gel (Clindagel).

- CMA results also showed that, for rosacea, generic metronidazole 1% gel, 0.75% lotion, and 0.75% cream were the most cost-effective, followed by azelaic acid 15% gel and foam (Finacea), brand metronidazole 0.75% gel and cream cleanser kits (Rosadan), ivermectin 1% cream (Soolantra), brimonidine 0.33% gel (Mirvaso), and brand metronidazole 1% cream (Noritate).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating generics as UF, with selected brand agents as UF and non step-preferred, and NF and non step-preferred, demonstrated the largest estimated cost avoidance for the MHS.

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

- **UF and step-preferred**
    - adapalene 0.1% lotion, gel, cream, and 0.3% gel (Differin, generics)
    - clindamycin 1% foam (Evoclin, generics)
    - clindamycin 1% gel, cream, foam, lotion, solution, and med swab (Cleocin T, generics)
    - clindamycin/benzoyl peroxide 1%/5% gel (Benzaclin, generics)
    - clindamycin/benzoyl peroxide 1.2%/5% gel (Duac, generics)
    - clindamycin/benzoyl peroxide 1%/5% gel kit (Duac CS (Kit))
    - metronidazole 0.75% cream (MetroCream, generics)
    - metronidazole 0.75% lotion (MetroLotion, generics)
    - metronidazole 1% gel (Metrogel, generics)
    - sulfacetamide sodium/sulfur 10% lotion (Klaron, generics)
    - tretinoin 0.01% and 0.025% gel (Retin-A, generics)
    - tretinoin 0.025% gel, cream (Avita, generics)
    - tretinoin 0.025%, 0.05%, and 0.1% cream, liquid (Retin-A, generics)
    - tretinoin 0.0375%, 0.075% cream (Tretin-X, generics)
    - tretinoin 0.05% gel (Atralin, generics)

- **UF and non step-preferred**
    - azelaic acid 20% cream (Azelex)
    - azelaic acid 15% gel, foam, kit (Finacea)
    - clindamycin/benzoyl peroxide 1.2% and 2.5% gel (Acanya)

- **NF and non step-preferred**
    - adapalene/benzoyl peroxide 0.1% /2.5% gel (Epiduo)
    - adapalene/benzoyl peroxide 0.3% /2.5% gel (Epiduo Forte)
    - brimonidine tartrate 0.33% gel (Mirvaso)
    - clindamycin 1% cleansing kits (Clindacin ETZ, Clindacin PAC)
    - clindamycin 1% gel (Clindagel)
    - clindamycin/benzoyl peroxide 1.2%/ 3.75% gel (Onexton)
    - clindamycin/benzoyl peroxide 1.2%/5% gel/cream kit (Neuac Kit)
    - clindamycin/tretinoin 1.2% /0.025% gel (Veltin; Ziana, generics)
    - dapsone 5% and 7.5% gel (Aczone)
    - ivermectin 1% cream (Soolantra)
    - metronidazole 1% cream (Noritate)
    - metronidazole 0.75% cream/cleanser kit (Rosadan Cream Kit)
    - metronidazole 0.75% gel/cleanser kit (Rosadan Gel Kit)
    - tretinoin microsphere 0.04%, 0.08%, and 0.1% gel (Retin-A Micro, generics; Retin-A Micro Pump, generics)
    - tazarotene 0.1% foam (Fabior)

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

acne agents previously designated as BCF, prior to the implementation of the UF Rule in 2005, should be retained on the BCF, with two additions. The BCF products recommended are as follows:

- **Added to the BCF:**
  - clindamycin/benzoyl peroxide 1.2% /5% gel (generic Duac)
  - metronidazole 1% gel (generic Metrogel)

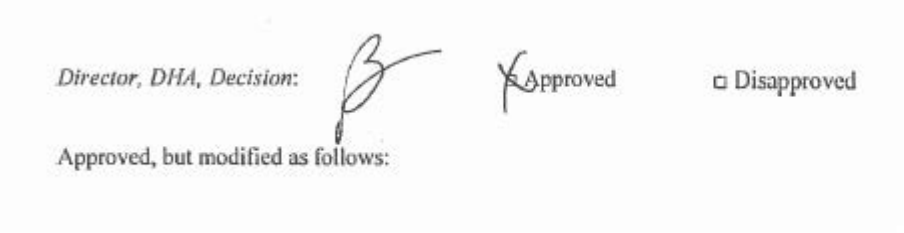
- **Remain on the BCF:**
  - clindamycin phosphate 1% gel, cream, lotion, and solution (generic Cleocin T)
  - sulfacetamide sodium/sulfur 10% lotion (generic Klaron), which has additional uses outside of acne and rosacea
  - tretinoin 0.025% and 0.05% cream (generic Retin-A)

3. ***COMMITTEE ACTION: AUTOMATED PRIOR AUTHORIZATION (PA) (STEP THERAPY) and MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) step therapy and manual PA criteria for the acne and rosacea drugs. Separate step therapies will be required for acne and rosacea products. Within the acne subclass, there are additional step therapies, based on mechanism of action. All branded formulations are non step-preferred. Step therapy for the acne products generally requires use of at least three step-preferred products first, prior to use of a non-preferred product. For the rosacea products, one generic metronidazole step-preferred formulation is required prior to use of the non step-preferred products. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MANUAL PA CRITERIA FOR BENZOYL PEROXIDE—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for legend single-ingredient benzoyl peroxide formulations (e.g., those products that are not in combination with a topical antibiotic). A trial of at least two step-preferred topical acne products will be required prior to use of a prescription benzoyl peroxide product (formulations ranging in concentration from 3% to 10%). See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for the topical acne and rosacea agents. See Appendix B for the full criteria.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 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 February 8, 2017.



B. Migraine Agents: Triptans

Background—The triptans for migraine headache were previously reviewed for formulary placement in June 2008. There are currently 12 products marketed, with many available in generic oral formulations. Eletriptan (Relpax) has patent expiration expected in December 2016. Four sumatriptan formulations are available only as branded products (Sumavel Dose Pro, Zembrace SymTouch, Onzetra Xsail, and Treximet). Sumatriptan transdermal system (Zecuity) was removed from the market in June 2016 due to safety issues, but is included in the review.

The clinical effectiveness evaluation focused on the triptans approved since the last review, and updated meta-analyses and clinical practice guidelines.

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

- Clinical practice guidelines and systematic reviews found that the triptans as a class have quality evidence to support use in the treatment of moderate to severe migraine headache. Compared to placebo, the triptans achieve numbers needed to treat (NNT) ranging from three to six for the preferred endpoints of two-hour pain-free and 24-hour sustained pain-free after dosing.
- Available data suggests all triptans are significantly superior to placebo for treating acute migraine. The oral agents, particularly generically available triptans, are the most convenient and easy to use, and are often preferred by patients and providers as the first choice treatment. The available data is not sufficient to clearly establish relative superiority of one oral triptan over another.
- For patients who are unable to manage their migraines with oral options, alternative delivery options are required on the formulary if the initial choice is not successful.
- While subcutaneous sumatriptan formulations provide the quickest onset of action and highest response rate, they also have the highest incidence of adverse effects and intolerability issues, along with a higher risk of recurrent migraine.
- Naratriptan (Amerge, generics) and frovatriptan (Frova, generics) have a therapeutic niche for treatment of menstrual-associated migraines, but are not specifically FDA-approved for this indication.
- Sumatriptan/naproxen (Treximet) is a fixed-dose combination of a nonsteroidal anti-inflammatory drug (NSAID) with a triptan that has shown efficacy in migraine

headache versus using the individual components alone. However, using any NSAID concurrently with a triptan will likely increase efficacy.

- Overall, the class has mild to moderate adverse effects, which are usually transient. Some of the adverse effects are often unique to the delivery route. Nasal administration typically causes more pronounced nasal-related adverse effects, transdermal routes have been associated with application site reactions, and subcutaneous routes have injection-related concerns.
- The newly-approved triptans do not offer compelling clinical advantages over the older agents.
    - Sumatriptan nasal powder (Onzetra Xsail) does not have clinically or statistically significant differences in efficacy compared with oral sumatriptan and was associated with nasal discomfort.
    - The sumatriptan 3 mg autoinjector (Zembrace SymTouch) provides headache relief at two hours in 60% of patients. In contrast, the sumatriptan 4 mg and 6 mg injection (Imitrex STATdose) achieves headache relief in 57%–60% of patients.
    - The available evidence with sumatriptan transdermal system (Zecuity) suggests it may not be as effective as other triptan formulations; this product is no longer marketed.
- The triptans have a moderate to high degree of therapeutic interchangeability. Some patients will prefer one formulation over another due to their personal headache characteristics and, based on available clinical data, 40% to 50% of patients will not respond to the initial agent chosen. Overall, the majority of patients in the MHS are well served by the available formulary options.

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

- CMA results found the following, ranked from most to least cost-effective: sumatriptan tablets generic, rizatriptan tablets generic, zolmitriptan orally dissolving tablet (ODT) generic, rizatriptan ODT generic, zolmitriptan tablets generic, Relpax, naratriptan tablets (Amerge and generics), Treximet, almotriptan tablets generic, sumatriptan nasal generic, frovatriptan tablets generic, Zomig Nasal Spray, Onzetra Xsail, sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generic), Sumavel DosePro, Zembrace SymTouch, and Zecuity.

- 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. However, the most cost-effective scenario for the MHS was designating generic formulations of sumatriptan tablets, nasal spray and injection, and rizatriptan and zolmitriptan tablets and ODT, along with branded eletriptan (Relpax), as UF and step-preferred; naratriptan tablets and zolmitriptan nasal (Zomig Nasal Spray) as UF and non step-preferred; and, all

other products as NF and non step-preferred.

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

    - Oral Triptans
        - UF and step-preferred
            - eletriptan tablets (Relpax)
            - rizatriptan tablets and orally dissolving tablets (ODT) (Maxalt, Maxalt MLT, generics)
            - sumatriptan tablets (Imitrex, generics)
            - zolmitriptan tablets and ODT (Zomig, generics; Zomig-ZMT, generics)
        - UF, non step-preferred
            - naratriptan tablets (Amerge, generics)
        - NF, non step-preferred
            - almotriptan (Axert, generics)
            - frovatriptan (Frova, generics)
            - sumatriptan/naproxen tablets (Treximet)

    - Nasal Triptans
        - UF, step-preferred
            - sumatriptan nasal spray (Imitrex, generics)
        - UF, non step-preferred
            - zolmitriptan nasal spray (Zomig Nasal Spray)
        - NF, non step-preferred
            - sumatriptan nasal powder (Onzetra Xsail)

    - Injectable Triptans
        - UF, step-preferred
            - sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generics)
        - NF, non step-preferred
            - sumatriptan 4 mg and 6 mg needle-free injection (Sumavel DosePro)
            - Sumatriptan 3 mg autoinjector (Zembrace SymTouch)

    - Transdermal Triptans
        - NF, non step-preferred
            - sumatriptan transdermal system (Zecuity), if reintroduced to the market

Note that the NF triptans will be exempt from the requirement to use the Mail Order Pharmacy as the sole source of dispensing, as they fall into the "acute use" exception.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) designating the following drugs with BCF status:

    - Remain on the BCF
        - sumatriptan tablets (generic)
        - rizatriptan tablets and ODT (generic)
    - Add to the BCF
        - zolmitriptan tablets and ODT (Zomig, generic; Zomig-ZMT, generic)

    Note that as part of the BCF recommendation, generic sumatriptan 4 mg and 6 mg injection (Imitrex STATdose) will be designated as BCF when cost-effective multi-source formulations are available.

3. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) and MANUAL PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) step therapy for the triptans in new users. There are three separate step therapies for the oral triptans, injectable triptans, and nasal triptans, respectively. A step-preferred formulation of the same dosage form must be tried first, prior to the use of the NF, non step-preferred product.

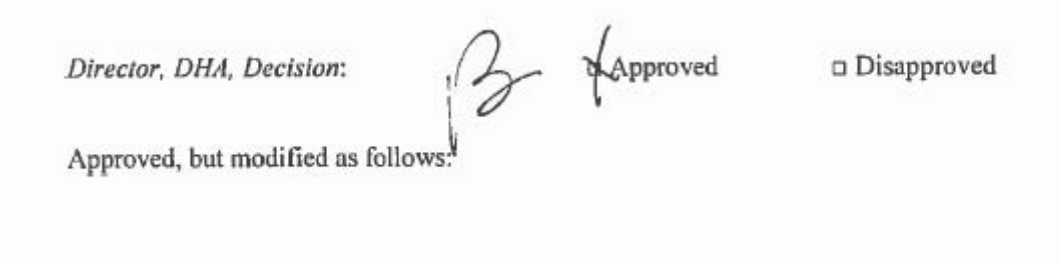
    For the oral and ODT triptans, a trial of at least two different step-preferred products (e.g., two products with differing active ingredients) is required before use of a non step-preferred product. For the nasal and injectable triptans, a trial of one generic formulation is required first. For the withdrawn transdermal system, if the product is reintroduced into the market, it will also be subject to step therapy, requiring use of at least two UF triptans, regardless of formulation, first. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for almotriptan (Amerge, generics), frovatriptan (Frova, generics), Treximet, Onzetra Xsail, Sumavel DosePro, Zembrace SymTouch, and Zecuity. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for the new triptan products Onzetra Xsail, Zembrace SymTouch, and Zecuity. The current QLs for the older triptan products will be

maintained. QLs were determined based on product packaging and FDA-labeled maximum daily dose. See Appendix D for the newly recommended QLs.

6. ***COMMITTEE ACTION: UF, and PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period; and, 2) DHA send a letter to beneficiaries currently receiving Treximet. Based on the P&T Committee's recommendation, the effective date is February 8, 2017



C. Alcohol Deterrents: Narcotic Antagonists

Background—The narcotic antagonists were reviewed for formulary placement. The products all contain naloxone as the active ingredient; their differences lie in the route of administration and delivery device—injectable versus nasal. Two new naloxone formulations approved by the FDA specifically for bystander-administration are the Evzio autoinjector and Narcan Nasal Spray. If opioid overdose is suspected, these products must be administered by someone other than the patient, including a family member or caregiver.

The formulary decision will only apply to naloxone products that are FDA-approved for use in the bystander setting, as part of the outpatient TRICARE pharmacy benefit. Use in the Military Treatment Facility (MTF) clinic setting or for MTF first responders is not affected by this formulary recommendation. Other formulations of naloxone, including the vials, ampules, pre-filled syringes, and luer lock syringes are also not affected by the formulary decision.

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

- The Evzio autoinjector and Narcan Nasal Spray are therapeutically equivalent.
- FDA approval of Evzio and Narcan Nasal Spray was via bioequivalence studies to generic naloxone administered intramuscularly (IM) or subcutaneously (SQ). Evzio has a published human factors validation (or ease of use) study, which concluded the autoinjector was easy to administer correctly with minimal training. Narcan Nasal Spray appears easy to use, based on unpublished data submitted to the FDA by the manufacturer.
- There are no trials comparing the effectiveness of Evzio and Narcan Nasal Spray in terms of onset of action or efficacy in the opioid overdose setting.

- For the Evzio autoinjector, advantages include the ease of use, provision of audio and visual administration cues, and the retractable needle, which decreases the risk of accidental exposure. Disadvantages include the short shelf life of 24 months and that patients with needle aversion may be apprehensive about using the device.
- For the Narcan Nasal Spray, advantages include the ease of use and minimal training required, the small size and portability of the device, the fact that it is a needle-free alternative to injectable naloxone, and the low volume of liquid. Disadvantages include the lack of published usability studies, the need for placing patients in the supine position for administration and then the recovery position, and the unknown effect in patients with significant nasal malformations or blockage.
- The Evzio autoinjector and Narcan Nasal Spray provide naloxone formulations that are easy to administer by bystanders to reverse opioid overdose and respiratory depression, but neither product has data showing outcomes in the real world setting or has data in patients receiving prescriptions for opioids. However, data from studies using the intranasal or IM naloxone kits in the community setting to reverse heroin overdose has shown that these products can successfully reverse opioid-induced respiratory depression.

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

- CMA results showed Narcan Nasal Spray was the most cost-effective naloxone formulation specifically approved for bystander-administration, followed by Evzio.

- BIA was performed to evaluate the potential impact of various formulary scenarios. The scenario with Narcan Nasal Spray as formulary, with the Tier 2 copayment reduced to the Tier 1 copayment in the Retail Pharmacy Network and the TRICARE Mail Order Pharmacy, and Evzio designated as NF, was a cost-effective option for the MHS.

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

    - **UF:** naloxone nasal spray (Narcan Nasal Spray)
    - **NF:** naloxone autoinjector (Evzio)

      Note that Evzio will be exempt from the requirement to use Mail Order as the sole source of dispensing, as it falls into the "acute use" exception.

    As part of the UF recommendation, the P&T Committee also recommended that the brand (Tier 2) formulary cost share of $20.00 for Narcan Nasal Spray in the TRICARE Mail Order Pharmacy and $24 in the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share of $0 in the TRICARE Mail Order Pharmacy and $10.00 in the Retail Pharmacy Network.

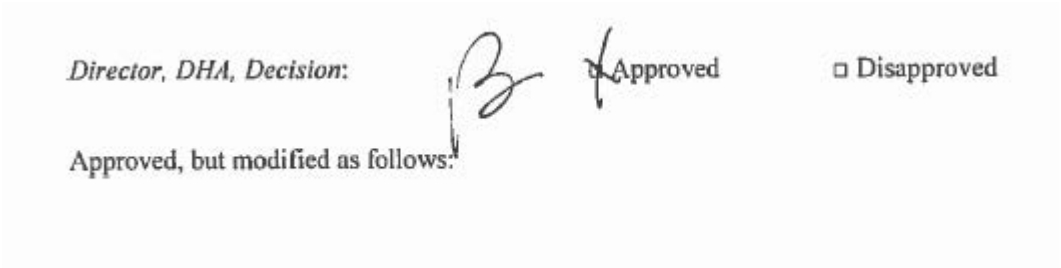
The authority for the last recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate." Lowering the cost share for the branded product Narcan Nasal Spray will provide a greater incentive for beneficiaries to use Narcan Nasal Spray, rather than the less cost-effective naloxone autoinjector (Evzio) in the purchased care setting.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) designating Narcan Nasal Spray with BCF status.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) MN criteria for Evzio, allowing use in those situations where Narcan Nasal Spray would not be appropriate (e.g., for patients with significant nasal malformations or disfiguring injuries or in cases where only a juvenile caregiver/bystander is available). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs) AND REFILL LIMITS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) QLs for Evzio of 1 carton per prescription and for Narcan Nasal Spray of 2 cartons per prescription at all three points of service (POS). Additionally, the P&T Committee also recommended that no refills be allowed for Evzio and Narcan Nasal Spray; a new prescription will be required for every fill.

5. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 60-day implementation period; and, 2) DHA send a letter to beneficiaries currently receiving Evzio. Based on the P&T Committee's recommendation, the effective date is January 11, 2017.



V. INNOVATOR DRUGS

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (16 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 August 2016 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, see Appendix E.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended the following:

   - UF (16 for, 0 opposed, 0 abstained, 1 absent):
     - Antihemophilic Agents: antihemophilic (recombinant) Factor VIII injection (Afstyla)
     - Oral Oncology Agents (Renal Cell Carcinoma): cabozantinib (Cabometyx)
     - Antiretroviral Agents: emtricitabine/tenofovir alafenamide (Descovy)
     - Miscellaneous Agents: nitisinone oral suspension (Orfadin)
     - Miscellaneous Agents: obeticholic acid (Ocaliva)
     - Hepatitis C Virus Direct Acting Agents: sofosbuvir/velpatasvir (Epclusa)
     - Oral Oncology Agents (Chronic Lymphocytic Leukemia): venetoclax (Venclexta)

   - NF (16 for, 0 opposed, 0 abstained, 1 absent):
     - Topical Corticosteroids – medium potency: betamethasone dipropionate 0.05% spray (Sernivo)
     - Anticonvulsant and Anti-Mania Agents: brivaracetam tablets and oral solution (Briviact)
     - Topical Antineoplastic and Premalignant Lesions Agents: fluorouracil 4% cream (Tolak)
     - Topical Corticosteroids – high potency: halobetasol propionate 0.05% lotion (Ultravate)
     - Non-Insulin Diabetes Drugs—DPP-4 Inhibitors: linagliptin/metformin XR tablets (Jentadueto XR), which is additionally recommended to be non step-preferred, due to existing step therapy in the class
     - Atypical Antipsychotics: pimavanserin (Nuplazid)
     - Narcotic Analgesics and Combinations: oxycodone extended-release capsules (Xtampza ER)

   - NF (10 for, 6 opposed, 0 abstained, 1 absent):
     - Iron Chelators: deferiprone oral solution (Ferriprox) due to the lack of compelling clinical advantages over other oral iron chelator

products, three times daily dosing, and the risk of agranulocytosis

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for betamethasone dipropionate 0.05% spray (Sernivo), brivaracetam tablets and oral solution (Briviact), deferiprone oral solution (Ferriprox), fluorouracil 4% cream (Tolak), halobetasol propionate 0.05% lotion (Ultravate), linagliptin/metformin XR tablets (Jentadueto XR), oxycodone extended-release capsules (Xtampza ER), and pimavanserin (Nuplazid). See Appendix B for the full criteria.

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

   - Applying the same step therapy and manual PA criteria for Jentadueto XR as is currently in place for linagliptin/metformin immediate release (IR) (Jentadueto) and the other non step-preferred dipeptidyl peptidase-4 (DPP-4) inhibitor combinations with metformin. Existing step therapy currently applies to the DPP-4 inhibitors, including Jentadueto. Patients must first use metformin or a sulfonylurea, and the preferred DPP-4 inhibitor sitagliptin before using a non step-preferred DPP-4 inhibitor. See Appendix C for the full criteria.
   - Applying manual PA criteria to the following: new users of the hepatitis C virus (HCV) direct acting antiviral agent (DAA) sofosbuvir/velpatasvir (Epclusa), the atypical antipsychotic pimavanserin (Nuplazid), the iron chelator deferiprone oral solution and oral tablet (Ferriprox), and the orphan drug obeticholic acid (Ocaliva). See Appendix C for the full criteria.

4. ***EXPANDED MTF/MAIL PHARMACY INITIATIVE (EMMPI) AND NF TO MAIL ORDER REQUIREMENT***—The P&T Committee reviewed all of the innovator drugs with respect to their status on the EMMPI program and the requirement to use the TRICARE Mail Order Pharmacy as the sole source of dispensing for NF drugs. Refer to the August 2015 DoD P&T Committee meeting minutes for additional information regarding the requirements and exceptions for these two programs, available at http://www.health.mil/PandT.

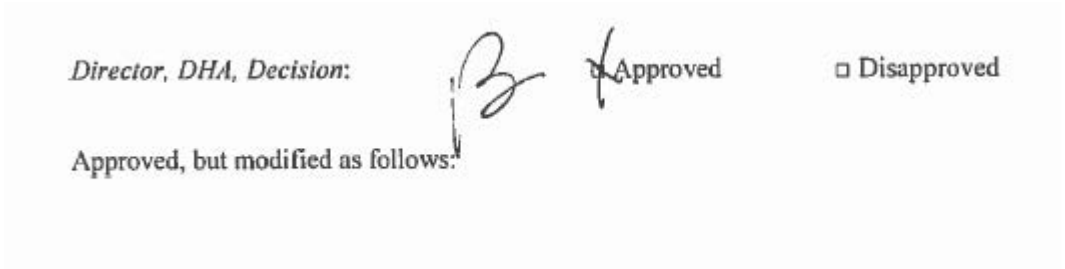
   With respect to the innovator drugs recommended for UF status, the P&T Committee noted that none fall into classes already defined as included on the EMMPI program, most have not yet been filled at mail order, and that more information is needed to determine their suitability.

   With respect to the drugs recommended for NF status, the P&T Committee commented that the previously established exceptions applied to the following: Nuplazid due to the previously established exception for the atypical antipsychotics and Xtampza ER due to the previously established exception for scheduled II medications.

The P&T Committee also recommended creating a specific exception to the requirement for the iron chelators, based on feedback from providers that these products are not appropriate candidates for the Mail Order Pharmacy because of their intermittent use and frequent need for dosage adjustments.

a) ***COMMITTEE ACTION: NF TO MAIL ORDER REQUIREMENT***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) adding deferiprone (Ferriprox) and the iron chelators drug class to the list of medications exempted from the requirement to use Mail Order as the sole point of dispensing.

5. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date upon signing of the minutes in all POS.



VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. **Analgesics and Combinations: Butalbital/Acetaminophen/Caffeine Oral Liquid (Vanatol LQ) Manual PA Criteria**—Vanatol LQ is an oral liquid formulation containing the same active ingredients as Fioricet and is approved for tension or muscle headaches.

   a) ***COMMITTEE ACTION: BUTALBITAL/ACETAMINOPHEN/CAFFEINE (VANATOL LQ) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Vanatol LQ in new and current users, due to cost disadvantages compared to generic Fioricet tablets and capsules. See Appendix C for the full criteria.

2. **Newer Sedative Hypnotics (SED-1s): Suvorexant (Belsomra) Removal of automated PA and new Manual PA Criteria**—Belsomra is a first-in-class orexin receptor antagonist indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or maintenance. The SED-1s Drug Class has automated PA criteria that require a trial of a step-preferred agent (zolpidem IR or zaleplon). Belsomra was designated as NF in August 2015, with step therapy implemented in October 2015. Removal of the automated PA criteria was recommended for Belsomra with the addition of manual PA criteria required for all new users, due to the lack of compelling clinical advantages and cost-disadvantages over the existing formulary SED-1s. Zolpidem ER (Ambien CR) and eszopiclone (Lunesta) have the same FDA

indications as Belsomra.

a) ***COMMITTEE ACTION: SUVOREXANT (BELSOMRA) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removing the automated PA criteria and establishing manual PA criteria for Belsomra in new users. Patients will be required to try zolpidem extended release and eszopiclone before using Belsomra. See Appendix C for the full criteria.

3. **Growth-Stimulating Agents (GSAs) Manual PA Criteria**—GSAs have varying indications including treatment of patients with growth hormone deficiency, Turner Syndrome, patients who are small for gestational age, and for patients with idiopathic short stature, among others. The GSAs were last reviewed in 2007, and Manual PA criteria apply. Idiopathic short stature has not been a covered indication by the MHS. Since the previous review, several agents have been discontinued and new agents approved. All newly-approved GSAs will be subject to the PA criteria, which expires after one year.

   a) ***COMMITTEE ACTION: SOMATROPIN (GSAs) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updating the manual PA criteria for GSAs in new and current users to reflect the current products on the market, and to exclude idiopathic short stature as a covered indication for all products. See Appendix C for the full criteria.

4. **Topical Pain Agents: Diclofenac Sodium 2% Topical Solution (Pennsaid) Manual PA Criteria**—Diclofenac topical solution (Pennsaid) is FDA-approved for the treatment of pain from osteoarthritis of the knee. The originally approved 1.5% branded product is now available as a generic formulation, and the branded product was changed to a 2% concentration. Pennsaid 2% offers no compelling advantages over diclofenac 1.0% gel (Voltaren) or generic 1.5% topical preparations, and was designated as a NF line extension in May 2014. Manual PA criteria were recommended for the branded Pennsaid 2% formulation.

   a) ***COMMITTEE ACTION: DICLOFENAC SODIUM 2% TOPICAL SOLUTION (PENNSAID) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for new and current users of Pennsaid 2%. Coverage of Pennsaid 2% will be approved if the patient has tried and failed generic diclofenac 1.0% gel (Voltaren generic) and generic 1.5% topical solution, and is unable to take a NSAID due to contraindications or adverse effects. See Appendix C for the full criteria.

B. QLs AND PRECRIPTION REFILL LIMITS

1. **QLs**—Quantity limits were reviewed for 10 drugs: venetoclax (Venclexta) for chronic lymphocytic leukemia (CLL), cabozantinib (Cabometyx) for advanced renal cell carcinoma (RCC), sofosbuvir/velpatasvir (Epclusa), and ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira XR) for HCV, lidocaine5% patch (Lidoderm) for pain, and for five agents approved to treat hereditary angioedema.

    a) ***COMMITTEE ACTIONS: QLs—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) QLs for Venclexta, Cabometyx, Epclusa, Viekira XR, Lidoderm, and the agents used for hereditary angioedema (Cinryze, Berinert, Ruconest, Firazyr, Kalbitor). See Appendix D for the QLs.

2. **METHYLNALTREXONE (RELISTOR) REMOVAL OF PRESCRIPTION REFILL LIMITS**—In April 2008, methylnaltrexone (Relistor) was originally FDA-approved in a vial formulation intended for treatment of opioid-induced constipation (OIC) in the palliative care setting. The package insert states that use is limited to 4 months, and in May 2009, no refills were recommended by the Committee. Since then, Relistor is now approved in a pre-filled syringe (September 2014), and oral tablets (July 2016) for OIC in patients with non-cancer pain.

    a) ***COMMITTEE ACTION: METHYLNALTREXONE (RELISTOR) VIALS REFILL LIMITS***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removing the "no refill" requirement for Relistor vials in the palliative care setting. Removing the no refill requirement ensures patients will have the same access to the vials in the palliative care setting as with the pre-filled syringes in the ambulatory care setting.

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, 3 absent—the manual PAs for butalbital/acetaminophen/caffeine oral liquid (Vanatol LQ), suvorexant (Belsomra), diclofenac sodium 2% topical solution (Pennsaid), and the somatropin GSAs 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 February 8, 2017.
    - 14 for, 0 opposed, 0 abstained, 3 absent—the QLs for venetoclax (Venclexta), cabozantinib (Cabometyx), sofosbuvir/velpatasvir (Epclusa), ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira XR), lidocaine 5% patch (Lidoderm), and agents for hereditary angioedema become effective upon signing of the minutes.

- 14 for, 0 opposed, 0 abstained, 3 absent—removing the current requirement for no refills on the Relistor 12 mg/0.6 mL vials for use in the palliative care setting become effective upon signing of the minutes.

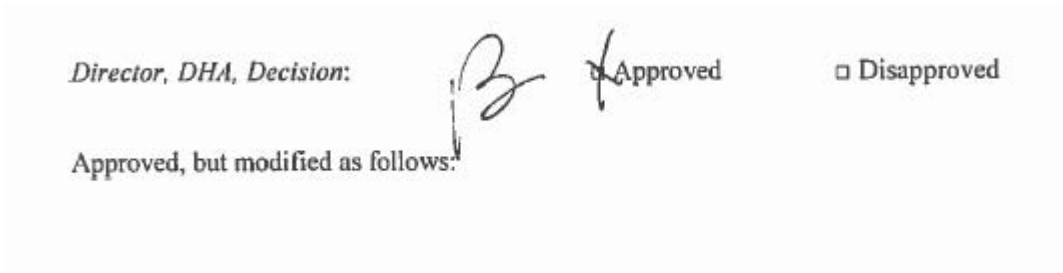
D. Utilization Management for Brand over Generic Authority and PA Criteria

1. **Mandatory Generic Substitution Policy: Removal of PA Requiring Brand over Generic Niacin ER (Niaspan)—**TRICARE policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, when AB-rated generic formulations for niacin ER (Niaspan) were launched in September 2013, pricing for the branded product was 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. Additionally, PA criteria allowing for a patient to receive generic niacin ER instead of branded Niaspan (i.e., the reverse of the current brand to generic policy) were recommended by the P&T Committee in May 2014.

   In May 2016, the P&T Committee recommended the DHA Pharmacy Operations Division (POD) be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost-effective than generic formulations. In these cases, the branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. Authority was also given to the POD to remove the "brand over generic" requirement when it is no longer cost-effective to the MHS.

   As of June 2016, the AB-rated generic formulations for niacin ER (Niaspan) are cost-effective compared to the branded Niaspan product.

   a) ***COMMITTEE ACTION: REMOVAL OF PA REQUIRING BRAND OVER GENERIC NIACIN ER (NIASPAN)***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removal of the Brand over Generic PA, and removal of the Tier 1 (generic) co-pay for branded Niaspan. Branded Niaspan will now be available at the Tier 2 (UF) co-pay in the Retail Network and Mail Order Pharmacy, and the requirement for mandatory generic substitution is re-instated.



VII. LINE EXTENSIONS

A. TARGETED IMMUNOMODULATORY BIOLOGICS (TIBs): ABATACEPT (ORENCIA CLICKJECT AUTOINJECTOR)

The TIBs were reviewed for formulary status in August 2014, and step therapy and manual PA criteria were implemented in February 2015, requiring a trial of the step-preferred TIB, adalimumab (Humira). Abatacept (Orencia) pre-filled syringes were designated as NF and non-preferred at that time. Additionally, QLs apply to the TIBs Drug Class.

A new autoinjector formulation of abatacept (Orencia ClickJect Autoinjector) was approved in June 2016. The ClickJect Autoinjector has the same FDA-approved indication (rheumatoid arthritis), and contains the same dosage (125 mg/mL) and dosing frequency (once weekly) as the pre-filled syringes.

1. ***COMMITTEE ACTION: ABATACEPT 125 mg/mL (ORENCIA CLICKJECT AUTOINJECTOR) FORMULARY STATUS CLARIFICATION, MN CRITERIA, STEP THERAPY, MANUAL PA CRITERIA, AND QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the Orencia 125 mg/mL Clickject Autoinjector follow the same formulary status, MN criteria, step therapy, and manual PA criteria that are currently in place for the Orencia pre-filled syringes, as outlined in the August 2014 DoD P&T Committee meeting minutes. Additionally, QLs were also recommended, consistent with the class. These recommendations will become effective upon signing of the minutes. See Appendix D.

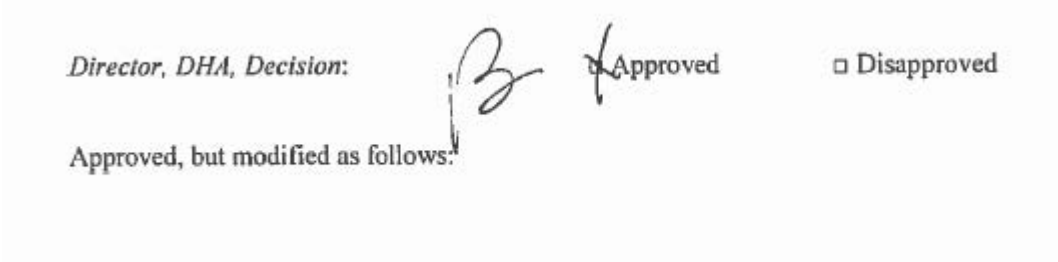
B. PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 (PCSK-9) INHIBITORS: EVOLOCUMAB PUSHTRONEX (REPATHA)

The PCSK-9 inhibitors have not yet been reviewed for UF status. Evolocumab is an innovator drug that was recommended for NF status at the November 2015 DoD P&T Committee meeting. MN criteria are currently in place. Manual PA and QLs currently apply to the PCSK-9 inhibitor drug class.

A new pre-filled cartridge formulation of evolocumab (Repatha Pushtronex) was approved in July 2016. The Pushtronex device contains evolocumab 420 mg/3.5 mL, which adheres to the skin and is subcutaneously infused over a period of 9 minutes and administered once monthly. The Pushtronix device is only approved for homozygous familial hypercholesterolemia (HoFH). For patients with HoFH, Repatha is also available in pre-filled syringes and single-use prefilled autoinjectors containing140 mg. A dosage of 420 mg/month can be obtained by administering three of the 140 mg injections consecutively with 30 minutes. The Pushtronex device allows for administration of the entire dosage in a single injection.

1. ***COMMITTEE ACTION: REPATHA 420 mg/3.5 mL PUSHTRONEX FORMULARY STATUS CLARIFICATION, MN CRITERIA, MANUAL PA CRITERIA, AND QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the Repatha 420 mg/3.5 mL Pushtronex formulation follow the

same formulary status, MN criteria, and manual PA criteria that are currently in place for the Repatha 140 mg single-use pre-filled syringes and autoinjectors, as outlined in the November 2015 DoD P&T Committee meeting minutes. Additionally, QLs were also recommended, consistent with the class. These recommendations will become effective upon signing of the minutes. See Appendix D.



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

The P&T Committee reviewed three 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, 3 absent) the following products be designated NF on the UF:

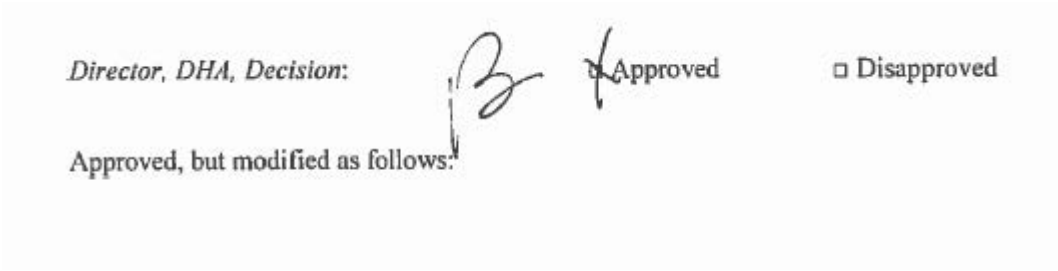
- Veloxis Pharma: tacrolimus ER (Envarsus XR) 1 mg and 4 mg oral tablets
- Lachlan Pharma: benzyl alcohol (Ulesfia) 5% topical lotion
- Mist Pharma: propranolol ER (Inderal XL) 80 mg and 120 mg oral capsules

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following pre-authorization criteria for Envarsus XR, Ulesfia, and Inderal XL:

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.

C. *COMMITTEE ACTION: IMPLEMENTATION PERIOD*—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Envarsus XR, Ulesfia, and Inderal XL; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is February 8, 2017.



IX. OVER-THE-COUNTER (OTC) DRUG BENEFIT: STATUS OF SECOND GENERATION ANTIHISTAMINES

The Deployment Prescription Program requested that the DoD P&T Committee consider adding fexofenadine (generic Allegra) to the UF as part of the OTC pharmacy benefit, which would make it available by mail to deployed Service members in theater.

The final rule implementing the legislative authority for the OTC Drug Program was published on July 27, 2015, and is found at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy. The OTC medications currently on the UF include omeprazole, loratadine, loratadine/pseudoephedrine, cetirizine, cetirizine/pseudoephedrine, levonorgestrel 1.5 mg (Plan B One-Step and its generics), and doxylamine 25 mg.

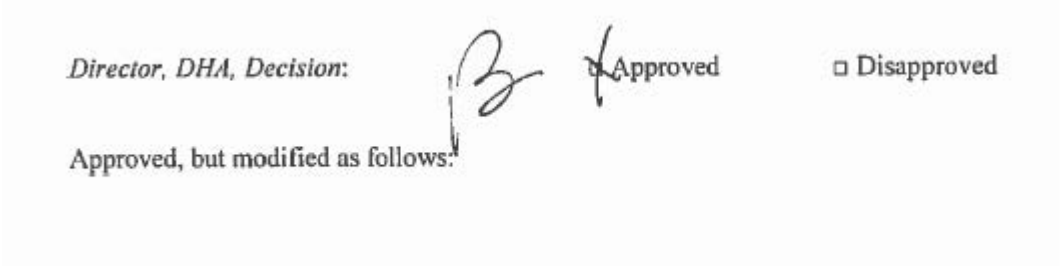
The P&T Committee reviewed the status of the second generation antihistamines on the various Aerospace Medicine lists of medications approved for use by U.S. Air Force, U.S. Army, U.S. Navy, and U.S. Coast Guard flyers. All of the lists include loratadine and all, except for the U.S. Army, list include fexofenadine. Cetirizine is not included on any of the lists since it is more likely to cause sedation than loratadine or fexofenadine.

Generic cetirizine OTC and generic loratadine OTC were the least costly second generation antihistamines, followed by generic fexofenadine OTC, levocetirizine (generic Xyzal), and desloratadine (generic Clarinex). The costs of combination products with pseudoephedrine ranged from 5 to 18 times higher than, and were used less frequently than, their respective single ingredient products. The P&T Committee also noted cetirizine/pseudoephedrine has not been available through the Mail Order POS over the last few months due to the lack of a Trade Agreements Act (TAA) compliant generic product.

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

- adding OTC fexofenadine to the UF
- removing OTC cetirizine/pseudoephedrine from the UF

- removing OTC loratadine/pseudoephedrine from the UF



X. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EMMPI): PROPROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 (PCSK-9) INHIBITORS

Two PCSK-9 inhibitors are currently available: alirocumab (Praluent), which is on the UF, and evolocumab (Repatha), which became available after the innovator program went into effect on August 25 2015, and is currently designated NF. The two products have relatively similar FDA approved indications. Both drugs are maintenance medications that are predominantly being filled at mail order. The P&T Committee agreed with adding the PCSK-9 inhibitors, as a subclass under the Antilipidemics-1 Class, to the EMMPI program.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following, effective upon signing of the minutes:
    - Adding the PCSK-9 inhibitors to the EMMPI list, and
    - Modifying the existing class definition for the Antilipidemics-1 class to include the PCSK-9 inhibitors (First Data Bank GC3 class M4T) and direct that: "Branded, legend products in GC3s M4D, M4E, M4I, M4L, M4M, or M4T that are intended for chronic use be added to the EMMPI list (note that M4E overlaps with Antilipidemics-2 [fenofibrates, fibric acid, omega-3 fatty acids])," allowing for automatic placement of future marketed PCSK-9 inhibitors products on the EMMPI program

XI. RE-EVALUATION OF GENERICALLY AVAILABLE NF AGENTS

The P&T Committee continued the process of implementing the requirement that NF pharmaceutical agents generally be unavailable at MTFs or the Retail Network, but available in the Mail Order program. (See DoD P&T Committee meeting minutes from

August 2015 and May 2016.) Implementation of the mail order requirement for generically available NF agents was temporarily deferred to allow for review of the continued necessity for NF (Tier 3) status, given price decreases typically associated with generic availability.

The P&T Committee reviewed the current utilization, formulary status, generic availability, comparative clinical effectiveness, and relative cost effectiveness, including the weighted average cost per unit, for all generically available NF agents in eight previously reviewed UF drug classes. Utilization trends by POS found limited dispensing of the NF generic products, compared to the UF products in the respective classes.

Clinical Effectiveness Conclusion and Cost-Effectiveness Conclusion—The P&T Committee concluded that for all eight drug classes, there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusion from when the class was originally reviewed for UF placement. The Committee also concluded that the costs of all the NF generic products were significantly higher than the currently available UF products, with two exceptions: generic calcitonin-salmon nasal spray and diclofenac 1.5% topical solution were comparable in price to the UF products in their respective classes. Specific comments are below:

- *Second Generation Antihistamines: Levocetirizine (Xyzal) and Desloratadine (Clarinex)*—Levocetirizine and desloratadine continue to offer no significant, therapeutically meaningful advantage over other similar agents on the UF (loratadine, cetirizine, and fexofenadine).
- *Osteoporosis/Oral Bisphosphonates and Calcitonin: Risedronate (Actonel, Atelvia), Calcitonin-Salmon Nasal Spray (Miacalcin)*
    - The oral bisphosphonates are highly therapeutically interchangeable, and there are no compelling advantages to the delayed release formulation of weekly risedronate (Atelvia). New safety data for the bisphosphonates (osteonecrosis of the jaw, esophageal cancer, atrial fibrillation, and atypical femur fractures), has led to an overall decline in use.
    - There is currently step therapy for the bisphosphonates, with alendronate (generic Fosamax) designated as step-preferred. Generic formulations of ibandronate 150 mg monthly (-) are now available. The P&T Committee noted that generic ibandronate 150 mg is newly available to MTFs and through mail order at substantially decreased cost under a Joint National Contract.
    - Calcitonin nasal spray is considered a third line and/or niche agent in clinical practice guidelines. The cost per 28 days for calcitonin nasal spray was similar for recombinant calcitonin (Fortical) and for generic calcitonin-salmon (generic Miacalcin).
- *Non-Insulin Diabetes Mellitus Drugs/Biguanides: Metformin ER (Fortamet, Glumetza)*—There is no evidence to suggest that differences in the ER formulations of Glumetza and Fortamet confer clinically relevant benefits in

efficacy or safety when compared to generic metformin IR or ER preparations (Glucophage, Glucophage XR, generic).

- *Selective Serotonin Reuptake Inhibitors (SSRIs): Fluoxetine 90 mg Delayed Release (Prozac Weekly) and Products for Premenstrual Dysphoric Disorder (PMDD) (Sarafem)*—Neither the special packaging for PMDD (Sarafem) nor a higher dosing strength for weekly administration (Prozac Weekly) offer significant clinical advantages compared to generic Prozac. Brand Sarafem is now available as tablets instead of capsules; the availability of generics for the tablets is unclear at this time, based on the FDA website.
- *Benign Prostatic Hypertrophy (BPH) Medications/5-Alpha Reductase Inhibitors (ARIs): Dutasteride (Avodart), Dutasteride/Tamsulosin (Jalyn)*—Finasteride (Proscar, generic) and dutasteride are highly therapeutically interchangeable for the treatment of BPH, and the combination product dutasteride/tamsulosin offers no additional benefit compared to the individual components. There is existing step therapy in the class.
- *Alzheimer's Medications: Donepezil 23 mg (Aricept 23 mg)*—Donepezil 23 mg shows statistical improvement in cognition but not global functioning, and tolerability is likely limited by increased adverse effects, compared to donepezil 10 mg.
- *Antilipidemics-1/Statins and Combos: Fluvastatin ER 80 mg (Lescol XR)* Lescol XR remains a moderate low-density lipoprotein (LDL) lowering statin, with LDL-lowering capacity ranging between 30% to <50%. Eight other statins fall into the moderate LDL-lowering category. Step therapy also exists in this class; a trial of a generic step-preferred statin with similar LDL-lowering capacity is required first.
- *Topical Pain Agents: Diclofenac 1.5% Topical Solution (Pennsaid 1.5% Drops)* Topical diclofenac (including the topical solution and gel) was effective for managing superficial pain (e.g., osteoarthritis, sprain, strain, contusions). Gastro-intestinal adverse events were lower with topical therapy compared to oral NSAIDs. Brand Pennsaid is now available as a diclofenac 2% topical solution, with only generic versions of the 1.5% formulation remaining on the market. (See UM section VI on page 16 for information on the PA criteria). Weighted average cost per day for generic diclofenac 1.5% topical solution is comparable to the weighted average cost per day for generic lidocaine 5% patch, providing another alternative in this class both overall and specifically as an alternative to Pennsaid 2% topical solution, which is far more costly.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended the following (16 for, 0 opposed, 0 abstained, 1 absent), effective upon signing of the minutes:
    - The following products will remain NF, with both brand and generics subjected to mail order requirements:

- Second Generation Antihistamines: levocetirizine (Xyzal, generics) and desloratadine (Clarinex, generics)
- Osteoporosis/Oral Bisphosphonates and Calcitonin: risedronate (Atelvia, Actonel, and their generics); these products will remain as non step-preferred
- Non-Insulin Diabetes Mellitus Drugs/Biguanides: metformin ER (Fortamet, Glumetza, and their generics)
- Selective Serotonin Reuptake Inhibitors: fluoxetine 90 mg (Prozac Weekly); generic Sarafem caps; Sarafem tabs
- BPH Medications/5-ARIs: dutasteride (Avodart, generics); dutasteride/tamsulosin (Jalyn, generics); these products will remain as non step-preferred
- Alzheimer's Medications: donepezil 23 mg (Aricept, generics)
- Antilipidemics/Statins and Combos: fluvastatin ER (Lescol XL, generics); will remain non step-preferred

- Return to UF status
  - Osteoporosis/Oral Bisphosphonates and Calcitonin: calcitonin-salmon nasal spray (brand Miacalcin and generics)
  - Topical Pain Agents: diclofenac 1.5% topical solution (generic Pennsaid 1.5%)

- Automated PA (step therapy) Changes
  - Osteoporosis Agents/Oral Bisphosphonates: designate ibandronate 150 mg monthly (Boniva, generics) as step-preferred. Patients must now try either step-preferred alendronate formulations or ibandronate prior to use of Actonel, Atelvia, Binosto, and Fosamax Plus D

    The automated and manual PA criteria for the oral bisphosphonates will now state: "The patient has filled a prescription for alendronate or ibandronate at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days." Manual PA criteria requirements (if the automated PA criteria were not met) for ibandronate will also be removed, effective upon signing of the minutes. See Appendix C.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

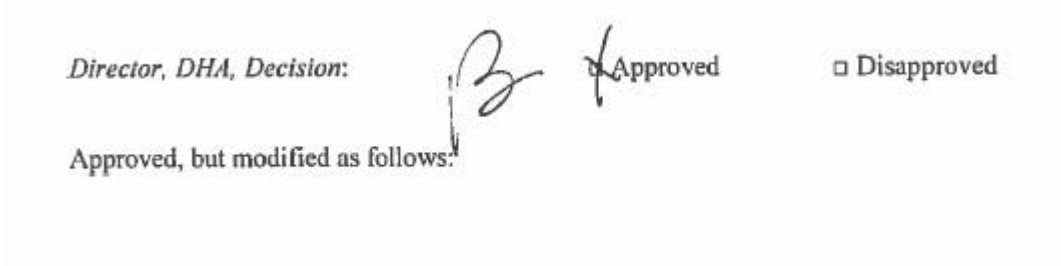
Approved, but modified as follows:

XII. Opiate Safety Edit Review: Comparison to Commercial Standard

The opiate safety edit is an automated medication profile review that warns pharmacies when it detects that an opiate naïve patient is prescribed a high potency opiate. The program has been in place in the MHS since August 2007. Additions to the targeted opioids are currently updated manually by the POD Formulary Management Branch when new products enter the market.

In May 2016, the current DoD and Express Scripts commercial program were compared, and included an evaluation of the medications currently subject to the safety edit, medication daily dose limits, technical parameters to operationalize the edit, and the resulting volume of warnings generated to the dispensing pharmacists. The opiate safety edit program Express Scripts currently offers to their commercial clients was found to be acceptable for DoD use. However, unique aspects of DoD's current program, including such things as a look back period of 60 days (rather than 180 days with Express Scripts) and the alert messaging to the pharmacist (the pharmacist must confirm the patient is opioid tolerant, if there is no documented use of a high potency opioid in the prior 60 days) should be maintained.

1. ***COMMITTEE ACTION: ADOPTION OF COMMERCIAL STANDARD***
   The P&T Committee recommended (13 for, 0 opposed, 1 abstained, and 3 absent) DoD follow the Express Scripts commercial opiate safety edit for the historical qualifying drug list (Step 1) and the inbound drug list (Step 2). Unique aspects of DoD's current program will remain unchanged.



XIII. ITEMS FOR INFORMATION

A. Joint Deployment Formulary (JDF) Review

The P&T Committee reviewed the approximately 700 pharmaceutical line items on the JDF and found no significant conflict with items designated as NF (Tier 3) on the UF. In addition, Pharmacy Data Transaction Service theater data for calendar year 2015 showed minimal use of NF (Tier 3) drugs. The P&T Committee concluded that use of medications in theater was consistent with Uniform Formulary NF designations.

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—MTF Request for Liraglutide (Victoza) to be Added to the UF

The P&T Committee reviewed an MTF request to add liraglutide (Victoza) to the UF. Currently, Victoza is NF and non step-preferred. The GLP1RAs subclass was reviewed in August 2015 and exenatide once weekly (Bydureon) and albiglutide once weekly

(Tanzeum) were designated UF and step-preferred. Patients must first try both Bydureon and Tanzeum prior to use of the NF and non-preferred agents Victoza, dulaglutide (Trulicity), and exenatide twice daily (Byetta).

Based on the comparative clinical and cost-effectiveness analyses previously reviewed, and the information submitted by the requesting MTF (including results of a newly published outcomes trial with Victoza – *LEADER)*, there was a consensus among the DoD P&T Committee members that no formulary status change is recommended at this time. The GLP1RA subclass is expected to be re-reviewed in the next 12-24 months when results from additional cardiovascular outcomes trials are completed with the other products, additional single agents are approved, and combinations with insulin are available.

XIV. ADJOURNMENT

The meeting adjourned at 1215 hours on August 11, 2016. The next meeting will be in November 2016.

Appendix A—Attendance: August 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—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary
Appendix G—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.

R.C. Bono
VADM, MC, USN
Director

16 1108
Date

Appendix A—Attendance: August 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 William Hannah, MC (Aug 11)	Air Force, Internal Medicine Physician
Maj Jeffrey Colburn, MC for Col William Hannah, MC (Aug 10)	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Karl Kronmann, MC for CDR Brian King, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
LCDR Richard Koch, MC for CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ Dausen Harker, MC	Army, Family Practice Physician
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
LTC Kevin Ridderhoff, MSC for COL John Spain, MSC	Army, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
Doreen Lounsbery COL (Ret.), MC, USA for 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
Nonvoting Members Present	
Mr. David Hurt	DHA, Office of General Counsel
Guests	
MAJ Randall Sweeney	Defense Logistics Agency Troop Support
MAJ Norman Tuala	Defense Logistics Agency Troop Support
CAPT Matt Baker	Indian Health Service
CDR Paul Michaud	U.S. Coast Guard

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
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
David Meade, PharmD via DCS	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via DCS	DHA Integrated Utilization Branch
Robert Conrad, PharmD via DCS	DHA Operations Management Branch
Ms. Melanie Richardson via DCS	DHA Operations Management Branch
LCDR David Sohl, MSC	DHA Purchased Care Branch
LT Teisha Robertson via DCS	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
▪ clindamycin 1% kits (Clindacin ETZ; Clindacin PAC) ▪ clindamycin 1% gel (Clindagel) ▪ clindamycin/benzoyl peroxide 1.2% - 3.75% gel (Onexton) ▪ clindamycin/benzoyl peroxide 1.2% - 5% gel/cream kit (Neuac Kit) **Topical Acne and Rosacea Agents: Topical Antibiotics and Combinations**	• Patient has tried and failed or experienced significant adverse effects from at least three formulary agents, including a clindamycin/benzoyl peroxide combination **Formulary Alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and sulfacetamide sodium/sulfur lotion
▪ adapalene/benzoyl peroxide 0.1% - 2.5% gel (Epiduo) ▪ adapalene/benzoyl peroxide 0.3% - 2.5% gel (Epiduo Forte) ▪ clindamycin/tretinoin 1.2% - 0.025% gel (Veltin; Ziana, generics) ▪ tretinoin microsphere 0.04%, 0.08% and 0.1% gel (Retin-A Micro, generics; Retin-A Micro Pump, generics) ▪ tazarotene 0.1% foam (Fabior) **Topical Acne and Rosacea Agents: Topical Retinoids and Combinations**	• Patient has tried and failed or experienced significant adverse effects from at least three formulary agents, including a clindamycin/benzoyl peroxide combination • No alternative formulary agents: ▪ Veltin and Ziana: Patient requires combination clindamycin/tretinoin 1.2% - 0.025% strength **Formulary Alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and sulfacetamide sodium/sulfur lotion
▪ dapsone 5% and 7.5% gel (Aczone) **Topical Acne and Rosacea Agents: Topical Dapsone Products**	• Patient is an adult female with inflammatory acne who has tried AND failed or experienced significant adverse effects from at least three formulary agents, including combination therapy with clindamycin and benzoyl peroxide **Formulary Alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and sulfacetamide sodium/sulfur lotion
▪ metronidazole 1% cream (Noritate) ▪ metronidazole 0.75% cream/ cleanser kit (Rosadan Cream Kit) ▪ metronidazole 0.75% gel/ cleanser kit (Rosadan Gel Kit) **Topical Acne and Rosacea Agents: Topical Metronidazole Products**	• Patient has tried and failed or experienced significant adverse effects from formulary topical metronidazole or azelaic acid **Formulary Alternatives:** metronidazole (1% gel; 0.75% lotion and 0.75% cream) and azelaic acid
▪ brimonidine tartrate 0.33% gel (Mirvaso) ▪ ivermectin 1% cream (Soolantra) **Topical Acne and Rosacea Agents: Miscellaneous Topical Agents**	• Use of preferred formulary agents is contraindicated • Patient has tried and failed metronidazole and azelaic acid • Patient has experienced significant adverse effects from metronidazole and azelaic acid • No formulary alternative ▪ Mirvaso: Patient has non-transient, persistent facial erythema of rosacea ▪ Soolantra: Patient has inflammatory lesions (papulopustular) of rosacea caused by Demodex mites **Formulary Alternatives:** metronidazole (metronidazole (1% gel; 0.75% lotion and 0.75% cream) and azelaic acid

Drug / Drug Class	Medical Necessity Criteria
▪ frovatriptan (Frova, generics) ▪ almotriptan (Axert, generics) ▪ sumatriptan/naproxen (Treximet) **Migraine Agents: Oral Triptans**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • The patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** rizatriptan (Maxalt, Maxalt MLT, generics), sumatriptan (Imitrex, generics), zolmitriptan (Zomig, Zomig ZMT, generics), eletriptan (Relpax), naratriptan (Amerge)
▪ sumatriptan 4 mg and 6 mg needle-free injection (Sumavel DosePro) ▪ sumatriptan 3 mg autoinjector (Zembrace SymTouch) **Migraine Agents: Injectable Triptans**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • The patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generics)
▪ sumatriptan nasal powder (Onzetra Xsail) **Migraine Agents: Nasal Triptans**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • The patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** sumatriptan nasal spray (Imitrex, generics), zolmitriptan nasal (Zomig Nasal Spray)
▪ sumatriptan transdermal (Zecuity) **Migraine Agents: Transdermal Triptans**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • The patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** any step-preferred oral, injectable, or nasal triptan
▪ naloxone autoinjector (Evzio) **Narcotic Antagonists Subclass**	• There is no formulary alternative. ▪ Patient caregiver is unable to administer Narcan Nasal Spray due to the following reason: _____ (the reason must be documented on the PA form; an acceptable reason is that the bystander/caregiver is a juvenile ▪ Patient has a nasal malformation/disfiguring injury that precludes use of Narcan Nasal Spray **Formulary Alternative:** naloxone nasal spray (Narcan Nasal Spray)
▪ pimavanserin (Nuplazid) **Atypical Antipsychotic**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • The patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** quetiapine IR, quetiapine ER, clozapine

Drug / Drug Class	Medical Necessity Criteria
▪ fluorouracil 4% cream (Tolak) **Topical Antineoplastic & Premalignant Lesions Agents**	• Formulary alternatives have resulted in therapeutic failure **Formulary Alternatives:** fluorouracil 5% cream (Efudex, generic)
▪ linagliptin/metformin XR (Jentadueto XR) **Non-Insulin Diabetes Mellitus: DPP-4 Inhibitors**	• The patient cannot take generic metformin XR and Tradjenta separately or Jentadueto IR **Formulary Alternatives:** Jentadueto IR, Tradjenta, Januvia, Janumet, Janumet XR
▪ halobetasol propionate 0.05% lotion (Ultravate) **High Potency Topical Corticosteroid**	• The use of ALL formulary alternatives is contraindicated • ALL formulary alternatives have resulted in therapeutic failure **Formulary Alternatives:** Topical clobetasol (Clobex, Olux, Temovate, generics), halobetasol (Halonate, generics), flurandrenolide (Cordran tape), desoximetasone (Topicort, generics), fluocinonide (non-Vanos products), betamethasone dipropionate augmented (Diprolene/-AF, generics)
▪ betamethasone dipropionate 0.05% spray (Sernivo) **Medium Potency Topical Corticosteroid**	• The use of ALL formulary alternatives is contraindicated • ALL formulary alternatives have resulted in therapeutic failure **Formulary Alternatives:** medium and high potency topical corticosteroids (See existing MN form for the actual formulary products)
▪ brivaracetam (Briviact) **Anticonvulsant and Anti-Mania Agents**	• The patient has experienced significant adverse effects from the formulary alternatives **Formulary Alternatives**: levetiracetam IR (Keppra, generics), levetiracetam ER (Keppra XR)
▪ oxycodone (Xtampza ER) **Narcotic Analgesics: Long-Acting High Potency Narcotic Analgesics**	• Patient has had therapeutic failure of at last two formulary long acting narcotic analgesics. • No alternative formulary agent due to swallowing difficulties or dysphagia **Formulary Alternatives:** oxycodone controlled release (Oxycontin, generic), and other long acting narcotic analgesics including fentanyl transdermal system (Duragesic, generics), morphine sulfate sustained release (MS Contin, generics)
▪ deferiprone oral solution (Ferriprox) **Iron Chelators**	• The patient has experienced significant adverse effects from the formulary alternatives **Formulary Alternatives:** deferiprone tablet (Ferriprox), deferasirox oral tablet for dispersion (Exjade), deferasirox tablet (Jadenu)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• benzoyl peroxide 4% to 10% gel, foam, cleanser, towelette, kit (Benzac, Benzac Wash, BenzEFoam, BenzEFoam Ultra, BenzePrO, Benzoyl Peroxide, BP Foam, BPO, BP Wash, Brevoxyl, Brevoxyl-4, Brevoxyl-8, Desquam E, Desquam X, Inova, NuOx, PanOxyl, Panoxyl-10, PR Benzoyl Peroxide, Riax, Sulfoxyl Regular, SE BPO, Vanoxide-HC) **Topical Acne and Rosacea Agents: Legend Benzoyl Peroxide Products**	PA applies to both new and current users of legend benzoyl peroxide products. Manual PA Criteria: • Patient has a diagnosis of acne vulgaris, AND o Patient has failed over-the-counter benzoyl peroxide formulations (e.g., washes, gels, cleansers, lotions), OR o Patient has tried and failed at least 2 step-preferred topical acne agents (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur). • PA expires in six months.
• clindamycin 1% kits (Clindacin ETZ; Clindacin PAC) • clindamycin 1% gel (Clindagel) • clindamycin/benzoyl peroxide 1.2% - 3.75% gel (Onexton) • clindamycin/benzoyl peroxide 1.2% - 5% gel/cream kit (Neuac Kit) • clindamycin/benzoyl peroxide 1.2% - 2.5% gel (Acanya) **Topical Acne and Rosacea Agents: Topical Antibiotics and Combinations**	All new and current users of Clindacin ETZ, Clindacin PAC, Clindagel, Onexton, Neuac Kit, and Acanya are required to try three step-preferred topical generic acne products first. Automated PA Criteria: • The patient has filled a prescription for at least three step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene, or sulfacetamide sodium/sulfur) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. Manual PA Criteria: If automated PA criteria are not met, Clindacin ETZ, Clindacin PAC, Clindagel, Onexton, Neuac Kit, or Acanya will be approved if: • The patient has a diagnosis of acne vulgaris AND • Patient has tried and failed or experienced adverse effects to at least three step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide products. PA expires in 365 days.
• adapalene/benzoyl peroxide 0.1% - 2.5% gel (Epiduo) • adapalene/benzoyl peroxide 0.3% - 2.5% gel (Epiduo Forte) • clindamycin/tretinoin 1.2% - 0.025% gel (Veltin; Ziana, generics) • tretinoin microsphere 0.04%, 0.08%, and 0.1% gel (Retin-A Micro, generics; Retin-A Micro Pump, generics) • tazarotene 0.1% foam (Fabior)	All new and current users of Epiduo, Epiduo Forte, Veltin, Ziana, Retin-A Micro, Retin-A Micro Pump, Fabior, and generics are required to try three step-preferred topical generic acne products, including at least two different strengths of tretinoin. Automated PA Criteria: • The patient has filled a prescription for at least three step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, adapalene, or sulfacetamide sodium/sulfur), including at least two different strengths of tretinoin, at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days. Manual PA Criteria: If automated PA criteria are not met, the non step-preferred product will be approved if: • The patient has a diagnosis of acne vulgaris AND • Patient has tried and failed at least three step-preferred topical generic acne products, including at least two different strengths of tretinoin (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene, or sulfacetamide sodium/sulfur) OR

Drug / Drug Class	Prior Authorization Criteria
Topical Acne and Rosacea Agents: Topical Retinoids and Combinations	• The patient has experienced an adverse reaction/inadequate response with formulary step-preferred topical tretinoin agents that is not expected to occur with the non-preferred product, OR • There is no other formulary agent alternative o For Epiduo, Epiduo Forte: The patient requires a combination topical adapalene/benzoyl peroxide o For Veltin or Ziana: The patient requires this particular strength of combination topical tretinoin 0.025%/clindamycin 1.2% PA expires in 365 days.
• azelaic acid 20% cream (Azelex) • azelaic acid 15% gel, foam, kit (Finacea) **Topical Acne and Rosacea Agents: Topical Azelaic Acid Products**	All new and current users of Azelex and Finacea are required to try three step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene, or sulfacetamide sodium/sulfur) or metronidazole). <u>Automated PA Criteria:</u> • The patient has filled a prescription for at least three step-preferred topical generic products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene, or sulfacetamide sodium/sulfur) at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days. <u>Manual PA Criteria:</u> If automated PA criteria are not met, Azelex or Finacea will be approved if: • For Azelex: The patient has a diagnosis of acne vulgaris or rosacea AND o Patient is pregnant, OR o Patient has tried and failed at least three preferred formulary topical acne agents, including combination therapy with clindamycin and benzoyl peroxide • For Finacea: Patient is pregnant, OR o Patient has tried and failed, or cannot tolerate a step-preferred topical generic metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) PA expires in 365 days.
• dapsone 5% gel (Aczone) • dapsone 7.5% gel (Aczone) **Topical Acne and Rosacea Agents: Topical Dapsone Products**	All new and current users of Aczone are required to try three step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide. <u>Automated PA Criteria:</u> • The patient has filled a prescription for at least three step-preferred topical generic acne products (generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene or sulfacetamide sodium/sulfur) at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days. <u>Manual PA Criteria</u>: If automated PA criteria are not met Aczone will be approved if: • The patient has a diagnosis of acne vulgaris, AND o Patient is an adult female with a diagnosis of inflammatory acne, AND o The patient has tried and failed at least three step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide. PA expires in 365 days.

Drug / Drug Class	Prior Authorization Criteria
• metronidazole 1% cream (Noritate) • metronidazole 0.75% cream/ cleanser kit (Rosadan Cream Kit) • metronidazole 0.75% gel/ cleanser kit (Rosadan Gel Kit) **Topical Acne and Rosacea Agents: Topical Metronidazole Products**	All new and current users of Noritate and Rosadan are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream). Automated PA Criteria: • The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days. Manual PA Criteria: If automated PA criteria are not met, Noritate or Rosadan will be approved if: • The patient has a diagnosis of rosacea, AND • The patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream). PA expires in 365 days.
• brimonidine tartrate 0.33% gel (Mirvaso) • ivermectin 1% cream (Soolantra) **Topical Acne and Rosacea Agents: Miscellaneous Topical Agents**	All new and current users of Mirvaso and Soolantra are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream). Automated PA Criteria: • The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days. Manual PA Criteria: If automated PA criteria are not met, Mirvaso or Soolantra will be approved if: • Patient is at least 18 years of age and has the following diagnosis: o For Mirvaso: Patient has non-transient, persistent facial erythema of rosacea o For Soolantra: Patient has inflammatory lesions (papulopustular) of rosacea caused by Demodex mites **AND** o Patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream). **AND** o Patient has tried and failed topical azelaic acid. PA expires in 365 days.
• naratriptan tablets (Amerge, generic) • almotriptan tablets (Axert, generics) • frovatriptan tablets (Frova, generics) • sumatriptan/naproxen tablets (Treximet) **Migraine Agents: Oral Triptan Subclass**	All new users of naratriptan (Amerge, generics), almotriptan (Axert, generics), frovatriptan (Frova generics), and sumatriptan/naproxen (Treximet) tablets are required to try two different step-preferred generic oral tablets or ODT triptan formulations or Relpax tablets first (e.g., two products with differing active ingredients/chemical entities). Step-preferred oral and ODT triptan formulations include sumatriptan, rizatriptan, zolmitriptan, and Relpax. Automated PA Criteria: • The patient has filled a prescription for at least two different step-preferred oral/ODT triptans with different active ingredients at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order pharmacy) during the previous 365 days. Manual PA Criteria: If automated PA criteria are not met, naratriptan, almotriptan, frovatriptan, or Treximet will be approved if: • The patient has experienced an adverse reaction, has had an inadequate response, to, or has a medical contraindication to two different (e.g., two different chemical entities) step-preferred oral/ODT triptan formulations of Relpax,

Drug / Drug Class	Prior Authorization Criteria
	rizatriptan, sumatriptan, or zolmitriptan) that is not expected to occur with the non step-preferred product (naratriptan, almotriptan, frovatriptan, or Treximet). Prior Authorization does not expire.
• zolmitriptan (Zomig Nasal Spray) • sumatriptan nasal powder (Onzetra Xsail) **Migraine Agents: Nasal Triptan Subclass**	All new users of zolmitriptan nasal spray (Zomig Nasal Spray) or sumatriptan nasal powder (Onzetra Xsail) are required to try generic sumatriptan nasal spray first. Automated PA Criteria: • The patient has filled a prescription for generic sumatriptan nasal spray at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days. Manual PA Criteria: If automated PA criteria are not met, Zomig Nasal Spray or Onzetra Xsail will be approved if: • The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to generic sumatriptan nasal spray that is not expected to occur with the non step-preferred product (Zomig Nasal Spray or Onzetra Xsail). Prior Authorization does not expire.
• sumatriptan 4 mg/6 mg needle-free injection (Sumavel DosePro) • sumatriptan 3 mg autoinjector (Zembrace SymTouch) **Migraine Agents: Injectable Triptan Subclass**	All new users of sumatriptan 4 mg/6 mg needle-free injection (Sumavel DosePro), or sumatriptan 3 mg autoinjector (Zembrace SymTouch) are required to try sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) first. Automated PA Criteria: • The patient has filled a prescription for sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days. Manual PA Criteria: If automated PA criteria are not met, Sumavel DosePro or Zembrace SymTouch will be approved if: • The patient has experienced an adverse reaction, has had an inadequate response, to, or has a medical contraindication to sumatriptan injection 4 mg/6 mg (Imitrex STATdose, generics) that is not expected to occur with the non step-preferred product (Sumavel DosePro or Zembrace SymTouch). Prior Authorization does not expire.
• sumatriptan transdermal system (Zecuity) **Migraine Agents: Transdermal Triptan Subclass**	All users of sumatriptan transdermal (Zecuity), if it is reintroduced to the market, are required to try two different step-preferred triptans with different active ingredients, regardless of dosage formulation first. Automated PA Criteria: • The patient has filled a prescription for at least two different step-preferred triptans with different active ingredients, regardless of dosage formulation, at any MHS pharmacy point of service (MTFs, retail network pharmacies, or the TRICARE Mail Order Pharmacy) during the previous 365 days. Manual PA Criteria: If automated PA criteria are not met, Zecuity will be approved if: • The patient has experienced an adverse reaction, has had an inadequate response to, or has a medical contraindication to two different step-preferred triptans with different active ingredients, regardless of dosage formulation, that is not expected to occur with Zecuity. Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• pimavanserin (Nuplazid) **Atypical Antipsychotics (AAPs)**	Manual PA criteria apply to all new users of pimavanserin. Manual PA Criteria: Nuplazid is approved if all of the following criteria are met: 1. Patient is age ≥ 18 AND 2. Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis AND 3. Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin AND 4. Mini-Mental State Examination (MMSE) score ≥ 21 Prior Authorization does not expire. Non-FDA approved uses are not approved.
• obeticholic acid (Ocaliva) for primary biliary cholangitis (PBC) **Miscellaneous**	Manual PA criteria apply to all new users of obeticholic acid (Ocaliva). Manual PA criteria: Ocaliva is approved for 6 months for Primary Biliary Cholangitis (PBC) for initial therapy if the patient meets the following criteria (i, ii, iii, and iv): i. Patient is age ≥ 18 years old; AND ii. Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND iii. Patient has a diagnosis of PBC as defined by at least TWO of the following criteria (a, b, and/or c) according to the prescribing physician: a. alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values; AND/OR b. positive anti-mitochondrial antibodies (AMAs); AND/OR c. histologic evidence of PBC from a liver biopsy; AND iv. Patient meets ONE of the following criteria (a or b): a. Patient has been receiving ursodiol therapy (e.g., ursodiol generics, Urso 250,Urso Forte, Actigall) for ≥ 1 year and has had an inadequate response OR b. The patient is unable to tolerate ursodiol therapy. Renewal criteria: Ocaliva is approved indefinitely for PBC for continuation therapy if the patient meets the following criteria (i, ii, iii, and iv): Patients Currently Receiving Therapy (renewal criteria): approve indefinitely if the patient meets the following criteria (i, ii, and iii): i. Age ≥ 18 years old; AND ii. Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician; AND iii. Patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC: e.g., ALP, bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT) levels). Expiration date: 6 months or indefinite depending on initial or renewal criteria Non FDA-approved uses are not approved.
• Deferiprone oral solution and oral tablets (Ferriprox) **Iron Chelators**	Manual PA criteria apply to new users of deferiprone oral solution and oral tablets (Ferriprox). Manual PA Criteria: Ferriprox will be approved if:: • The patient has tried Exjade or Jadenu and was unable to tolerate due to adverse effects. Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• linagliptin / metformin XR (Jentadueto XR) Non-Insulin Diabetes Mellitus – DPP-4 Inhibitors	Jentadueto XR will be non step-preferred, similar to the other non step-preferred DPP-4 inhibitors. All new and current users of a DPP-4 inhibitor are required to try metformin or a sulfonylurea before receiving a DPP-4 inhibitor. Additionally, sitagliptin-containing products (Januvia, Janumet, Janumet XR) are the preferred agents in the DPP-4 inhibitors subclass. New users of a DPP-4 inhibitor, including Jentadueto XR, must try a sitagliptin product first. Automated PA Criteria • The patient has filled a prescription for metformin or a sulfonylurea at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. • The patient has received a prescription for a preferred DPP-4 inhibitor (Januvia, Janumet, or Janumet XR) 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, Jentadueto XR is approved if: • The patient has had an in adequate response to metformin or sulfonylurea. • The patient has experienced any of the following adverse events while receiving a sulfonylurea: hypoglycemia requiring medical treatment. • The patient has experienced an adverse event with sitagliptin-containing products, which is not expected to occur with linagliptin-containing products. • The patient has had an inadequate response to a sitagliptin-containing product. • The patient has a contraindication to sitagliptin. PA does not expire.

<table>
<tr><th>Drug / Drug Class</th><th>Prior Authorization Criteria</th></tr>
<tr><td>

• sofosbuvir/velpatasvir (Epclusa)

HCV Direct-Acting Antivirals

</td><td>

• New users of sofosbuvir/velpatasvir (Epclusa) are required to undergo the PA process.
• Current users are not affected by PA; they can continue therapy uninterrupted.
• 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.

<u>Manual PA Criteria</u>:
• Age ≥ 18
• Has laboratory evidence of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection
  o State the HCV genotype and HCV RNA viral load on the PA form.
• Sofosbuvir/velpatasvir (Epclusa) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

<u>Treatment Regimens and Duration of Therapy</u>
• 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 based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for sofosbuvir/velpatasvir (Epclusa)

<table>
<tr><th>Geno-type</th><th>Patient Population</th><th>Treatment</th><th>Duration</th></tr>
<tr><td rowspan="2">1-6</td><td>Patients without cirrhosis and with compensated (Child-Pugh A) cirrhosis</td><td>SOF / VEL</td><td>12 weeks</td></tr>
<tr><td>Patients with decompensated cirrhosis (Child-Pugh B and C)</td><td>SOF / VEL + RBV</td><td>12 weeks</td></tr>
<tr><td colspan="4">A dosage recommendation cannot be made for patients with severe renal impairment (GFR < 30 mL/min) or with end stage renal disease (ESRD)</td></tr>
</table>

Regimen other than those listed above: Explain the rationale for treatment and duration of therapy.

Consult the AASLD/IDSA HCV guidelines for new updates.

</td></tr>
<tr><td>

• Butalbital/ acetaminophen/ caffeine oral liquid (Vanatol LQ)

Analgesics and Combinations

</td><td>

All new and current users of butalbital/ acetaminophen/ caffeine (Vanatol LQ) are required to undergo manual prior authorization criteria.

<u>Manual PA Criteria</u>: Coverage will be approved if:
• Patient cannot tolerate generic Fioricet oral tablet or capsule formulations due to documented swallowing difficulties.

Prior Authorization expires in 6 months.
Non FDA-approved uses are not approved.

</td></tr>
</table>

Drug / Drug Class	Prior Authorization Criteria
• suvorexant (Belsomra) **SED-1s**	**The current automated prior authorization (step therapy) will be removed.** Manual PA criteria apply to all new users of Belsomra. Manual PA Criteria: Belsomra is approved if: • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance AND • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive therapy, sleep hygiene AND • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release AND eszopiclone • Patient has no current or previous history of narcolepsy AND • Patient has no current or previous history of drug abuse. Prior Authorization does not expire. Non FDA-approved uses are not approved.
• somatropin (Zomacton, Genotropin, Genotropin MiniQuick, Humatrope, Norditropin FlexPro, Nutropin AQ NuSpin, Nutropin AQ Pen, Omnitrope, Saizen, Serostim, Zorbtive) **Growth-Stimulating Agents (GSAs)**	Manual PA criteria apply to all new and current users of growth-stimulating agents. The following drugs will be added to the existing PA form for the GSAs: Nutropin AQ NuSpin, Nutropin AQ Pen, Genotropin, Humatrope, Omnitrope, Saizen Manual PA Criteria: Criteria #5 - Use for Idiopathic Short Stature is not covered for: Nutropin AQ NuSpin, Nutropin AQ Pen, Genotropin, Humatrope, Omnitrope, Saizen Prescriptions for newly approved GSAs will be subject to the PA criteria currently in place for the class. Prior Authorization expiration: 365 days
• diclofenac sodium 2% topical solution (Pennsaid) **Topical Pain Agents**	Manual PA criteria apply to all new and current users of diclofenac sodium 2% topical solution. Manual PA criteria: Pennsaid 2% topical solution is approved if: • Patient has a documented diagnosis of osteoarthritis of the knee AND o Patient is unable to take oral NSAIDs or acetaminophen due to documented intolerance, contraindication, or adverse reaction OR o The patient is ≥ 75 years old AND • The patient is unable to use preferred generic diclofenac 1.5% topical solution AND diclofenac 1.0% topical gel (Voltaren generics) due to documented inadequate effects. Prior Authorization does not expire. Non-FDA approved uses are not approved.

Drug / Drug Class	Prior Authorization Criteria
~~• **Ibandronate (Boniva, generics)**~~ • risedronate (Actonel) • risedronate delayed release (Atelvia) • alendronate effervescent tablet (Binosto) • alendronate with vitamin D (Fosamax Plus D) **Oral Bisphosphonates**	Ibandronate is now step-preferred. **Changes are highlighted in bold and strikethrough.** 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 or **ibandronate** 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: o 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 o Contraindication

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• sumatriptan nasal powder (Onzetra Xsail) **Migraine Agents: Nasal Triptans**	▪ Retail: 8 pouches / 30 days ▪ MTF and Mail: 24 pouches / 90 days ▪ Each pouch has 2 nosepieces that provide one dose
• sumatriptan 3 mg autoinjector (Zembrace SymTouch) **Migraine Agents: Injectable Triptans**	▪ Retail: 8 autoinjectors (2 cartons) / 30 days ▪ MTF & Mail: 24 autoinjectors (3 cartons) / 90 days ▪ Each carton contains 4 autoinjectors
• sumatriptan transdermal system (Zecuity) **Migraine Agents: Transdermal Triptans**	▪ Retail: 4 systems (1 carton) / 30 days ▪ MTF & Mail: 12 systems (3 cartons) / 90 days ▪ Each system is contained in a sealed pouch, with 4 systems per carton
• naloxone nasal spray (Narcan Nasal Spray) **Narcotic Antagonists Subclass**	▪ MTF, Mail Order Pharmacy, and Retail Network: 2 cartons (2 nasal spray devices/carton) ▪ No refills allowed; one fill per prescription
• naloxone autoinjector (Evzio) **Narcotic Antagonists Subclass**	▪ MTF, Mail Order Pharmacy, and Retail Network: 1 carton (2 Evzio autoinjectors and one trainer/carton) ▪ No refills allowed; one fill per prescription
• venetoclax (Venclexta) **Oral Oncologic Agent**	For the 100mg: (unit dose/bottle) ▪ Retail: 120 tabs / 30 days ▪ MTF and Mail Order: 240 tabs /60 days ▪ No refills allowed for the starter packs
• cabozantinib (Cabometyx) **Oral Oncologic Agent**	▪ Retail: 30 tabs / 30 days ▪ MTF and Mail Order: 45 tabs / 45 days
• sofosbuvir / velpatasvir (Epclusa) **Hepatitis C Virus (HCV) Direct-Acting Antiviral Agents (DAAs) Subclass**	▪ Retail, MTF, and Mail Order: 28 tablets / 28 days
• ombitasvir / paritaprevir / ritonavir / dasabuvir (Viekira XR) **HCV DAAs Subclass**	▪ Retail, MTF, and Mail Order: 84 tablets / 28 days
• lidocaine 5% patch (Lidoderm) **Topical Pain Agents**	▪ Retail: 30 patches / 30 days ▪ MTF and Mail Order: 90 patches / 90 days
• Cinryze, Berinert, Ruconest, Firazyr, Kalbitor **Hereditary Angioedema (HAE) Agents**	▪ Retail (30 days) / MTF/ Mail Order (90 days) o Cinryze: Retail: 20 vials; MTF and Mail: 60 vials o Berinert: Retail: 30 vials; MTF and Mail: 90 vials o Ruconest: Retail: 60 vials; MTF and Mail: 180 vials o Firazyr: Retail: 4 syringes; MTF and Mail: 12 syringes o Kalbitor: Retail 24 vials; MTF and Mail: 72 vials
• methylnaltrexone tab (Relistor) vials **Drugs for Opioid-Induced Constipation**	Previous requirement limiting the Relistor 12 mg / 0.6 mL vials to one fill per prescription removed

Drug / Drug Class	Quantity Limits
• abatacept 125 mg/mL autoinjector (Orencia ClickJect Autoinjector) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail: 4-week supply (#4 125mg/ml ClickJect Autoinjectors) ▪ MTF and Mail Order: 8-week supply (#8 125mg/ml ClickJect Autoinjectors)
• evolocumab 420 mg/3.5 mL (Repatha Pushtronex) **PCSK-9 Inhibitors**	▪ Retail: 1 device /30 days ▪ MTF and Mail Order: 3 devices/90 days

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
antihemophilic factor VIII (recombinant) injection (Afstyla)	Antihemophilic Agents	Eloctate	Hemophilia	• Additional Factor VIII with potential for reduced dosing frequency	• UF
betamethasone dipropionate 0.05% spray (Sernivo)	Topical Corticosteroid – Medium Potency	Betamethasone 0.05% (generics) lotion, cream, oint, gel	Plaque psoriasis in adults	• 505 (b) approval – Spray • Effective in treating plaque psoriasis • Sprays cover larger areas • Within potency classes (high, medium, low) and vehicle, the topical steroids are highly interchangeable • UF has several generic medium potency topical steroids options including sprays	• NF
brivaracetam tablets and oral solution (Briviact)	Anticonvulsant and Anti-Mania	Keppra IR and XR and generics	Adjunctive therapy in the treatment of partial-onset seizures in pts ≥16 yo	• Adjuvant for partial onset seizures in patients 16 or older	• NF
cabozantinib (Cabometyx)	Oral Oncologic Agent	Inlyta, Nexavar, Sutent, Votrient, Afinitor	Renal cell carcinoma (RCC)	• Small molecule tyrosine kinase (TK) inhibitor targeting multiple pathways • For advanced RCC patients who have received at least one prior antiangiogenic therapy • National Cancer Care Network (NCCN) Category 1 for subsequent therapy in RCC	• UF
deferiprone oral solution (Ferriprox)	Iron Chelators	Exjade, Jadenu	Iron chelators, iron overdose	• Provides an additional oral solution option in treatment of iron overload • TID dosing, agranulocytosis • PA applies	• NF

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
emtricitabine/ tenofovir alafenamide (Descovy)	Antiretrovirals	Truvada	HIV	• Alternative NNRTI-based regimen option only for patients with pre-treatment HIV RNA <100,000 copies/ml and CD4 cell count >200 cells/mm^3	• UF
fluorouracil 4% cream (Tolak)	Topical Antineoplastic & Premalignant Lesions Agents	Generic FU 5% cream, Efudex 5% cream	Topical treatment of actinic keratosis of the face	• Approved via NDA with 2 randomized, double-dummy 4-week studies with Tolak versus vehicle • No head-to-head studies versus 5% cream • Class not previously reviewed • Efudex 5% cream approved in 1970 • 5% topical solution generic also available	• NF
halobetasol propionate 0.05% lotion (Ultravate)	Topical Corticosteroid - High Potency	Generic halobetasol propionate 0.05% cream and ointment	Plaque psoriasis in adults	• 505 (b) approval – Lotion • Ultravate lotion is effective in treating plaque psoriasis • Gels, lotions, and solutions: greaseless, drying, and easier to apply to hairy area • Within potency classes (high, medium, low) and vehicle, the topical steroids are highly interchangeable • UF has several generic high potency topical steroids options including lotions	• NF
linagliptin/ metformin XR (Jentadueto XR)	Non-Insulin Diabetes Drugs DPP-4 Inhibitor	Jentadueto, Tradjenta, Metformin XR, Janumet XR	Diabetes	• Once daily metformin XR combination • Step therapy exists in this class • Sitagliptin family is BCF and step-preferred • Linagliptin family is UF and non step-preferred	• NF
nitisinone oral suspension (Orfadin)	Miscellaneous	No clinical comparators	Hereditary type 1 tyrosinemia	• Treatment is standard of care for high mortality genetic disease • Capsules, approved in 2002, can be used in suspension	• UF
obeticholic acid (Ocaliva)	Miscellaneous	No clinical comparators	Primary biliary cholangitis (PBC)	• First in class farnesoid X receptor (FXR) agonist • Used in combo with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA • PA applies	• UF

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
oxycodone extended-release capsules (Xtampza ER)	Narcotic Analgesics and Combinations	Oxycontin, generics	For pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate	• 505(b)(2) approval • Abuse-deterrent oxycodone • Capsule strengths may cause dosing confusion	• NF
pimavanserin (Nuplazid)	Atypical Antipsychotic (AAP)	Quetiapine Clozapine	Hallucinations and delusions associated with Parkinson's disease psychosis	• First AAP approved for psychosis in Parkinson's disease • 5-HT_{2A} inverse agonist which lacks dopamine receptor interaction and the associated motor function effects • FDA agreed in 2013 to approve NDA on 1 positive study despite three failed trials • Black Box Warning like other AAPs, many drug interactions • Use after quetiapine and clozapine according to current standard of care • No head-to-head studies with other AAPs • PA applies	• NF
sofosbuvir/ velpatasvir (Epclusa)	HCV Direct-Acting Antiviral (DAA)	Zepatier, Viekira Pak, Harvoni	Pangenomic HCV	• Pangenomic, 12-week and almost completely ribavirin (RBV)-free regimens • Sustained virologic response (SVR) >95% in all genotypes • RBV added only in decompensated cirrhosis • Advancement in treating genotypes 2, 3, and decompensated cirrhosis • Simplified regimen • PA applies	• UF
venetoclax (Venclexta)	Oral Oncologic Agent	Zydelig, Imbruvica	Chronic lymphocytic leukemia (CLL)	• 1st selective inhibitor of BCL-2 protein for CLL • Indicated for those who have failed one prior therapy • Approval contingent on additional confirmatory studies	• UF

Appendix F—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
Aug 2016	**Topical Acne & Rosacea Agents**	Subclass not previously reviewed	▪ Clindamycin phosphate 1% gel, cream, lotion and solution (Cleocin T, generics) ▪ clindamycin/benzoyl peroxide 1.2% - 5% gel (Duac, generics) ▪ metronidazole 1% gel (MetroGel, generics) ▪ sulfacetamide sodium/sulfur 10% lotion (Klaron, generics) tretinoin 0.025% and 0.05% cream (Retin-A, generics)	**UF step-preferred** ▪ adapalene 0.1% lotion, gel, cream; 0.3% gel (Differin, generics) ▪ clindamycin 1% foam (Evoclin, generics) ▪ clindamycin 1% foam, med swab (Cleocin T, generics) ▪ clindamycin/benzoyl peroxide 1% - 5% gel (Benzaclin, generics) ▪ clindamycin/ benzoyl peroxide 1% - 5% gel kit (Duac CS (Kit) ▪ metronidazole 0.75% cream & 0.75% lotion (MetroCream, MetroLotion generics) ▪ tretinoin 0.01%, 0.025% gel (Retin-A, generics) ▪ tretinoin 0.025% gel, cream (Avita, generics) ▪ tretinoin 0.1% cream, liquid (Retin-A, generics) ▪ tretinoin 0.0375%, 0.075% cream (Tretin-X, generics) ▪ tretinoin 0.05% gel (Atralin, generics) **UF non step-preferred** ▪ azelaic acid 20% cream (Azelex) ▪ azelaic acid 15% gel, foam, kit (Finacea) ▪ clindamycin/benzoyl peroxide 1.2% - 2.5% gel (Acanya)	**NF non step-preferred** ▪ adapalene/ benzoyl peroxide 0.1% - 2.5% gel (Epiduo) ▪ adapalene/ benzoyl peroxide 0.3% - 2.5% gel (Epiduo Forte) ▪ brimonidine tartrate 0.33% gel (Mirvaso) ▪ clindamycin 1% kits (Clindacin ETZ/PAC) ▪ clindamycin 1% gel (Clindagel) ▪ clindamycin/ benzoyl peroxide 1.2% - 3.75% gel (Onexton) ▪ clindamycin/ benzoyl peroxide 1.2% - 5% gel/cream kit (Neuac Kit) ▪ clindamycin/ tretinoin 1.2% - 0.025% gel (Veltin; Ziana, generics) ▪ dapsone 5% and 7.5% gel (Aczone) ▪ ivermectin 1% cream (Soolantra) ▪ metronidazole 1% cream (Noritate) ▪ metronidazole 0.75%	Pending signing of the minutes / 90 days The effective date is Feb 8, 2017	▪ Step therapy applies to the class See Appendix C.	▪ Two additions to BCF: Duac, and MetroGel generics ▪ Non step-preferred: Acanya, Azelex, Finacea ▪ Azelex is indicated for acne ▪ Finacea is indicated for rosacea

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
					cream/cleanser kit (Rosadan Cream Kit) ▪ metronidazole 0.75% gel/cleanser kit (Rosadan Gel Kit) ▪ tretinoin microsphere 0.04%, 0.08%, and 0.1% gel (Retin-A Micro, Retin-A Micro Pump, and generics) ▪ tazarotene 0.1% foam (Fabior)			
Aug 2016	**Migraine Agents Triptans**	UF class previously reviewed Jun 2008	▪sumatriptan tablets (Imitrex, generics) ▪rizatriptan tablets and ODT (Maxalt, Maxalt MLT, generics) ▪zolmitriptan tablets and ODT (Zomig, Zomig ZMT, generics)	**UF – Step-preferred:** ▪ sumatriptan nasal spray (Imitrex, generics) ▪ sumatriptan 4 mg and 6 mg injection (Imitrex STATdose, generics) ▪ eletriptan (Relpax) **UF – Non Step-preferred**: ▪ naratriptan (Amerge, generics) ▪ zolmitriptan nasal (Zomig Nasal Spray)	**NF and non step-preferred** ▪ sumatriptan/ naproxen(Treximet) ▪ almotriptan (Axert, generics) ▪ frovatriptan (Frova, generics) ▪ sumatriptan nasal powder (Onzetra Xsail) ▪ sumatriptan 4 mg and 6 mg needle-free injection (Sumavel DosePro) ▪ sumatriptan3mg autoinjector (Zembrace SymTouch) ▪ sumatriptan transdermal system (Zecuity)	Pending singng of the minutes / 90 days The effective date is Feb 8, 2017	▪Step therapy applies to new users of non-preferred oral, nasal, injectable, and transdermal formulations See Appendix C ▪QL for Onzetra Xsail, Zembrace SymTouch, and Zecuity See Appendix D	▪Note: sumatriptan 4 mg/6 mg injection (Imitrex STATdose) will be added to the BCF once multi-source cost-effective generics are available ▪Note zolmitriptan oral tabs & ODT were added to the BCF; eletriptan (Relpax) was made UF and step-preferred; naratriptan (Amerge) was made UF and non step-preferred; and Treximet was made NF.

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
Aug 2016	**Narcotic Antagonists**	UF class review	▪naloxone nasal spray (Narcan Nasal Spray)		▪ naloxone autoinjector (Evzio)	Pending signing of the minutes / 60 days The effective date is Jan 11, 2017	▪QLs for both products. See Appendix D ▪No refills allowed; 1 fill per prescription	-

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

BCF: Basic Core Formulary
ECF: Extended Core Formulary
ER: extended release
IR: immediate release

Appendix G—Table of Abbreviations

5-ARIs	5-alpha reductase inhibitors
AAP	Atypical Antipsychotic Drug Class
ALP	alkaline phosphatase
ALT	alanine aminotransferase
AMA	anti-mitochondrial antibodies
AST	aspartate aminotransferase
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
BPH	benign prostatic hypertrophy
CD	controlled delivery
CFR	Code of Federal Regulations
CLL	chronic lymphocytic leukemia
CMA	cost minimization analysis
DAA	direct acting antiviral agent
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DoD	Department of Defense
DPP-4	dipeptidyl peptidase-4 inhibitors
DR	delayed release
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	fiscal year
GCN	generic code number
GGT	gamma-glutamyl transpeptidase
GLP1RA	glucagon-like peptide-1 receptor agonist
GSA	Growth-Stimulating Agents Subclass
HCV	hepatitis C virus
HoFH	homozygous familial hypercholesterolemia
IM	intramuscular
IR	immediate release
JDF	Joint Deployment Formulary
LDL	low-density lipoprotein
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NCCN	National Cancer Care Network
NDA	New Drug Application
NDAA	National Defense Authorization Act
NF	nonformulary
NSAIDs	non-steroidal anti-inflammatory drugs
ODT	orally dissolving tablet

OIC	opioid-induced constipation
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PBC	primary biliary cholangitis
PMDD	premenstrual dysphoric disorder
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PCSK-9	proprotein convertase subtilisin/kexin type 9 inhibitors
QD	once daily
QLs	quantity limits
RBV	ribavirin
RCC	renal cell carcinoma
SQ	subcutaneous
SSRIs	selective serotonin reuptake inhibitors
SVR	sustained virologic response
TAA	Trade Agreements Act
TIBs	targeted immunomodulatory biologics
TK	tyrosine kinase
UCDA	ursodeoxycholic acid
UF	Uniform Formulary
ULN	upper limit of normal
VA	U.S. Department of Veterans Affairs
XR	extended release

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

May 2016

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 11 and 12, 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 February Minutes—**VADM R.C. Bono, MC, USN, Director, DHA, approved the minutes from the February 2016 DoD P&T Committee meeting on May 5, 2016.

2. **Correction to the February 2016 Minutes**

   a) **Ivabradine (Corlanor) Prior Authorization (PA) for Heart Failure—**For the dosing of the preferred beta blockers in heart failure, the dosage for carvedilol was corrected to reflect a dose of 50 mg twice daily for patients weighing greater than 85 kg. The PA form includes the correct weight.

   b) **Section 703—Calcitonin-Salmon (Miacalcin) Nasal Spray—**The implementation date was changed to 60 days (July 6, 2016).

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. Renin-Angiotensin Antihypertensives (RAAs): Sacubitril/Valsartan (Entresto)

Background—Entresto is a fixed-dose combination product approved for treating patients with chronic heart failure with reduced ejection fraction. It contains the angiotensin receptor blocker (ARB) valsartan (Diovan, generic) with sacubitril, a neprilysin inhibitor.

FDA approval was based on the results of the PARADIGM-HF trial, which compared Entresto with the angiotensin converting enzyme (ACE) inhibitor enalapril (Vasotec, generic) in over 8,000 patients for 27 months. Treatment with Entresto resulted in a significant 20% relative risk reduction in the rate of death due to cardiovascular causes or hospitalization for heart failure compared to enalapril. The relative risk of all-cause death was reduced by 16% with Entresto.

Limitations to the PARADIGM-HF study included the strict entry criteria (patients who could not tolerate target doses of ARBs or ACE inhibitors, and those with hypotension, reduced renal function, or a history of angioedema were excluded) and the enrollment of small numbers of African Americans and women.

Adverse effects associated with Entresto that occurred more frequently than enalapril were angioedema, particularly in African Americans, and hypotension. Theoretical risks of Entresto contributing to dementia are unknown at this time; the manufacturer is required to conduct studies in this area.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that Entresto showed benefit in the limited patient population studied in the PARADIGM-HF trial. Whether patients with chronic heart failure who are currently stabilized on ACE inhibitors/ARBs should be switched to Entresto remains to be determined.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed the following rankings from most to least cost-effective for the UF after step therapy scenario: losartan (Cozaar, generic), enalapril (Vasotec, generic), valsartan (Diovan, generic), candesartan (Atacand, generic), valsartan/sacubitril (Entresto), ivabradine (Corlanor).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) sacubitril/valsartan (Entresto) be designated formulary on the UF based on the clinical results of the PARADIGM-HF trial.

2. ***COMMITTEE ACTION: PA RECOMMENDATION***—There is existing step therapy in the RAAs class requiring use of losartan, telmisartan, or valsartan prior to use of one of the non-preferred RAAs drugs. Step-therapy and manual PA criteria for Entresto were

recommended in February 2016, with an implementation date of August 10, 2016.

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) revising the manual PA criteria for Entresto since it is solely indicated for heart failure and not hypertension. The PA criteria will now require use of a step-preferred ARB for heart failure (losartan or valsartan) or a generic ACE inhibitor prior to use of Entresto in new and current users. Additionally, the Entresto PA criteria will reflect the study population from the PARADIGM-HF trial, including patients with a left ventricular ejection fraction less than or equal to 35%, with New York Heart Association Class II–IV chronic heart failure, receiving concomitant treatment with a beta blocker, and patients with no history of angioedema. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 60-day implementation period; 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 September 28, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Gastrointestinal-2 (GI-2) Miscellaneous Drugs: Eluxadoline (Viberzi)

Background—The P&T Committee previously reviewed the GI-2 Miscellaneous Drugs in November 2015. Eluxadoline is indicated to treat diarrhea-predominant irritable bowel syndrome (IBS-D) and has a novel mechanism of action compared to alosetron and rifaximin. Professional guidelines for IBS-D recommend that providers should consider offering antispasmodic agents along with dietary and lifestyle advice for patients.

Eluxadoline was compared to placebo in two randomized controlled trials. The results showed statistical significance in improving the composite endpoint and stool consistency, but not abdominal pain. Clinical significance is difficult to determine due to the large placebo effect.

Common adverse reactions of eluxadoline include constipation and abdominal pain. Because of the potential for abuse, eluxadoline is a Schedule IV controlled substance. Limitations to use of eluxadoline include numerous drug interactions, contraindications, and lack of long-term safety data.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) that despite a unique mechanism of action, eluxadoline offers no compelling advantages over existing formulary agents used to treat IBS-D.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: rifaximin (Xifaxan), eluxadoline (Viberzi), alosetron (Lotronex).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) eluxadoline (Viberzi) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term data, and cost disadvantage compared to other UF agents used for IBS-D.

2. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for eluxadoline (Viberzi). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Prior authorization was approved for eluxadoline (Viberzi) in February 2016, with an implementation date of August 10, 2016. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updating the current PA criteria to include the requirement that the initial prescription be written by or in consultation with a gastroenterologist and the patient has failed a trial of rifaximin. See Appendix C for full criteria.

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period; 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 November 2, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Atypical Antipsychotic (AAP) Drugs

Background—The P&T Committee evaluated the AAP drugs. Since the last review in May 2011, generic formulations of several products are now available. The remaining branded AAP drugs include quetiapine extended release (Seroquel XR), asenapine (Saphris), iloperidone (Fanapt), and lurasidone (Latuda). Generic formulations for Seroquel XR are expected in November 2016. Brexpiprazole (Rexulti) and cariprazine (Vraylar) are two new products in the class. Vraylar is an innovator drug; however, it is included in this review.

This clinical effectiveness review focuses on the branded products and indications for schizophrenia, adjunctive therapy to antidepressants for major depressive disorder (MDD), and bipolar disorder. Military Health System (MHS) provider opinions were evaluated and incorporated into the review and UF recommendations.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 against, 0 abstained, 1 absent) the following for the AAP drugs:

- Brexpiprazole (Rexulti) is FDA-approved to treat schizophrenia, and as an adjunct to antidepressant therapy for MDD. Cariprazine (Vraylar) is FDA-approved for schizophrenia and bipolar disorder. Brexpiprazole and cariprazine offer no clinically compelling advantages over the AAP drugs currently on the UF.
- There are no significant efficacy or safety updates since the May 2011 review. The safety profiles of individual AAP drugs are well known, in terms of metabolic, neurologic, and cardiovascular effects. In May 2016, the FDA released safety warnings for aripiprazole (for impulse control problems) and olanzapine (for Drug Reaction with Eosinophilia and Systemic Symptoms); however, these are rare adverse events.
- According to the German Institute for Quality and Efficiency in Health Care, manufacturer claims of added benefit for fewer adverse events with lurasidone compared to risperidone, olanzapine, and quetiapine extended release (ER) could not be proven. However, lurasidone is dosed once daily and is rated as Pregnancy Category B.
- Generic formulations of AAP drugs currently on the UF are adequate to meet the needs of the majority of DoD patients with schizophrenia, bipolar disorder, or MDD requiring adjunctive therapy.
- For patients requiring an AAP drug, treatment choice should be based on efficacy, safety and tolerability of the drug, and individual patient characteristics.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed the following rankings for the AAP drugs from least costly to most costly to the MHS: risperidone, ziprasidone, quetiapine, Risperdal, olanzapine, Seroquel XR, generic aripiprazole, Saphris, Latuda, Fanapt, Rexulti, and Vraylar.
- 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; however, the scenario where lurasidone was added to the UF was the most cost-effective option.

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

    - **UF:**
        - aripiprazole tablets, orally dissolving tablet (ODT), and oral solution (Abilify, Abilify Discmelt, generics)
        - clozapine tablets and orally dissolving tablets (Clozaril, generics; FazaClo ODT)
        - lurasidone (Latuda)
        - olanzapine tablets and ODT (Zyprexa, Zyprexa Zydis, generics)
        - olanzapine/fluoxetine (Symbyax, generics)
        - paliperidone (Invega, generics)
        - quetiapine (Seroquel, generics)
        - quetiapine ER (Seroquel XR)
        - risperidone tablets, ODT, and oral solution (Risperdal, Risperdal ODT, generics)
        - ziprasidone (Geodon, generics)

    - **NF**
        - asenapine (Saphris)
        - brexpiprazole (Rexulti)
        - cariprazine (Vraylar)
        - iloperidone (Fanapt)

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed , 0 abstained, 1 absent) maintaining risperidone tablets and ODT (Risperdal, Risperdal ODT, generics), quetiapine (Seroquel, generics), and quetiapine ER (Seroquel XR) on the BCF, and adding aripiprazole tablets (Abilify, generics) to the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Manual PA criteria for brexpiprazole (Rexulti) in all new patients were recommended at the February 2016 P&T Committee meeting, with an implementation date of August 10, 2016. The P&T Committee recommended (15 for, 0 opposed , 0 abstained, 1

absent) maintaining the existing PA criteria for Rexulti. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Saphris, Rexulti, Vraylar, and Fanapt. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period; 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 November 2, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Anticonvulsant and Anti-Mania Drug Class

Background—The Anticonvulsant and Anti-mania Drug Class has not been previously reviewed for UF status. Prior to implementation of the UF Rule in 2005, several drugs in the class were previously designated as BCF.

There are over 40 anti-epileptic drugs (AEDs) available in the United States. Most are available in generic formulations, and several products now have ER versions. Generic formulations of levetiracetam ER (Keppra XR) and lamotrigine ER (Lamictal XR) recently entered the market.

Five of the AEDs are unique, branded products with no generic or therapeutic equivalents: lacosamide (Vimpat), perampanel (Fycompa), clobazam (Onfi), vigabatrin (Sabril), and rufinamide (Banzel). Five other products are branded formulations with therapeutic alternatives: topiramate ER (Trokendi XR and Qudexy XR), oxcarbazepine ER (Oxtellar XR), eslicarbazepine (Aptiom), and carbamazepine (Equetro ER).

The clinical effectiveness review focused on the efficacy and safety of the branded products and the newer extended release AEDs. The older AEDs and anti-mania drugs will remain on the UF.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed , 0 abstained, 1 absent) that:

- Topiramate IR (Topamax) is approved for several types of seizure disorders and for prophylaxis of migraine headaches. Off-label uses for topiramate IR include weight loss, bipolar disorder, alcohol dependency, obsessive compulsive disorder, and post-traumatic stress disorder. The newer branded topiramate ER products, Trokendi XR and Qudexy XR, do not offer clinically compelling advantages over generic topiramate IR.
- Lacosamide (Vimpat) has a unique mechanism of action at the sodium channels, is well tolerated except for dizziness and somnolence, is easy to titrate, and is approved for partial-onset seizures in patients 17 years and older. An oral solution and tablets are available.
- Perampanel (Fycompa) has a unique mechanism of action at the glutamate receptor. Its place in therapy is for refractory patients with secondary generalized seizures or exclusively for focal seizures as a second- or third-line agent. Fycompa is the only AED with a black box warning for hostility, aggression, and homicidal ideation. Its long duration of action can prolong adverse effects of sedation, headache, and dizziness.
- Clobazam (Onfi) is indicated as adjunctive therapy for Lennox-Gastaut seizures in patients as young as two years old. The compound causes less sedation than typical benzodiazepines, due to receptor selectivity. It is primarily used in pediatric patients with refractory seizures.
- Vigabatrin (Sabril) is approved for infantile spasms in patients as young as one year old and for refractory complex partial seizures in patients as young as ten years old. The risk of vision loss associated with Sabril requires restricted distribution and enrollment in a patient registry.
- Rufinamide (Banzel) is approved for Lennox-Gastaut seizures in children as young as one year old, but there are concerns of shortened QT interval and risk of inducing status epilepticus.
- When used for the appropriate seizure type, the AEDs are roughly equivalent in efficacy. Clinical guidelines indicate that a variety of medications are required to be available to treat seizures effectively.
- AED treatment selection should be based on drug characteristics, including side effect profile, ease of administration, potential drug interactions, as well as patient characteristics, including seizure type and epilepsy syndrome.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that generic products in the class were the most cost-effective, followed by brand carbamazepine ER (Equetro), oxcarbazepine ER (Oxtellar XR), levetiracetam ER (Keppra XR), lacosamide (Vimpat), topiramate ER (authorized generic), topiramate ER (Trokendi XR), perampanel (Fycompa),

topiramate ER (Qudexy XR), clobazam (Onfi), eslicarbazepine (Aptiom), rufinamide (Banzel), and vigabatrin (Sabril).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating all agents in the Anticonvulsant and Anti-Mania Drug Class with formulary status on the UF demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 2 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:

    - UF:
        - Carbamazepine IR (Tegretol, generics)
        - Carbamazepine ER (Tegretol XR, Carbatrol, generics)
        - Carbamazepine ER (Equetro XR)
        - Clobazam (Onfi)
        - Divalproex IR, ER, and delayed release (Depakote, Depakote ER generics; Depakote Sprinkles)
        - Eslicarbazepine (Aptiom)
        - Ethosuximide (Zarontin, generics)
        - Felbamate (Felbatol, generics)
        - Lacosamide (Vimpat)
        - Lamotrigine IR, ER, and chewable tablets (Lamictal, Lamictal XR, Lamictal CD, generics)
        - Lamotrigine ODT (Lamictal ODT)
        - Levetiracetam IR, ER (Keppra; Keppra XR, generics)
        - Oxcarbazepine (Trileptal, generics)
        - Oxcarbazepine ER (Oxtellar XR)
        - Perampanel (Fycompa)
        - Phenytoin (Dilantin, generics)
        - Phenobarbital (Luminol, generics)
        - Primidone (Mysoline, generics)
        - Rufinamide (Banzel)
        - Topiramate IR and sprinkle capsules (Topamax, Topamax Sprinkle, generics)
        - Topiramate ER (Trokendi XR)
        - Topiramate ER (Qudexy XR)
        - Valproic Acid (Depakene, generics)
        - Vigabatrin (Sabril)
        - Zonisamide (Zonegran, generics)

    - NF:
        - None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the following drugs on the on the BCF:

   - Carbamazepine tablets, chewable tablets, and oral suspension (Tegretol, generics)
   - Carbamazepine ER tablets (Tegretol XR, generics)
   - Divalproex (Depakote, Depakote ER generics; Depakote Sprinkles)
   - Phenytoin ER capsules, chewable tablets, and oral suspension (Dilantin; Dilantin-125, generics)
   - Phenobarbital

3. ***COMMITTEE ACTION: TOPIRAMATE ER (TROKENDI XR AND QUDEXY XR) PA CRITERIA***—Manual PA criteria were recommended in August 2014 and implemented in December 2014 to limit use of Qudexy XR and Trokendi XR to the FDA-approved indications for seizures and appropriate age ranges. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining the current PA criteria for Trokendi XR and Qudexy XR. Patients are required to try generic topiramate IR first, unless there is a contraindication or adverse reaction with the generic product. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: LACOSAMIDE (VIMPAT) REMOVAL OF PA CRITERIA***—Manual PA criteria were recommended for new users of Vimpat at the February 2016 P&T Committee meeting, with an implementation date of August 10, 2016. A review of MHS prescribing patterns for Vimpat found a low percentage of off-label use. The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 1 absent) removing the manual PA criteria for Vimpat upon signing of the minutes.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Contraceptive Agents: Emergency Contraceptives

Background—The emergency contraceptives reviewed for formulary placement included levonorgestrel 1.5 mg (Plan B One Step, generics), levonorgestrel 0.75 mg (Plan B, generics), and ulipristal acetate 30 mg (Ella). The levonorgestrel 1.5 mg single dose has largely replaced use of the 0.75 mg two-tablet regimen.

The Emergency Contraceptives were previously reviewed for UF placement in August 2011. Since then, the branded product Plan B One Step (levonorgestrel 1.5 mg) now has at least 10 AB-rated generic equivalent formulations. Plan B One Step is available over-the-counter (OTC) with no age restrictions while Ella requires a prescription.

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (15 for, 0 opposed , 0 abstained, 1 absent) the following:

- Both levonorgestrel and ulipristal acetate are effective in preventing unintended pregnancies by delaying or inhibiting ovulation. Levonorgestrel is effective when taken within 72 hours of unprotected intercourse; however, its efficacy declines over time. Ulipristal acetate is effective when taken up to 120 hours after unprotected intercourse.

- In terms of relative effectiveness, ulipristal acetate is more effective compared to levonorgestrel in preventing unintended pregnancies, based on findings from one meta-analysis and pooled data from two randomized, multicenter trials. Ulipristal acetate prevented 67% of expected pregnancies versus 52% with levonorgestrel.

- The World Health Organization guidelines state that emergency contraceptives may be less effective in women with body mass indexes (BMIs) ≥ 30 kg/m^2 compared to women with BMIs < 25 kg/m^2. However, there are no safety concerns associated with the use of either levonorgestrel or ulipristal acetate in obese patients.

- The most commonly reported adverse effects ($\geq$10%) with either levonorgestrel or ulipristal acetate are headache, nausea, and abdominal pain. Both products have a similar safety profile and contraindications.

- To ensure adequate clinical coverage for emergency contraception, both levonorgestrel and ulipristal acetate are required on the UF, and at least one agent should be considered for placement on the BCF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the emergency contraceptives. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed the relative rankings for the emergency contraceptives.

- BIA was performed to evaluate the potential impact of bids offered. No significant impact was found for any scenario.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 0 opposed , 2 abstained, 1 absent) the following, based on clinical and cost effectiveness:

- **UF:**
  - levonorgestrel 0.75 mg (Plan B, generics)
  - levonorgestrel 1.5 mg (Plan B One Step, generics)
  - ulipristal acetate 30 mg (Ella)

- **NF:** None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—In the MHS, levonorgestrel 1.5 mg has the highest utilization and is currently the most cost-effective emergency contraceptive. The P&T Committee, recommended (14 for, 0 opposed , 1 abstained, 1 absent) designating levonorgestrel 1.5 mg (Plan B One Step, generics) with BCF status upon signing of the minutes.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. INNOVATOR DRUGS

A. Newly-Approved Innovator Drugs

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analysis presented for the innovator drugs. For the complete list of innovator drugs reviewed at the May 2016 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, see Appendix E.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:
   - UF:
     - antihemophilic factor (recombinant) (Kovaltry)
     - calcipotriene/betamethasone dipropionate foam (Enstilar)
     - coagulation factor IX (recombinant)/albumin fusion protein (Idelvion)
     - emtricitabine/rilpivirine/tenofovir alafenamide (Odefsey)
     - grazoprevir/ elbasvir (Zepatier)
     - tofacitinib ER tablets (Xeljanz XR)
     - uridine triacetate oral granules (Xuriden)

- NF:
    - amphetamine ER ODT (Adzenys XR ODT)
    - buprenorphine buccal film (Belbuca)
    - ixekizumab injection (Taltz)
    - methylphenidate ER chewable tablets (QuilliChew ER)

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for buprenorphine buccal film (Belbuca), methylphenidate ER chewable tablets (QuilliChew ER), amphetamine ER ODT (Adzenys XR ODT), and ixekizumab injection (Taltz). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Existing step therapy and manual PA criteria currently apply to the Targeted Immunomodulatory Biologics (TIBs), and manual PA criteria currently apply to the Hepatitis C direct-acting antiviral agents (DAAs). The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) PA criteria for the TIBs tofacitinib XR (Xeljanz XR) in new users, and izekizumab injection (Talz) in new and current users; for the hepatitis C Direct Acting Agent grazoprevir/elbasvir/ (Zepatier) in new users; and for the orphan drug uridine triacetate (Xuriden) in new and current users. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: U AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date upon signing of the minutes in all points of service (POS).

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Oral Oncologic Agents: Palbociclib (Ibrance) Manual PA Criteria**—Ibrance was approved by the FDA in February 2015 for specific types of metastatic breast cancer. Manual PA criteria were recommended for this agent.

a) ***COMMITTEE ACTION: PALBOCICLIB (IBRANCE) PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Ibrance in new patients. See Appendix C for the full criteria.

2. **Parkinson's Disease Agents: Carbidopa/Levodopa ER Capsules (Rytary) Manual PA Criteria**—Rytary is FDA-approved for the treatment of Parkinson's disease. Rytary is dosed three times daily and is available in the following ER capsule dosages: 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg /245 mg. Sustained-release formulations of carbidopa/levodopa (Sinemet CR) are dosed twice daily to three times daily.

    a) ***COMMITTEE ACTION: CARBIDOPA/LEVODOPA ER CAPSULES (RYTARY) PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Rytary in new patients. Rytary will be approved if the patient has tried and failed a generic controlled release formulation of carbidopa/levodopa. See Appendix C for the full criteria.

3. **GI-2 Opioid-Induced Constipation Drugs: Naloxegol (Movantik) Manual PA Criteria**—Movantik is FDA-approved for opioid-induced constipation in patients with chronic non-cancer pain. It is a mu-opioid receptor antagonist given orally once daily, and has warnings regarding gastrointestinal perforation and opioid withdrawal.

    a) ***COMMITTEE ACTION: NALOXEGOL (MOVANTIK) PA CRITERIA***
    The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Movantik in new patients. Patients are required to have a trial of two standard laxative therapies prior to use of naloxegol. See Appendix C for the full criteria.

4. **Beta-Blockers: Nebivolol (Bystolic) Manual PA Criteria**—Bystolic is an adrenergic blocking agent that is solely FDA-approved for the treatment of hypertension. It was reviewed and designated NF in June 2008. There is now widespread cost-effective generic availability of other beta blockers, which have other indications in addition to hypertension, including heart failure, angina, and arrhythmias. There is no compelling clinical data to support use of nebivolol over the other beta blockers in the class.

    a) ***COMMITTEE ACTION: NEBIVOLOL (BYSTOLIC) MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updating the current MN criteria for Bystolic, to require failure of or intolerance to two generic beta blockers. See Appendix B for the full criteria.

b) ***COMMITTEE ACTION: NEBIVOLOL (BYSTOLIC) PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users of Bystolic, requiring failure of or intolerance to two generic beta blockers. Coverage will only be approved for hypertension. See Appendix C for the full criteria.

5. **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): Esomeprazole/Naproxen (Vimovo) and Ibuprofen/Famotidine (Duexis) Manual PA Criteria**—The NSAIDs were reviewed in August 2012. Vimovo is currently designated formulary on the UF, while Duexis is NF. Manual PA criteria were recommended for Vimovo and Duexis due to the wide availability of other cost-effective generic NSAIDs, including celecoxib (Celebrex) and OTC availability of several proton pump inhibitors.

    a) ***COMMITTEE ACTION: ESOMEPRAZOLE/NAPROXEN (VIMOVO) AND IBUPROFEN/FAMOTIDINE (DUEXIS) PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for Vimovo and Duexis in new and current patients requiring documentation that the patient must take a fixed-dose combination product and cannot take the two drugs separately. See Appendix C for the full criteria.

6. **Non-Opioid Pain Syndromes: Cyclobenzaprine ER Capsules (Amrix) Manual PA Criteria**—Cyclobenzaprine IR was reviewed in November 2011 as part of the Non-Opioid Pain Syndrome Drug Class and designated with formulary status on the UF. Cost-effective generic formulations of the IR tablets are available. Cyclobenzaprine ER capsules (Amrix) do not offer compelling advantages over cyclobenzaprine IR tablets (Flexeril, generics).

    a) ***COMMITTEE ACTION: CYCLOBENZAPRINE ER CAPSULES (AMRIX) PA CRITERIA***—The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 1 absent) manual PA criteria for Amrix in new and current patients, requiring a trial of generic immediate release cyclobenzaprine. See Appendix C for the full criteria.

7. **Topical Pain Drugs: Lidocaine 5% Patch (Lidoderm) Removal of Manual PA Criteria**—PA criteria were recommended for Lidoderm at the February 2013 P&T Committee meeting and implemented in August 2013.

    a) ***COMMITTEE ACTION: LIDOCAINE 5% PATCH (LIDODERM) REMOVAL OF PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) removing the PA for Lidoderm. Cost-effective generic formulations are now available.

8. **Attention Deficit Hyperactivity Disorder (ADHD) Stimulants: Amphetamine ER Oral Suspension (Dyanavel XR) MN Criteria**—Dyanavel XR was reviewed in February 2016 as an innovator drug and designated NF, with MN criteria implemented on May 5, 2016. The P&T Committee recommended updating the MN criteria for Dyanavel XR to be consistent with the MN criteria recommended at this meeting for the innovator drug amphetamine ER ODT (Adzenzys XR ODT). Other ADHD stimulants are available on the UF and approved for patients as young as 6 years of age.

    a) ***COMMITTEE ACTION: AMPHETAMINE ER ORAL SUSPENSION (DYANAVEL XR) MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) revised MN criteria for Dyanavel XR, to require use of at least two ADHD formulary stimulants first. See Appendix B for the full criteria.

B. Quantity Limits (QLs)

Quantity limits were reviewed for seven drugs, including two oral inhalers, three products in the TIBs Drug Class, and one drug for hepatitis C virus genotypes 1 and 4. QLs already exist for these drug classes. QLs were also recommended for the skeletal muscle relaxant cyclobenzaprine ER (Amrix), consistent with the package labeling for duration of use.

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) QLs for fluticasone/salmeterol (Advair HFA), flunisolide (Aerospan), tofacitinib ER (Xeljanz XR), ixekizumab (Taltz), secukinumab (Cosentyx), grazoprevir/elbasvir (Zepatier), and cyclobenzaprine ER (Amrix). See Appendix D for the QLs.

C. PA, MN, and QLs Implementation Periods

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

    - 14 for, 0 opposed, 0 abstained, 2 absent—the manual PAs for palbociclib (Ibrance), carbidopa/levodopa ER capsules (Rytary), naloxegol (Movantik), nebivolol (Bystolic), cyclobenzaprine ER capsules (Amrix), esomeprazole/naproxen (Vimovo), and ibuprofen/famotidine (Duexis); and, the revised MN criteria for Bystolic 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 November 2, 2016.
    - 14 for, 0 opposed, 0 abstained, 2 absent—the revised MN criteria for amphetamine ER oral suspension (Dyanavel XR) and the QLs for fluticasone/salmeterol (Advair HFA), flunisolide (Aerospan), tofacitinib ER (Xeljanz XR), ixekizumab (Taltz), secukinumab (Cosentyx), grazoprevir/

elbasvir (Zepatier), and cyclobenzaprine ER (Amrix) become effective upon signing of the minutes.

- 14 for, 0 opposed, 0 abstained, 2 absent—the PA for Lidoderm be removed effective upon signing of the minutes.

Director, DHA, Decision: ☒ Approved □ Disapproved

Approved, but modified as follows:

D. Utilization Management for Brand over Generic Authority and PA Criteria

Currently in the Retail Network and Mail Order Pharmacy, there is a mandatory generic substitution policy. When AB-rated generic formulations enter the market, the generic formulation is dispensed instead of the branded product. Prior Authorization criteria do allow dispensing of the branded product in certain cases (e.g., allergy or hypersensitivity).

Currently, the DHA Pharmacy Operations Division (POD) has noticed a trend for new generic products to have a higher cost than the corresponding proprietary product for several months after market launch. The DHA POD is requesting authority to implement "brand over generic" requirements in the Retail Network and Mail Order Pharmacy when there is a cost benefit to the MHS. The recommended authority below will allow the MHS to respond quickly to instances when high cost generic formulations enter the market.

1. ***COMMITTEE ACTION: BRAND OVER GENERIC AUTHORITY***—The P&T Committee recommended (14 for, 0 opposed, 1 abstain, 1 absent):
    a) The DHA POD be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost effective than generic formulations. In these cases, the branded product will continue to be dispensed, and the generic product will only be available upon prior authorization.
    b) The branded product will adjudicate at the Tier 1 co-pay in the Retail Network and Mail Order Pharmacy.
    c) The "brand over generic" requirement will be removed when it is no longer cost effective to the MHS.
    d) The P&T Committee will be updated during the next quarterly meeting on DHA POD administrative actions for brand over generic products.

2. ***COMMITTEE ACTION: BRAND OVER GENERIC PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstain, 1 absent) the following PA criteria will apply to cases when the "brand over generic" authority is implemented. Patients meeting the criteria below will receive the generic formulation, rather than the specified branded product.

   a) The prescriber must complete a clinical assessment and provide a patient-specific justification as to why the branded product cannot be used in the patient.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. BCF CLARIFICATION

A. Beta Blockers—Metoprolol Tartrate

The beta blockers were last reviewed in November 2007. At that time, metoprolol tartrate 25, 50, and 100 mg tablets (Lopressor, generics) were maintained on the BCF. New generic tablets in strengths of 37.5 mg and 75 mg have entered the market. There is currently low utilization of these new metoprolol tartrate dosages at the MTFs.

1. ***COMMITTEE ACTION: BCF CLARIFICATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) metoprolol tartrate 37.5 mg and 75 mg tablets be excluded from the BCF; they will remain on the UF.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

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

Drugs from pharmaceutical manufacturers that are not included on a DoD Retail Refund Pricing Agreement are not in compliance with the 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 require pre-authorization prior to use in the retail point of service and medical necessity at military treatment facilities. These NF drugs will remain available in the Mail Order POS without pre-authorization.

A. Tobramycin 300 mg/5 mL Inhalation Solution (Kitabis Pak)—At the November 2015 P&T Committee meeting, Kitabis Pak was designated NF with pre-authorization criteria for use in the Retail Network. Because Kitabis Pak was only available in the Retail Network via a specialty distributor network of pharmacies, it was exempt from the requirement to limit availability to the Mail Order Pharmacy. In February 2016, supply and distribution of Kitabis Pak became available through the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: TOBRAMYCIN 300 mg/5 mL INHALATION SOLUTION (KITABIS PAK) REMOVAL OF EXEMPTION FROM MAIL ORDER PHARMACY AVAILABILITY***—The P&T Committee recommended (15 for, 0 opposed , 0 abstained, 1 absent) removing the exemption from mail order availability for tobramycin 300 mg/5 mL inhalation solution (Kitabis Pak). Kitabis Pak will now be available through the Mail Order Pharmacy without pre-authorization. However, pre-authorization prior to use in the retail POS and MN at MTFs is still required.

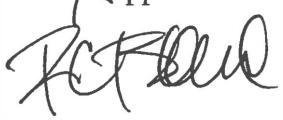
2. ***COMMITTEE ACTION: TOBRAMYCIN 300 mg/5 mL INHALATION SOLUTION (KITABIS PAK) IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Kitabis Pak. Based on the P&T Committee's recommendation, the effective date is November 2, 2016.

B. Section 703 Program Updates—The P&T Committee discussed drugs that are not compliant with Section 703 and are limited in availability. The circumstances when a Section 703 non-compliant drug can be exempted from the Mail Order Pharmacy requirement include when drugs are available only via limited distribution networks or when drugs are not compliant with the Trade Agreements Act (TAA).

1. ***COMMITTEE ACTION: SECTION 703 PROGRAM UPDATES***—The P&T Committee recommended (15 for, 0 opposed , 0 abstained, 1 absent) administrative authority for the DHA Pharmacy Operations Division to allow availability of drugs that are non-complaint with Section 703 through the Mail Order Pharmacy when product supply or distribution issues (e.g., limited distribution or TAA non-compliance) are resolved. Drugs that are made available through the Mail Order Pharmacy will not have to undergo a formal re-review by the P&T Committee.

Director, DHA, Decision: ☒ Approved □ Disapproved

Approved, but modified as follows:



X. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EXPANDED MTF/MAIL PHARMACY INITIATIVE), AND NF (TIER 3) PHARMACEUTICALS AT MAIL ORDER

The P&T Committee was briefed on the progress of implementing the requirement that NF pharmaceutical agents generally be unavailable at MTFs or the Retail Network, but available in the Mail Order program. For more information, refer to the August 2015 and November 2015 DoD P&T Committee meeting minutes at http://www.health.mil/PandT.

As of April 15, 2016, all NF agents have been added to the program, except for:

1) Drugs excluded from the requirement to use Mail Order as the sole point of dispensing based on exceptions previously established by the P&T Committee, including clinical characteristics and feasibility/availability issues, and

2) NF agents that are now available in generic formulations, but do not fall into previously established exceptions. A complete list of medications that are available at the Retail Network for two initial prescription fills only and then which must be filled at MTFs/Mail (formulary medications intended for chronic use) or at mail only (NF agents that do not fall into previously established exception) is available at http://www.tricare.mil/CoveredServices/Pharmacy/Drugs/SelectMaintDrugs.aspx.

Implementation of the mail order requirement for generically available NF agents was temporarily deferred to allow for review of the continued necessity for NF (Tier 3) status, given price decreases typically associated with generic availability. Generically available NF drugs from two major classes are being reviewed at this meeting (see sections XI and XII); the remaining agents are slated for review at an upcoming meeting.

XI. RE-EVALUATION OF NF AGENTS: CALCIUM CHANNEL BLOCKERS (CCBs)

The P&T Committee re-evaluated the UF status of the six NF CCBs, all of which are now available in generic formulations: verapamil capsule 24 hr (Verelan PM); verapamil capsule 24h (Verelan); diltiazem tablet ER 24h (Cardizem LA); isradipine capsule (generic only); nicardipine (generic only); and, nisoldipine tablet ER 24h (Sular).

Clinical Effectiveness Conclusion—The CCBs were last evaluated for UF status at the August 2005 meeting. The P&T Committee did not find new clinical evidence that would alter the overall conclusion that little to no difference in clinical effectiveness exists among the CCBs.

Cost Effectiveness Conclusion—The current costs for the CCBs was evaluated. The P&T Committee voted (15 for, 0 opposed, 0 abstained, 1 absent) that none of the NF CCBs were cost effective relative to similar UF products, when the generic prices for the NF verapamil, diltiazem, and dihydropyridine products were compared to their formulary alternatives. Given the maturity of the drug class, generic prices are not expected to decline in the future, and may

increase substantially as fewer generic products remain on the market. Overall, unit costs for these six current NF products tended to be lower at mail order compared to retail.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed. 0 abstained, and 1 absent) that verapamil capsule 24hr (Verelan PM, generics); verapamil capsule 24h (Verelan, generics); diltiazem tablet ER 24h (Cardizem LA, generics); isradipine capsule (generic only); nicardipine (generic only); and nisoldipine tablet ER 24h (Sular, generics) remain NF. Additionally, all six NF CCBs will remain subject to the requirement that they be generally available only at mail order, regardless of generic status.

Director, DHA, Decision: ☒ Approved □ Disapproved

Approved, but modified as follows:

XII. RE-EVALUATION OF NF AGENTS: PROTON PUMP INHIBITORS (PPIs)

The P&T Committee re-evaluated the UF status of the NF PPIs: dexlansoprazole (Dexilant), esomeprazole strontium, lansoprazole (Prevacid, generics); omeprazole/sodium bicarbonate (Zegerid, generics), rabeprazole delayed release tablets (Aciphex, generics) and rabeprazole delayed release capsules (Aciphex Sprinkle). The PPIs were previously evaluated for UF status at the May 2007 meeting. Automated PA (step therapy) requiring a trial of omeprazole, esomeprazole (Nexium), or pantoprazole applies to new users presenting with a prescription for a nonformulary PPI.

Clinical Effectiveness Conclusion—At the May 2007 meeting, the P&T Committee reviewed evidence across a wide range of disease states and, in summary, concluded that PPIs appear very similar with regard to efficacy, safety, and tolerability. The P&T Committee did not find new clinical evidence that would alter this conclusion.

Cost-Effectiveness Conclusion—The current costs for the PPIs were evaluated. The P&T Committee voted (15 for, 0 opposed, 0 abstained, 1 absent) that, while not as cost effective as generic omeprazole or pantoprazole, generic rabeprazole delayed release (DR) tablets were more cost effective than the blended average of all UF PPIs, with additional generic price competition anticipated. The other NF PPIs were substantially less cost effective than the UF PPIs.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) that rabeprazole DR tablet (Aciphex, generics) be re-classified as formulary and step-preferred on the UF. This does not include Aciphex Sprinkle, which would therefore remain NF and non-step preferred. NF PPIs would be subject to the requirement that they generally be available only in the Mail Order Pharmacy, regardless of generic status.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XIII. ADJOURNMENT

The meeting adjourned at 1145 hours on May 12, 2016. The next meeting will be in August 2016.

Appendix A—Attendance: May 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—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary
Appendix G—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.

R.C. Bono
VADM, MC, USN
Director

16072 8
Date

Appendix A—Attendance: May 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, M.S.	Chief, DHA Operations Management Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
COL Jack Lewi, MC	Army, Internal Medicine Physician
Col William Hannah, MC	Air Force, Internal Medicine Physician
CDR Brian King, MC	Navy, Internal Medicine Physician
MAJ Dausen Harker	Army, Family Practice Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ David Keller for MAJ John Poulin, MC	Army, Physician at Large
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
LTC Kevin Ridderhoff for COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
Nonvoting Members Present	
Mr. Randy Stone	DHA, Office of General Counsel
Guests	
CAPT Matt Baker	Indian Health Service
LCDR Ebenezer Aniagyei	Defense Logistics Agency Troop Support
Ms. Joan Marie Grace	Defense Logistics Agency Troop Support
Capt Ryan Shaver	Air Force, Pharmacy Officer
Lauren Cimineri, PharmD, MPH	Centers for Disease Control and Prevention, World Trade Center Health Program
Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch

Appendix A—Attendance (continued)

Others Present	
MAJ Aparna Raizada, MS	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
David Meade, PharmD via DCS	DHA Integrated Utilization Branch
Robert Conrad, PharmD via DCS	DHA Operations Management Branch
LT Teisha Robertson via DCS	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
▪ Eluxadoline (Viberzi) **GI-2 Miscellaneous Drug Subclass**	• Formulary alternatives have resulted in therapeutic failure **Formulary Alternatives:** rifaximin, antispasmodics, tricyclic antidepressants
• Asenapine (Saphris) • Brexpiprazole (Rexulti) • Cariprazine (Vraylar) • Iloperidone (Fanapt) **Atypical Antipsychotics (AAPs)**	• The use of formulary alternatives is contraindicated • The patient has experienced significant adverse effects from the formulary alternatives • Formulary alternatives have resulted in therapeutic failure • Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** risperidone, quetiapine, aripiprazole, olanzapine, olanzapine/fluoxetine, ziprasidone, paliperidone, lurasidone (Latuda)
• Buprenorphine buccal film (Belbuca) **Narcotic Analgesics and Combinations**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** tramadol IR (Ultram, generics), buprenorphine transdermal (Butrans), buprenorphine sublingual (Subutex), butorphanol intranasal (Stadol), pentazocine/naloxone (Talwin NX), tramadol ODT(Rybix)
• Methylphenidate ER chewable tablets (QuilliChew ER) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	• No alternative formulary agent: Patient cannot take methylphenidate ER oral suspension (Quillivant XR) **Formulary alternatives:** mixed amphetamine salts (Adderall IR, XR; generic), methylphenidate OROS (Concerta, generic), methylphenidate ER oral suspension(Quillivant XR)
• Amphetamine ER ODT (Adzenys XR ODT) • Amphetamine ER oral suspension (Dyanavel XR) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	• Use of as least two formulary ADHD stimulants is contraindicated • Patient has experienced significant adverse effects from at least two formulary ADHD stimulants • Use of at least two the formulary ADHD stimulants has resulted in therapeutic failure **Formulary alternatives:** mixed amphetamine salts XR (Adderall XR, generic), methylphenidate ER (Ritalin LA); methylphenidate ER oral suspension(Quillivant XR)
• Ixekizumab injection (Taltz) **Targeted Immunomodulatory Biologic (TIB)**	• Use of adalimumab (Humira) and secukinumab (Cosentyx) are contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) and secukinumab (Cosentyx) • Adalimumab (Humira) and secukinumab (Cosentyx) result or are likely to result in therapeutic failure • Patient previously responded to non-formulary agent and changing to adalimumab (Humira) or secukinumab (Cosentyx) would incur unacceptable risk **Formulary Alternatives:** adalimumab (Humira) or secukinumab (Cosentyx)

Drug / Drug Class	Medical Necessity Criteria
• Nebivolol (Bystolic) **Beta-blockers**	• The patient has experienced significant adverse effects from two generic beta blockers • A trial of at least two generic beta blockers resulted in therapeutic failure • Patient previously responded to nebivolol (Bystolic) and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** atenolol, carvedilol IR and ER, metoprolol tartrate, metoprolol succinate, acebutolol, bisoprolol, betaxolol, labetolol, nadolol, penbutolol, propranolol, pindolol, timolol, including above agents in combination with diuretics

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Sacubitril/valsartan (Entresto) **Renin Angiotensin Antihypertensive Agents**	The criteria below will replace the criteria recommended at the February 2016 meeting. Updates are bolded. Manual PA criteria apply to all new and current users of sacubitril/valsartan (Entresto) Manual PA criteria: Coverage is approved for Entresto if all of the following criteria apply: • **The initial prescription is written by or in consultation with a cardiologist.** • The patient is at least 18 years of age. • Documented diagnosis of chronic heart failure (New York Heart Association class II-IV) with a left ventricular ejection fraction ≤ 35% with continued heart failure symptoms. • Receiving concomitant treatment with a β-blocker that has been shown to have a survival benefit in heart failure, at maximally tolerated doses 1. metoprolol succinate ER 200 mg QD; carvedilol 25 mg BID or 50 mg BID if > 85 kg; carvedilol ER 80 mg QD; bisoprolol 10 mg QD OR • The patient has a contraindication to a β-blocker 1. Hypersensitivity, cardiogenic shock or overt cardiac failure, 2nd or 3rd degree heart block, asthma, COPD • **Patient has been stable on any ACE inhibitor or preferred ARB shown to have benefit in heart failure (losartan, valsartan) for at least 4 weeks at maximally tolerated doses** • Patient does not have a history of angioedema due to ACE inhibitor or ARB Prior Authorization does not expire
• Eluxadoline (Viberzi) **GI-2 Miscellaneous Drugs**	Manual PA criteria apply to all new users of eluxadoline (Viberzi). Updates to the Manual PA criteria recommended at the February 2016 meeting are bolded. Manual PA criteria: Coverage will be approved if: • **Initial prescription written by or in consultation with a gastroenterologist; AND** • The patient is ≥ 18 years; AND • Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink ≤ 3 alcoholic beverages per day; AND • Patient has no history of marijuana use or illicit drug use in the previous 6 months; AND • Patient does not have severe hepatic impairment (Child-Pugh C); AND • Patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D); AND o The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium) AND o The patient has had failure, intolerance, or contraindication to at least one tricyclic antidepressant (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline AND o **The patient has failed a trial of rifaximin** • Non-FDA approved uses are not approved. • Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Brexpiprazole (Rexulti) **Atypical Antipsychotics (AAPs)**	No change from February 2016. All new users of brexpiprazole (Rexulti) are required to undergo manual prior authorization criteria. Manual PA criteria: Coverage will be approved if: • Diagnosis of Major Depressive Disorder o The patient is ≥ 18 years; AND o The patient has had treatment failure of at least two other antidepressant augmentation therapies (one of which must be aripiprazole); OR o Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) AND o Patient has concurrent use of an antidepressant • Diagnosis of schizophrenia o The patient is ≥ 18 years; AND o The patient has had treatment failure of at least two other atypical antipsychotics (one of which must be aripiprazole); OR o Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) • Non-FDA approved uses are not approved. Prior Authorization does not expire.
• Topiramate ER (Trokendi XR and Qudexy XR) **Anti-convulsant and Anti-mania**	No change from August 2014 Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR: • Coverage approved for o Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years o Lennox-Gastaut seizures in patients ≥ 6 years for Trokendi XR and age ≥ 2 years for Qudexy XR. o Adjunctive therapy for partial onset seizure or primary generalized tonic clonic seizure in patients 2 years of age or older (Qudexy XR) or 6 years and older (Trokendi XR). • Coverage not approved for o Non-FDA approved indications, including migraine headache and weight loss • Patient is required to try topiramate first, unless the following has occurred: o Inadequate response not expected to occur with Trokendi XR or Qudexy XR o Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR
• Ixekizumab injection (Taltz)) **Targeted Immunomodulatory Biologics (TIBs)**	Changes from previous TIB automated PA criteria are bolded Step therapy and Manual PA Criteria applies to all new and current users of ixekizumab (Taltz). Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) and **secukinumab (Cosentyx)** 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 Taltz if: • Contraindications exist to Humira and **Cosentyx** • Inadequate response to Humira and **Cosentyx** • Adverse reactions to Humira and **Cosentyx** not expected with Taltz. AND

Drug / Drug Class	Prior Authorization Criteria
	Coverage approved for patients > 18 years with: • Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy Coverage NOT provided for concomitant use with other TIBS (abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, tocilizumab, rituximab or infliximab) • Prior Authorization does not expire.
• tofacitinib (Xeljanz) • **tofacitinib ER tablets (Xeljanz XR)** **Targeted Immunomodulatory Biologics (TIBs)**	Changes from previous TIB automated PA criteria are bolded. Step therapy and Manual PA Criteria applies to all new users of tofacitinib and all new users of **tofacitinib ER (Xeljanz XR).** 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 Xeljanz/Xeljanz XR if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF AND Coverage approved for patients > 18 years with: • Mod to severe active RA who have had an inadequate response or intolerance to methotrexate • Not approved for use in combination with other biologics or potent immunosuppressants (azathioprine and cyclosporine) Coverage NOT provided for concomitant use with other TIBS (abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, tocilizumab, rituximab or infliximab) • Prior Authorization does not expire.
• uridine triacetate granules (Xuriden) **Binders-Chelators-Antidotes-Overdose Agents**	Prior Authorization applies to all new and current users of Xuriden Manual PA criteria: Coverage is approved for Xuriden if: • Diagnosis of hereditary orotic aciduria • Has laboratory evidence of increased urinary orotic acid • Off label uses are NOT approved • Prior Authorization expires in 6 months. • PA criteria for renewal: Reapproval requires confirmatory test. Assay of the Transferase and decarboxylase enzymes in the patient's erythrocytes. Enzymes are pyrimidine phosphoribosyltransferase and orotidylate decarboxylase • Once confirmed, PA does not expire

<table>
<tr><th>Drug / Drug Class</th><th>Prior Authorization Criteria</th></tr>
<tr><td>

- **Grazoprevir/elbasvir (Zepatier)**

Hepatitis C Virus: Direct Acting Antiviral Subclass

</td><td>

- New users of grazoprevir (GBZ) / elbasvir (EBZ) (Zepatier) are required to undergo the PA process.
- Current users are not affected by PA; they can continue therapy uninterrupted.
- 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 genotype 1 **or 4** infection
  - o State the HCV genotype and HCV RNA viral load on the PA form
- Grazoprevir/elbasvir (Zepatier) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

<u>Treatment Regimens and Duration of Therapy</u>

- 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 16 weeks, based on the treatment regimen selected.

Table of Recommended Treatment Regimens and Duration of Therapy for grazoprevir/elbasvir (Zepatier)

<table>
<tr><th>Geno-type</th><th>Patient Population</th><th>Treatment</th><th>Duration</th></tr>
<tr><td rowspan="2">1a</td><td>Treatment naïve or experienced* <u>without</u> baseline NS5A polymorphisms</td><td>GZB / EBR</td><td>12 weeks</td></tr>
<tr><td>Treatment naïve or experienced* <u>with</u> baseline NS5A polymorphisms</td><td>GZR / EBR +RBV</td><td>16 weeks</td></tr>
<tr><td>1b</td><td>Treatment naïve or experienced*</td><td>GZR / EBR</td><td>12 weeks</td></tr>
<tr><td>1</td><td>Treatment experienced (PI)**</td><td>GZR / EBR +RBV</td><td>12 weeks</td></tr>
<tr><td rowspan="2">4</td><td>Treatment naïve</td><td>GZB / EBR</td><td>12 weeks</td></tr>
<tr><td>Treatment experienced*</td><td>GZR / EBR +RBV</td><td>16 weeks</td></tr>
<tr><td colspan="4">*Treatment experience = failed RBV and IFN treatment;
**Treatment experience = failed RBV + IFN + protease inhibitor (boceprevir, simeprevir or telaprevir) treatment;</td></tr>
</table>

Regimen other than those listed above**:** Explain the rationale for treatment and duration of therapy.
Consult the AASLD/IDSA HCV guidelines for new updates.

</td></tr>
</table>

Drug / Drug Class	Prior Authorization Criteria
• Palbociclib (Ibrance) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Ibrance. Manual PA criteria—Ibrance is approved if: A. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND B. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND C. The patient meets ONE of the following criteria (i, ii, or iii): i. The patient is a postmenopausal woman and Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR ii. The patient is a premenopausal or perimenopausal woman and meets the following conditions (a and b): a. The patient is receiving ovarian suppression/ablation with a leutinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), surgical bilateral oophorectomy, or ovarian irradiation; AND b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR iii. The patient is a man and meets the following conditions (a and b): a. The patient is receiving a leutinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]); AND b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole. Prior Authorization does not expire. Other Non-FDA approved uses are not approved
• Carbidopa/levodopa (Rytary) **Parkinson's Disease Agents**	Manual PA criteria apply to all new users of Rytary. Manual PA criteria—Rytary is approved if: • Patient has tried and failed generic controlled release formulation of carbidopa/levodopa Prior Authorization does not expire.
• Noloxegol (Movantik) **Opioid Induced Constipation (OIC) Drugs**	Manual PA criteria apply to all new users of Movantik. Manual PA criteria—Movantik is approved if: • The patient does not have any of the following contraindications to naloxegol o known or suspected gastrointestinal obstruction or at an increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation o concomitantly taking strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole) **AND** • naloxegol is being prescribed for the treatment of opioid-induced constipation (OIC) in an adult patient with chronic non-cancer pain **AND** • The patient has tried a minimum of two standard laxative therapies (e.g. Miralax, sorbitol, lactulose, Mg citrate, bisacodyl, sennosides) Prior Authorization does not expire. Non-FDA approved uses are not approved

Drug / Drug Class	Prior Authorization Criteria
• Nebivolol (Bystolic) **Beta Blockers**	Manual PA criteria apply to all new users of Bystolic. Manual PA criteria—Bystolic is approved if: • Adult with hypertension **AND** • Patient has tried and failed or is intolerant to two generic beta-blockers Prior Authorization does not expire.
• Esomeprazole/naproxen (Vimovo) • Ibuprofen/famotidine (Duexis) **NSAIDs**	Manual PA criteria apply to all new and current users of Vimovo and Duexis. Manual PA criteria—Vimovo and Duexis are approved if: • Patient requires a fixed-dose combination and cannot take the two drugs separately Prior Authorization expires after six months. Non-FDA approved uses are not approved.
• Cyclobenzaprine (Amrix) **Non-Opioid Pain Syndrome Drugs**	Manual PA criteria apply to all new and current users of Amrix. Manual PA criteria—Amrix is approved if: • Patient has tried and failed generic IR cyclobenzaprine **AND** • Patient does not have any of the following (elderly greater than age 65 years, hepatic impairment, history of urinary retention, angle-closure glaucoma, increased intraocular pressure, taking anticholinergic medications) **AND** • Is prescribed for no more than 3 weeks Prior Authorization expires after six months. Non-FDA approved uses are not approved.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Fluticasone/Salmeterol (Advair HFA) **Pulmonary Is – Inhaled corticosteroids / Long Acting Beta Agonists**	Current ▪ Retail Network: 1 inhaler (60 actuations/30 days) ▪ MTF and Mail Order Pharmacy: 3 inhalers (180 actuations/90 days) Additional Recommendation ▪ The automated setup will check for HICL + Dosage Form + Strength to allow for different strengths of the same inhalers, without exceeding recommended salmeterol doses
• Flunisolide (Aerospan) **Pulmonary Is – Inhaled Corticosteroids**	5.1g inhaler =60 inhalations; 8.9g inhaler =120 inhalations ▪ Retail Network: 5.1g-#2 inhalers/30 days; 8.9g-#1 inhaler/30 days ▪ MTF and Mail Order Pharmacy: 5.1g-#6 inhalers/90 days; 8.9g-#3 inhalers/90 days
• Tofacitinib (Xeljanz XR) **Targeted Immunomodulatory Biologics (TIBs)**	• Retail Network: 30 tabs/30 days • MTF and Mail Order Pharmacy: 60 tabs/60 days
• Ixekizumab (Taltz) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail Network: 28 days supply ▪ MTF and Mail Order Pharmacy: 56 days supply
• Secukinumab (Cosentyx) **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail Network: 28 days supply ▪ MTF and Mail Order Pharmacy: 56 days supply
• Grazoprevir/elbasvir (Zepatier) **Hepatitis C Virus – Direct Acting Agent**	▪ Retail, MTF and Mail Order Pharmacy: 28 tablets/28 days
• Cyclobenzaprine extended-release (Amrix) **Non-Opioid Pain Syndrome Drugs**	▪ Retail, MTF, and Mail Order Pharmacy: o 15mg: #42/21 days o 30mg: #21/21 days

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
• Amphetamine ER ODT (Adzenys XR-ODT)	• ADHD Stimulants • Reviewed Nov 2015	• Mixed amphetamine salts ER (Adderall XR) • Amphetamine sulfate tablets (Evekeo)	• Treatment of ADHD in children ≥6 years	• Offers another dosage form for ADHD, but there are other options available on formulary including methylphenidate ER suspension	• NF
• Antihemophilic Factor VIII (Kovaltry)	• Antihemophilic Factors • Reviewed Feb 2010	• Eloctate • Adynovate (EHL Factor VIII)	• Hemophilia A in adults and children	• Treatment that can be dosed 2 to 3 times per week in adults, and every other day in children • Extended half-life (EHL) product, with same protein backbone as Kogenate FS (Bayer)	• UF
• Betamethasone dipropionate; calcipotriene foam (Enstilar)	• Psoriasis Agents • Not reviewed previously	• dipropionate • Calcipotriene (Sorilux) • Calcipotriene / betamethasone (Taclonex)	• Plaque psoriasis in adults	• Calcipotriene in combination with topical corticosteroids is highly effective for short-term control of plaque psoriasis • Provides for a foam which is a hair-friendly vehicles which is easier for scalp application	• UF
• Buprenorphine buccal film (Belbuca)	• Narcotic Analgesics and Combinations • Reviewed Feb 2007	• Buprenorphine transdermal (Butrans) • Tramadol (Ultram; generics)	• Severe pain requiring daily, around-the-clock, long-term opioid treatment	• An array of high potency (Schedule II) single analgesic agents are available on the UF with 12hr-ER morphine as a BCF agent	• NF
• Emtricitabine; rilpivirine; tenofovir alafenamide (Odefsey)	• Antiretroviral • Not previously reviewed	• Emtricitabine; Rilpivirine; Tenofovir (Complera	• HIV-1 infection in patients 12 years and older (weight ≥ 35kg) as initial therapy in antiretroviral naïve patients; or, to replace a stable regimen in virologically-suppressed patients AND CrCl ≥ 30ml/min	• Alternative NNRTI-based regimen option only for patients with pre-treatment HIV RNA <100,000 copies/ml and CD4 cell count >200 cells/mm^3	• UF

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
• Factor IX (Recombinant), Albumin Fusion Protein (Idelvion)	• Antihemophilic factors • Reviewed Feb 2010	• Factor IX (Recombinant), Fc Fusion Protein rFIXFc (Alprolix)	• Hemophilia B in children and adults	• 1st long-acting hemophilia B therapy to fuse factor IX to albumin • Can potentially extend infusions to once every 2 weeks	• UF
• Grazoprevir; Elbasvir (Zepatier)	• Hepatitis C Virus (HCV): Direct Acting Antiviral (DAA) • Previously reviewed	• Sofosbuvir (Sovaldi) • Simeprevir (Olysio) • Ledipasvir/ sofosbuvir (Harvoni) • Paritaprevir/ritonavir/ ombitasvir; dasabuvir (Viekira Pak) • Daclatasvir (Daklinza) • Paritaprevir/ritonavir/ ombitasvir (Technivie)	• Treatment of HCV genotypes (GT) 1 & 4 in adults	• Fifth highly potent oral DAA combination regimen for HCV genotype 1 & 4. • Has comparable efficacy and safety to Harvoni, Viekira, and DAC/SOF • Provides a treatment for patients with end stage renal disease, since there are no sofosbuvir-based regimen to treat patients with CrCl< 30mL/min.	• UF
• Ixekizumab injection (Taltz)	• TIB • Reviewed August 2014	<u>Step-preferred</u> • Adalimumab (Humira) <u>Non Step-preferred</u> • Apremilast (Otezla) • Ustekinumab (Stelara) • Apremilast (Otezla) • Secukinumab (Cosentyx)	• Adults with Moderate to severe plaque psoriasis	• Similar mechanism of action (IL-17A inhibitor), efficacy (PASI-75), and safety profile as Cosentyx. • Indirect comparisons suggest Taltz may have a higher PASI 90 than other TIBs (Cosentyx, Stelara, or Humira). • Solely indicated for plaque psoriasis. • There are 4 UF TIBs with different mechanisms of action and similar efficacy / safety profiles indicated to treat plaque psoriasis.	• NF
• Methylphenidate ER chewable tablets (QuilliChew ER)	• ADHD Stimulants • Reviewed Nov 2015	• Methylphenidate ER Suspension (Quillivant XR) • Methylphenidate OROS (Concerta)	• Treatment of ADHD: ≥6 years	• Offers another dosage form for ADHD, but there are other options available on formulary including methylphenidate ER oral suspension	• NF

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
• Tofacitinib extended release (Xeljanz XR)	• Targeted Immuno-modulatory Biologics (TIBs) • Reviewed Aug 2014	<u>Step-preferred</u> • Adalimumab (Humira) <u>Non Step preferred</u> • Apremilast (Otezla) • Golimumab (Simponi) • Secukinumab (Cosentyx) • Tofacitinib IR (Xeljanz IR) • Ustekinumab (Stelara)	• Moderate to severe rheumatoid arthritis in adults who are methotrexate-inadequate responders or intolerant	• Same active ingredient as tofacitinib (Xeljanz) but XR-released mechanism is a hard inert shell with hole • Xeljanz XR 11 mg once daily is pharmacokinetically equivalent to Xeljanz 5 mg administered twice daily	• UF
• Uridine triacetate granules (Xuriden)	• Binders-Chelators-Antidotes-Overdose Agents	• No comparators; orphan drug	• Hereditary orotic aciduria	• This is an orphan drug with no formulary alternatives.	• UF

Appendix F—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 2016	**Atypical Antipsychotics (AAPs)**	UF class review (previously reviewed May 2011)	▪aripiprazole tablets ▪quetiapine ▪quetiapine ER (Seroquel XR) ▪risperidone, risperidone ODT	▪ aripiprazole ODT and oral solution ▪ clozapine tabs and ODT (FazaClo ODT) ▪ lurasidone (Latuda) ▪ olanzapine tabs and ODT ▪ olanzapine/fluoxetine ▪ paliperidone ▪ risperidone oral solution ▪ ziprasidone	▪ asenapine (Saphris) ▪ brexpiprazole (Rexulti) ▪ cariprazine (Vraylar) ▪ iloperidone (Fanapt)	Pending singing of the minutes / 90 days The effective date is November 2, 2016	▪Manual PA applies to new and current users of brexpiprazole approved Feb 2016	▪ Updated Medical Necessity for NF agents. (See Appendix B) ▪ Note that aripiprazole was added to the BCF and lurasidone added to the UF.
May 2016	**Contraceptives: Emergency Contraceptives**	UF class review (previously reviewed Aug 2011)	▪ levonorgestrel 1.5mg (Plan B One Step, generics)	▪ levonorgestrel 0.75mg (Plan B, generics) ▪ ulipristal acetate 30mg (Ella)	▪None	Pending signing of the minutes for BCF selection	▪N/A	▪N/A
May 2016	**Anticonvulsant and Anti-Mania Drugs**	UF class review	▪ carbamazepine tabs, chewable tabs, oral susp (Tegretol, generics) ▪ carbamazepine ER tabs (Tegretol XR, generic) ▪ divalproex IR, ER and delayed release (Depakote, Depakote ER, generics; Depakote Sprinkles,)	▪ carbamazepine ER capsules (Carbatrol, generics) ▪ carbamazepine ER capsules (Equetro XR) ▪ clobazam (Onfi) ▪ eslicarbazepine (Aptiom) ▪ ethosuximide (Zarontin, generics) ▪ felbamate (Felbatol, generics) ▪ lacosamide (Vimpat) ▪ lamotrigine IR, ER, chewable tabs, (Lamictal, Lamictal XR,	▪None	N/A	▪N/A	N/A

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
			▪ phenytoin ER caps, chewable tabs, oral suspension (Dilantin, Dilantin-125, generics)	Lamictal CD, generics) ▪ lamotrigine orally dissolving tablets (Lamictal ODT) ▪ levetiracetam IR, ER, (Keppra; Keppra XR, generics) ▪ oxcarbazepine (Trileptal, generics) ▪ oxcarbazepine ER (Oxtellar XR) ▪ perampanel (Fycompa) ▪ phenytoin (Dilantin, generics) ▪ phenobarbital (Luminol, generics) ▪ primidone (Mysoline, generics) ▪ rufinamide (Banzel) ▪ topiramate IR and sprinkle (Topamax, Topamax Sprinkle, generics) ▪ topiramate ER (Trokendi XR) ▪ topiramate ER (Qudexy XR) ▪ valproic Acid (Depakene, generics) ▪ vigabatrin (Sabril) ▪ zonisamide (Zonegran, generics)				

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 2016	**Renin-Angiotensin Anti-Hypertensive Agents (RAAs)**	New Drugs Class previously reviewed Aug 2010	**ACE Inhibitors** ▪ lisinopril +/- HCTZ ▪ captopril ▪ ramipril **ACE-Inhibitor/CCB** ▪ benazepril/ amlodipine **ARBs** ▪ losartan +/- HCTZ ▪ valsartan +/- HCTZ	**ARB/Neprilysin Inhibitor** ▪ **sacubitril/valsartan (Entresto)** **ACE Inhibitors** ▪ benazepril +/- HCTZ ▪ captopril/HCTZ ▪ enalapril +/-/HCTZ) ▪ fosinopril+/- HCTZ ▪ moexipril +/- HCTZ ▪ perindopril ▪ quinapril+/- HCTZ ▪ trandolapril +/- verapamil SR **ARBs** ▪ telmisartan +/- HCTZ ▪ zilsartan (Edarbi) ▪ candesartan+/-/HCTZ ▪ eprosartan ▪ eprosartan/ HCTZ (Teveten HCT) ▪ irbesartan+/- /HCTZ ▪ olmesartan, olmesartan HCTZ (Benicar, Benicar HCT) **RAAs/CCB** ▪ telmisartan/amlodipine (Twynsta) ▪ olmesartan/amlodipine (Azor) ▪ valsartan/amlodipine (Exforge) ▪ valsartan/amlodipine/HCTZ (Exforge HCT) **Direct Renin Inhibitors** ▪ aliskiren (Tekturna) ▪ aliskiren/HCTZ (Tekturna HCT)	**DRI/CCB** ▪ aliskiren /amlodipine (Tekamlo) **ARB/CCB/HCTZ** ▪ olmesartan/ amlodipine/HCTZ (Tribenzor)	Pending signing of the minutes 60 days The effective date is September 28, 2016 for the PA	Updated PA requirements for Entresto	**Entresto PA required – 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 2016	**GI-2 Miscellaneous Drug Subclass**	New Drug Class previously reviewed Nov 2015	▪ metronidazole 250 mg and 500 mg tablets	▪ alosetron (Lotronex) ▪ fidaxomicin (Dificid) ▪ linaclotide (Linzess) ▪ lubiprostone (Amitiza) ▪ nitazoxanide (Alinia) ▪ rifaximin (Xifaxan) ▪ tegaserod (Zelnorm) – discontinued ▪ metronidazole (Flagyl, generics) ▪ neomycin ▪ vancomycin	**May 2016** ▪ **Eluxadoline (Viberzi)**	Pending singing of the minutes / 90 days The effective date is November 2, 2016	▪Manual PA applies to new and current users of eluxadoline approved Feb 2016	▪Viberzi PA updated – see Appendix C.

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

BCF: Basic Core Formulary
ECF: Extended Core Formulary
ER: extended release
IR: immediate release

Appendix G—Table of Abbreviations

AAPs	atypical antipsychotics
ACE	angiotensin converting enzyme
ADHD	attention deficit hyperactivity disorder
AED	anti-epileptic drug
ARB	angiotensin receptor blocker
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CCB	calcium channel blocker
CD	controlled delivery
CFR	Code of Federal Regulations
CMA	cost minimization analysis
Cmax	maximum (peak) plasma concentration
COPD	chronic obstructive pulmonary disease
CrCl	creatinine clearance
CV	cardiovascular
DAA	Direct Acting Antiviral Agent for Hepatitis C
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	fiscal year
GCN	generic code number
GI-2	Gastrointestinal-2 Miscellaneous Drugs
GLP1RA	glucagon-like peptide-1 receptor agonist
HCTZ	hydrochlorothiazide
HF	heart failure
IBS	irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
IM	intramuscular
IR	immediate release
LVEF	left ventricular ejection fraction
MADRS	Montgomery Åsberg Depression Rating Scale
MDD	major depressive disorder
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDA	New Drug Application
NDAA	National Defense Authorization Act
NF	nonformulary

NSAIDs	non-steroidal anti-inflammatory drugs
NYHA	New York Heart Association
OTC	over-the-counter
ODT	orally dissolving tablet
P&T	Pharmacy and Therapeutics
PA	prior authorization
PANSS	Positive and Negative Symptom Scale
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPIs	Proton Pump Inhibitors
RAAs	Renin Angiotensin-Antihypertensives Drug Class
SGLT2	sodium-glucose-co-transporter 2 inhibitor
QD	once daily
QLs	quantity limits
SC	subcutaneous
TAA	Trade Agreement Act
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs

DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

February 2016

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 10 and 11, 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 November Minutes**—VADM R.C. Bono, MC, USN, Director, DHA, approved the minutes from the November 2015 DoD P&T Committee meeting on January 29, 2016.

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. Non-Basal Insulins: Inhaled Human Insulin (Afrezza)

Background—Afrezza is rapid-acting inhaled human insulin indicated to improve glycemic control in adult patients with Type 1 or Type 2 diabetes mellitus. It is the only commercially available inhaled insulin. Afrezza has been compared head-to-head with insulin aspart (NovoLog) and was non-inferior in reducing hemoglobin A1c.

Common adverse effects include cough, throat pain or irritation, decreased pulmonary function, bronchitis, and urinary tract infection. Limitations to use of Afrezza include the need for concomitant subcutaneous basal insulin. Patients with dexterity issues may find manipulation of the small pieces of the device to be difficult.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that despite the novel drug delivery system, the inhaled insulin Afrezza offers no clinically compelling advantages over the rapid acting insulin agents currently included on the UF.

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

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: insulin aspart (NovoLog), insulin lispro (Humalog), insulin glulisine (Apidra), and inhaled insulin (Afrezza).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) inhaled insulin (Afrezza) be designated NF due to the lack of compelling clinical advantages, safety concerns, lack of long-term outcomes data, and cost disadvantage compared to the UF non-basal insulins.

2. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (PA) RECOMMENDATION***—Manual PA criteria for Afrezza were approved in May 2015 with an implementation date of October 21, 2015. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) maintaining the current PA criteria for Afrezza. See Appendix C for the full criteria.

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

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 90-day implementation period; 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 August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): Indomethacin Low Dose 20 mg and 40 mg capsules (Tivorbex)

Background—Tivorbex is a low-dose formulation of indomethacin available in 20 mg and 40 mg capsules. The formulation is intended for faster dissolution and absorption compared to other indomethacin products (indomethacin 25 mg and 50 mg; e.g., Indocin). According to the FDA, the manufacturer failed to demonstrate these theoretical advantages, as there were no significant differences in the pharmacokinetic profile when Tivorbex was compared to indomethacin. In the clinical trial used to obtain FDA approval, over 80% of patients received rescue narcotics for pain control. The Tivorbex package insert contains usual black box warnings and precautions for NSAIDs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that there were no clinical compelling advantages between Tivorbex and the other UF NSAIDs.

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

- CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: meloxicam (Mobic, generic), ibuprofen (Motrin, generic), naproxen (Naprosyn, generic), diclofenac sodium (Voltaren, generic), indomethacin (Indocin, generic), celecoxib (Celebrex, generic), diclofenac (Zorvolex), and indomethacin (Tivorbex).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) indomethacin low dose 20 mg and 40 mg capsules (Tivorbex) be designated NF, based on clinical and cost effectiveness.

2. ***COMMITTEE ACTION: MN RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Tivorbex, as well as revised MN for all current NF NSAIDs, including the following: diclofenac potassium liquid filled capsules 25 mg (Zipsor); diclofenac potassium powder packets 50 mg (Cambia); naproxen sodium 375 mg, 500 mg, and 750 mg extended release (ER) tablets (Naprelan CR, generics); mefenamic acid 250 mg capsules (Ponstel, generic); ketorolac nasal spray (Sprix); famotidine/ibuprofen (Duexis); and, diclofenac low dose 18 mg and 35 mg capsules (Zorvolex). A trial of at least three UF NSAIDs is required before MN is granted for the NF NSAIDs. See Appendix B for the full criteria.

3. ***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 period; 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 August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Long-Acting Beta Agonists (LABAs): Olodaterol Oral Inhaler (Striverdi Respimat)

Background—Olodaterol (Striverdi Respimat) is the sixth marketed LABA oral inhaler approved for maintenance treatment of moderate to severe chronic obstructive pulmonary disease (COPD). It has a long duration of action allowing for once daily dosing. There are no head-to-head trials available with olodaterol and other COPD drugs. Indirect comparisons of olodaterol with formoterol (Foradil) do not show clinically relevant differences in terms of changes in forced expiratory volume in one second (FEV_1). None of the LABAs are labeled to reduce COPD exacerbations or hospitalizations.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that other than the convenience of once daily dosing, olodaterol (Striverdi Respimat) offers no clinically compelling advantages over the existing UF LABAs. There is a high degree of therapeutic interchangeability among the LABAs.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed, comparing olodaterol with other Pulmonary II drugs. CMA results showed the following rankings from most to least cost-effective for the UF no-step scenario: olodaterol (Striverdi Respimat), salmeterol (Serevent), tiotropium (Spiriva), indacaterol (Arcapta), arformoterol inhalation solution (Brovana), and formoterol inhalation solution (Perforomist). The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that olodaterol (Striverdi Respimat) was cost effective compared with other LABA oral inhalers on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) olodaterol (Striverdi Respimat) be designated formulary on the UF, based on cost effectiveness.

   Note that salmeterol (Serevent) remains on the BCF for the LABA subclass.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Ophthalmic-1 Class: Olopatadine 0.7% Ophthalmic Solution (Pazeo)

Background—Pazeo is a dual action antihistamine/mast cell stabilizer (AH/MCS) ophthalmic agent and is the third strength of olopatadine approved for the prevention of itching associated with allergic conjunctivitis (AC). Several AH/MCS dual action agents are currently on the UF, including olopatadine 0.2% (Pataday) (once daily dosing) and olopatadine 01% (Patanol) (twice daily dosing). Generic formulations of olopatadine 0.1% (Patanol) recently entered the market.

In the placebo-controlled trials used to obtain FDA approval, Pazeo produced statistically and clinically significant results in treating ocular itching associated with AC both at the onset of action, and 24 hours after dosing. Overall, for relief of ocular itching due to AC, there do not appear to be clinically relevant differences in efficacy or safety between olopatadine 0.7% (Pazeo) and the other dual action AH/MCS agents.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 1 absent) that there were no clinically compelling advantages between Pazeo and the other UF AH/MCS dual action ophthalmic agents. A once daily olopatadine product (Pataday) is currently on the UF.

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

- CMA results showed the following rankings for the AH/MCS dual action ophthalmic agents from most to least cost-effective for the UF no-step scenario: azelastine 0.1%, olopatadine 0.1% generic, olopatadine 0.2% (Pataday), olopatadine 0.7% (Pazeo), olopatadine 0.1% (Patanol), alcaftadine (Lastacaft), and bepotastine (Bepreve).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) olopatadine 0.7% ophthalmic solution (Pazeo) be designated NF.

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

3. ***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 period; 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 August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Contraceptive Agents

Background—Two of the three Contraceptive Agents subclasses were reviewed for formulary placement; the oral contraceptive products (OCPs) and the miscellaneous contraceptives (comprised of the injection, transdermal patch, and vaginal ring). The OCPs are further sub-divided into eight categories, based on the amount of estrogen and type of progesterone contained in the product. The subclasses are outlined in Table 1 found on pages 11–14. The third subclass—the emergency contraceptives—will be reviewed for formulary placement at an upcoming meeting. The Contraceptive Agents were previously reviewed for UF placement in August 2011.

There are over 170 products in the OCPs and miscellaneous contraceptive subclasses. There is significant generic competition, and only eight branded, proprietary products that do not have generic equivalents remain in the class. The products were further classified based on 46 unique generic code number (GCN) sequence numbers. Recent entrants of note include AB-rated generic equivalents for the transdermal patch (Ortho Evra) and the multiphasic product Ortho Tri-Cyclen Lo.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 against, 0 abstained, 0 absent) the following for the OCPs and miscellaneous contraceptive subclasses:

- There are no new substantial updates to the clinical conclusions from the August 2011 Contraceptive Agents UF class review. Refer to P&T Committee meeting minutes for the full clinical effectiveness conclusion at http://www.health.mil/PandT.

- All oral and miscellaneous contraceptives are highly effective in preventing pregnancy when used as directed and have comparable efficacy benefits, as well as non-contraceptives benefits.

- New market additions since August 2011 include the replacement of former branded products with chewable formulations, introduction of a monophasic category containing 25 mcg ethinyl estradiol (EE) (e.g., Generess Fe chewable tablets), and the addition of supplements to the products, including iron (Fe) or folate. These new products do not provide clinically significant advantages or advancements in contraceptive therapy.

- Some formulations may offer better cycle control (e.g., vaginal ring), reduce adverse events associated with hormone withdrawal (e.g., extended cycle/continuous use OCPs), or provide better control of breakthrough bleeding (e.g., multiphasic OCPs).

- For the miscellaneous contraceptives, the vaginal ring and transdermal patch (NuvaRing; Xulane generic for Ortho Evra patch) offer similar contraceptive effectiveness as the OCPs. In contrast, improved contraceptive effectiveness occurs with the medroxyprogesterone injection (Depo-Provera; generic) compared to OCPs. The miscellaneous products also provide for an alternate route of administration for certain patient populations, result in sustained release of drug delivery, and offer

benefits to the patient by reducing or stopping menstrual bleeding.

- Overall, all contraceptive formulations have similar safety and adverse profiles, such as breakthrough bleeding, bloating, nausea, breast tenderness, headache, migraine, weight changes, and abnormal carbohydrate/lipid metabolism. An increased risk of venous thromboembolism may be associated with OCPs containing certain progestins (desogestrel, drospirenone) and the transdermal patch users.

- Given comparable contraceptive effectiveness among the various available contraceptive formulations and methods, factors which may affect contraceptive choice include individual patients' needs and characteristics, dosing convenience, and non-contraceptive benefits.

- The UF already contains a wide variety of oral contraceptive and miscellaneous products with various types and amounts of estrogen and progestin content, and also includes products with various regimens, phasic formulations, and routes of administration.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed to evaluate the oral and miscellaneous contraceptive subclasses, mentioned above. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed there were significant overlaps in prices across each of the nine contraceptive categories of medications.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 1 against, 1 abstained, 0 absent) the following, based on clinical and cost effectiveness:

    - **Reclassify to NF (previously UF):**
        - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate chewable (Minastrin 24 Fe chewable)
        - norethindrone acetate 0.8 mg/EE 25 mcg ferrous fumarate chewable (Generess Fe chewable; generics)

    - **Continue to Remain NF:**
        - drospirenone 3 mg/EE 20 mcg levomefolate (Beyaz)
        - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Lomedia 24 Fe; generics)
        - drospirenone 3 mg/EE 30 mcg levomefolate (Safyral)
        - norethindrone 0.4 mg/EE 35 mcg (Balziva; generics)

- norethindrone 0.4 mg/EE 35 mcg ferrous fumarate chewable (Wymzya Fe chewable; generics)
- levonorgestrel 0.09 mg/EE 20 mcg extended cycle (Amethyst; generics)
- levonorgestrel 0.15 mg/EE 30/10 mcg extended cycle (Camrese; generics)
- levonorgestrel 0.1 mg/EE 20/10 mcg extended cycle (Camrese Lo; generics)
- norethindrone acetate 1 mg/EE 10 mcg ferrous fumarate (Lo Loestrin Fe)
- norethindrone acetate 1 mg/EE 20/30/35 mcg ferrous fumarate (Tri-Legest Fe; generics)
- dienogest 2/3 mg and estradiol valerate 3/2/2/1 mg (Natazia)

- **Reclassify to UF (previously NF):**
  - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen AB-rated generics to Jolessa (including Quasense, Introvale, and Setlakin [equivalent to discontinued Seasonale])
- **Remain UF**
  - levonorgestrel 0.15 mg/EE 30 mcg extended cycle 91-day regimen (Jolessa)
  - norethindrone acetate 1 mg/EE 20 mcg ferrous fumarate (Microgestin Fe 1/20; generics)
  - norethindrone acetate 1 mg/EE 20 mcg (Microgestin 1/20 [21-day]; generics)
  - drospirenone 3 mg/EE 20 mcg (Yaz; generics)
  - levonorgestrel 0.1 mg/EE 20 mcg (Sronyx; Lutera; generics)
  - norgestrel 0.3 mg/EE 30 mcg (Low-Ogestrel; generics [equivalent to discontinued Lo/Ovral 28])
  - norethindrone acetate 1.5 mg/EE 30 mcg ferrous fumarate (Microgestin Fe 1.5/30; generics; [equivalent to Loestrin Fe 1.5/30])
  - norethindrone acetate 1.5 mg/EE 30 mcg (Microgestin 1.5/30; generics; [equivalent to Loestrin 1.5/30])
  - desogestrel 0.15 mg/EE 30 mcg (Reclipsen; Ortho-Cept; generics)
  - levonorgestrel 0.15 mg/EE 30 mcg (Levora-28; generics)
  - drospirenone 3 mg/EE 30 mcg (Yasmin; generics)
  - ethynodiol diacetate 1 mg/EE 35 mcg (Zovia 1-35E; generics)
  - norethindrone 0.5 mg /EE 35 mcg (Nortrel 0.5/35; generics)
  - norgestimate 0.25 mg/EE 35 mcg (Mononessa; generics)
  - norethindrone 1 mg/EE 35 mcg (Norinyl 1+35; generics)
  - norethindrone 1 mg + mestranol 50 mcg/EE 50 mcg (Norinyl 1+50; generics)
  - norgestrel 0.5 mg/EE 50 mcg (Ogestrel; generics)

- ethynodiol diacetate 1 mg/EE 50 mcg (Zovia 1-50E; generics)
- norethindrone 0.5/1 mg + EE 35 mcg (Necon 10/11; [equivalent to discontinued Ortho Novum])
- desogestrel 0.15 mg + EE 20/10 mcg (Azurette; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 25 mcg (Ortho Tri-Cyclen Lo; generics)
- norgestimate 0.18/0.215/0.25 mg + EE 35 mcg (TriNessa; generics)
- norethindrone 0.5/0.75/1 mg + EE 35 mcg (Necon 7/7/7; generics)
- norethindrone 0.5/1/0.5 mg + EE 35 mcg (Leena; generics)
- levonorgestrel 0.05/0.075/0.125 mg + EE 30/40/30 mcg (Trivora-28; generics)
- desogestrel 0.1/0.125/0.15 mg + EE 25 mcg (Velivet; generics)
- levonorgestrel 0.15 mg + EE 20/25/30/10 mcg (Quartette)
- norethindrone 0.35 mg (Nor-Q-D; Ortho Micronor; generics)
- etonogestrel 0.12 mg + EE 15 mcg vaginal ring (per day [NuvaRing])
- norelgestromin 150 mcg + EE 35 mcg transdermal system (per day [Xulane]; equivalent to discontinued Ortho Evra patch)
- depot medroxyprogesterone acetate 150 mg/mL IM vials (Depo-Provera vials; generic)
- depot medroxyprogesterone acetate 150 mg/mL IM syringes (Depo-Provera syringes; generic)
- depot medroxyprogesterone acetate 104 mg/0.65 mL SC (Depo-SubQ Provera 104)

[Refer to Table 1 on pages 11–14 for a complete list of the contraceptives.]

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) the contraceptive subclasses previously designated with BCF status in August 2011 should be retained on the BCF. The current BCF agents offer a wide variety of cost-effective oral progestin and estrogen contraceptives, including multiphasic formulations, which account for the highest utilization in the Military Treatment Facility (MTF) point of service (POS). The BCF products are as follows:

   - levonorgestrel 0.15 mg/EE 30 mcg extended cycle Jolessa branded generic formulation of the discontinued Seasonale remains BCF, while all other AB-rated generics to Jolessa (Quasense, Introvale, Setlakin, and generics) are reclassified as UF instead of NF
   - drospirenone 3 mg/EE 20 mcg (Yaz or equivalent)
   - levonorgestrel 0.1 mg/EE 20 mcg (Sronyx, Lutera or equivalent)
   - levonorgestrel 0.15 mg/EE 30 mcg (Levora-28 or equivalent)
   - drospirenone 3 mg/EE 30 mcg (Yasmin- or equivalent)
   - norgestimate 0.25 mg/EE 35 mcg (Mononessa or equivalent)

- norethindrone 1 mg/EE 35 mcg (Norinyl 1+35 or equivalent)
- norgestimate 0.18/0.215/0.25 mg + EE 35 mcg (TriNessa or equivalent)
- norethindrone 0.35 mg (Nor-Q-D or equivalent)

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) manual PA criteria for new users of Minastrin 24 Fe, Generess Fe, and Wymzya Fe chewable tablets, and their respective generics, to allow use for patients with special needs or those patients whose needs cannot be met with one of the formulary alternatives. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) MN criteria for the NF contraceptives. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: NF TO MAIL PROGRAM***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) adding the NF contraceptives to the list of medications excluded from the Nonformulary to Mail program.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period after signing of the minutes; and, 2) DHA send a letter to beneficiaries affected by the UF decision (applies to current users of Minastrin 24 FE and Generess Fe chewable tablets). Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Oral Contraceptives												
Monophasics with 20 mcg EE	BCF	*Alesse*	Aubra, Aviane, Falmina, Lutera, Orsythia, Levonorgestrel and Ethinyl Estradiol	AB1	Monophasic 28-days (21act + 7inert)	0.1 mg levonorgestrel	EE 20		Alesse	Low	Low	Low
	BCF	*Levlite*	Lessina, Sronyx, Levonorgestrel and Ethinyl Estradiol	AB2					Levlite	Low	Low	Low
	BCF	*Yaz*	Gianvi, Loryna, Nikki, Vestura	AB	Monophasic 28-days (24act + 4inert)	3 mg drospirenone	EE 20	Yaz		Low	Low/ Unclear	No
	UF	*Loestrin 1/20 (21)*	Gildess 1/20, Junel 1/20, Larin 1/20, Microgestin 1/20, Norethindrone and Ethinyl Estradiol	AB	Monophasic 21-days (21act)	1 mg norethindrone acetate	EE 20		Loestrin 1/20 (21)	Low	High	Medium
	UF	*Loestrin Fe 1/20*	Blisovi Fe 1/20, Gildess Fe 1/20, Junel Fe 1/20, Larin Fe 1/20, Microgestin Fe 1/20, Tarina Fe 1/20, Norethindrone and Ethinyl Estradiol Fe	AB	Monophasic 28-days (21act + 7Fe)	1 mg norethindrone acetate	EE 20	Loestrin Fe 1/20		Low	High	Medium
	NF	*Loestrin 24 Fe*	Gildess 24 Fe, Junel 24 Fe, Larin 24 Fe, Lomedia 24 Fe, Norethindrone and Ethinyl Estradiol Fe	AB	Monophasic 28-days (24act + 4Fe)	1 mg norethindrone acetate	EE 20		Loestrin 24 Fe	Low	High	Medium
	NF	*Minastrin 24 Fe*	Minastrin 24 Fe	-	Monophasic 28-days (24act + 4Fe) CHEWABLE TABLET	1 mg norethindrone acetate	EE 20	Minastrin 24 Fe		Low	High	Medium
	NF	*Beyaz*	Beyaz	-	Monophasic 28-days (24act w/ levomefolate 0.451mg + 4 levomefolate 0.451mg) [pts ≥ 14 y/o]	3 mg drospirenone	EE 20	Beyaz		Low	Low/ Unclear	No
Monophasics with 25 mcg EE	NF	*Generess Fe*	Kaitlib Fe, Layolis Fe, Norethindrone and Ethinyl Estradiol Fe	AB	Monophasic 28-days (24act + 4Fe) CHEWABLE TABLET	0.8 mg norethindrone acetate	EE 25	Generess Fe		Low	Medium	Medium
Monophasics with 30 mcg EE	BCF	*Yasmin*	Drospirenone and Ethinyl Estradiol, Ocella, Syeda, Zarah	AB	Monophasic 28-days (21act + 7inert) [patients ≥ 14 y/o]	3 mg drospirenone	EE 30	Yasmin		Low	Low/ Unclear	None
	BCF	*Levlen 28 Nordette 28*	Altavera, Chateal, Kurvelo, Levonorgestrel and Ethinyl Estradiol, Levora 28, Marlissa, Portia 28	AB	Monophasic 28-days (21act + 7inert)	0.15 mg levonorgestrel	EE 30		Levlen 28 Nordette 28	Low	Medium	Medium
	UF	*Lo-Ovral 28*	Cryselle, Elinest, Low-Ogestrel	AB	Monophasic 28 days (21act;7inert)	0.3 mg norgestrel	EE 30	Lo Ovral 28	Lo Ovral 28	Low	Medium	Medium
	UF	*Desogen Ortho-Cept*	Cyred, Apri, Desogestrel and Ethinyl Estradiol , Emoquette, Enskyce, Juliber, Isibloom, Reclipsen	AB	Monophasic 28 days (21act;7inert)	0.15 mg desogestrel	EE 30	Desogen Ortho-Cept		Low	High	Low
	UF	*Loestrin 1.5/30*	Gildess 1.5/30, Junel 1.5/30, Larin 1.5/30, Microgestin 1.5/30	AB	Monophasic 21-days (21act) [patients ≥ 15 y/o]	1.5 mg norethindrone acetate	EE 30		Loestrin 1.5/30	Low	High	High
	UF	*Loestrin Fe 1.5/30*	Blisovi Fe 1.5/30, Gildess Fe 1.5/30, Junel Fe 1.5/30, Larin Fe 1.5/30, Microgestin Fe 1.5/30	AB	Monophasic 28-days (21act + 7inert) [patients ≥ 15 y/o]	1.5 mg norethindrone acetate	EE 30	Junel Fe 1.5/30 Larin Fe 1.5/30	Loestrin Fe 1.5/30	Low	High	High
	NF	*Safyral*	Safyral	-	Monophasic 28-days (24act w/ levomefolate 0.451mg + 4 levomefolate 0.451mg) [patients ≥ 14 y/o]	3 mg drospirenone	EE 30	Safyral		Low	Low/ Unclear	None

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Monophasics with 35 mcg EE	BCF	*Norinyl 1+35 Ortho-Novum 1/35*	Alyacen, Cyclafem, Dasetta, Necon, Nortrel, Pirmella	AB	Monophasic 28-days (21act + 7inert) [patients ≥ 15 y/o]	1 mg norethindrone	EE 35	Norinyl 1+35 Ortho-Novum 1/35		Medium	High	Medium
	BCF	*Ortho-Cyclen*	Estarylla, Mono-Linyah, Mononessa, Norgestimate and Ethinyl Estradiol, Previfem, Sprintec	AB	Monophasic 28-days (21act + 7inert)	0.25 mg norgestimate	EE 35	Ortho-Cyclen		Medium	Low	Low
	UF	*Brevicon Modicon*	Cyclefem 0.5/35, Necon 0.5/35, Nortrel 0.5/35, Wera	AB	Monophasic 28-days (21act + 7inert)	0.5 mg norethindrone	EE 35	Brevicon		Medium	Low	Low
	UF	*Demulen 1-35*	Kelnor 1-35, Zovia 1-35E	AB	Monophasic 28-days (21act + 7inert)	1 mg ethynodiol diacetate	EE 35	Demulen 1-35	Demulen 1-35	Medium	High	Low
	NF	*Femcon Fe Wymzya Fe*	Zenchent Fe	AB	Monophasic 28-days (21act + 7inert) CHEWABLE TABLET	0.4 mg norethindrone	EE 35	Femcon Fe Wymzya Fe		Medium	Low	Low
	NF	*Ovcon-35*	Balziva, Briellyn, Gildagia, Philith, Vyfemla, Zenchent	AB	Monophasic 28-days (21act +7inert)	0.4 mg norethindrone	EE 35		Ovcon 35	Medium	Low	Low
Monophasics with 50 mcg Estrogen	UF	*Norinyl 1+50 Ortho-Novum*	Necon	AB	Monophasic 28-days (21act + 7inert)	1 mg norethindrone	Mestranol 50	Norinyl 1+50 Ortho-Novum	Ortho-Novum	Medium	Medium	Medium
	UF	*Demulen 1/50*	Zovia 1/50E	AB	Monophasic 28-days (21act + 7inert)	1 mg ethynodiol diacetate	EE 50		Demulen 1/50	High	High	Medium
	UF	*Ovral-28*	Ogestrel	AB	Monophasic 28-days (21act + 7inert)	0.5 mg norgestrel	EE 50		Ovral-28	High	High	High
Extended Cycle/ Continuous Use Regimen	BCF	*Seasonale*	Jolessa (Only Jolessa is BCF)	AB	Extended cycle 91-day (84act + 7inert)	0.15 mg levonorgestrel	EE 30		Seasonale	Low	Medium	Medium
	UF		Introvale, Quasense, Setlakin, Levonorgestrel and Ethinyl Estradiol									
	NF	*LoSeasonique*	Amethia Lo, Camrese Lo, Levonorgestrel and Ethinyl Estradiol	AB	Extended cycle 91-day (84act-EE20 + 7EE10 only)	0.1 mg levonorgestrel	EE 20/10	LoSeasonique		Low	Low	Low
	NF	*Lybrel*	Amethyst, Levonorgestrel and Ethinyl Estradiol	AB	Continuous 28-days regimen (Non-cyclic) (28act)	0.09 mg levonorgestrel	EE 20		Lybrel	Low	Low	Low
	NF	*Seasonique*	Amethia, Ashlyna, Camrese, Daysee, Levonorgestrel and Ethinyl Estradiol	AB	Extended cycle 91-days (84act-EE30 + 7EE10 only)	0.15 mg levonorgestrel	EE 30/10	Seasonique		Low	Medium	Medium
Multiphasics	Biphasics											
	UF	*Ortho-Novum*	Necon 10-11	-	Biphasic 28-days (10act 0.5mg + 11act 1mg + 7inert)	0.5 mg/1 mg norethindrone	EE 35		Ortho-Novum	Medium	Medium	Medium
	UF	*Mircette*	Azurette, Bekyree, Desogestrel and Ethinyl Estradiol, Kariva, Kimidess, Pimtrea, Viorele	AB	Biphasic 28-days (21act-0.15mg w/EE20 + 2inert + 5EE10 only)	0.15 mg desogestrel	EE 20/10	Mircette		Low	High	Low
	NF	*Lo Loestrin Fe*	Lo Loestrin Fe	-	Biphasic 28-day cycle (24/2/2 cycle regimen) (24act + 2EE10 only + 2Fe)	1 mg norethindrone acetate	EE 10	Lo Loestrin Fe		Low	High	Medium

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Multiphasics (Cont'd)	**Triphasics**											
	BCF	*Ortho Tri-Cyclen*	Norgestimate and Ethinyl Estradiol, Tri-Estarylla, Tri-Linyah, Trinessa, Tri-Previfem, Tri-Sprintec	AB	Triphasic 28-day cycle (7act-0.18mg; 7act 0.21mg; 7act 0.25mg; 7inert)	0.18/0.215/0.25 mg norgestimate	EE 35	Ortho Tri-Cyclen		Medium	Low	Low
	UF	*Ortho Tri-Cyclen Lo*	Tri-Lo-Estarylla, Tri-Lo-Marzia, Tri-Lo-Sprintec	AB	Triphasic 28-day cycle (7act-0.18mg; 7act 0.21mg; 7act 0.25mg; 7inert)	0.18/0.215/0.25 mg norgestimate	EE 25	Ortho Tri-Cyclen Lo		Low	Low	Low
	UF	*Cyclessa*	Caziant, Velivet	AB	Triphasic 28-day cycle (7act 0.1mg;7act 0.125mg, 7act 0.15mg, 7inert)	0.1/0.125/0.15 mg desogestrel	EE 25	Cyclessa		Low	High	Low
	UF	*Tri-Levlen 28 Triphasil-28*	Enpresse, Levonest, Elifemme, Myzilra, Trivora	AB	Triphasic 28-day cycle (6act-0.5mg+30EE; 5act 0.75mg+ 40EE; 10act 0.125mg+30EE; 7inert)	0.05/0.075/0.125 mg levonorgestrel	EE 30/40/30		Tri-Levlen 28 Triphasil-28	Medium	Low	Low
	UF	*Tri-Norinyl*	Aranelle, Leena	AB	Triphasic 28-day cycle (7act 0.5mg;9act 1mg, 5act 0.5mg; 7inert) (patients > 15 y/o)	0.5/1/0.5 mg norethindrone	EE 35	Tri-Norinyl		Medium	Medium	Medium
	UF	*Ortho-Novum 7/7/7*	Alyacen 7/7/7, Cyclafem 7/7/7, Dasetta 7/7/7, Necon 7/7/7, Nortrel 7/7/7, Pirmella 7/7/7	AB	Triphasic 28-day cycle (7act 0.5mg;7act 0.75mg, 7act 1mg, 7inert) (patients > 15 y/o)	0.5/0.75/1 mg norethindrone	EE 35	Ortho-Novum 7/7/7		Medium	Medium	Medium
	NF	*Estrostep FE*	Tilia FE, Tri-Legest FE	AB	Triphasic 28-day cycle (5act 20EE;7act 30EE, 9act 35EE, 7Fe) (patients ≥ 15 y/o)	1 mg norethindrone acetate	EE 20/30/35	Estrostep FE		Low	High	Medium
	Quadriphasics											
	UF	*Quartette*	Quartette	-	Quadriphasic 91-day (Extended cycle) (42act-20EE; 21act-25EE; 21act-30EE; 7-10EE only)	0.15 mg levonorgestrel	EE 20/25/30/10	Quartette		Low	Medium	Medium
	NF	*Natazia*	Natazia	-	Quadriphasic 28-day (2act-3mg EV only; 5act-2mg+2mg EV; 17act-3mg+2mg EV; 2act-1mg EV only; 2inert)	2 mg/3 mg dienogest	Estradiol valerate 3/2/2/1 mg	Natazia		Low	Low/ Unclear	None
Progestogen Only	BCF	*Nor-QD*	Camila, Deblitane, Heather, Nora-BE, Norethindrone, Norlyroc	AB1	Progestin Only 28-day cycle (28act)	0.35 mg norethindrone	-	Nor-QD		-	Low	Low
		Ortho Micronor Micronor	Errin, Jencycla, Jolivette, Lyza, Norethindrone, Sharobel	AB2				Ortho Micronor Micronor				

Table 1. Contraceptives Comparison Chart—February 2016

UF Subclass	Rec'd UF Status	Brand Name	Drug Name	OBC3	Cycle Regimen	Progestogen (aka Progestin)	Estrogen (mcg)	Branded NDC	Obsolete Drug	Hormone Activity		
										Estrogen	Progestin	Androgen
Non Oral Contraceptives (Transdermal Patch, Vaginal Ring, Injection)												
Miscellaneous Contraceptives	**Transdermal Patch (estrogen/progestin combination)**											
	UF	*Ortho Evra*	Xulane	AB	28 day regimen (3 patches/box) 1 patch/wk x 3 weeks; 7 days off	150 mcg/day norelgestromin	EE 35 mcg/day	Ortho Evra	Ortho Evra			
	Vaginal Ring (estrogen/progestin combination)											
	UF	*NuvaRing*	Nuvaring	-	28 day regimen (3 rings/box) 1 ring/wk x 3 weeks; 7 days off	0.12 mg/day etonogestrel	EE 15 mcg/day	Nuvaring				
	Injection (SubQ/IM) (progestin only)											
	UF	*Depo-SubQ Provera 104*	Depo-SubQ Provera 104	-	SubQ/90 days (12-14 weeks)	DMPA 104 mg/0.65mL	-	Depo-SubQ Provera 104				
	UF	*Depo-Provera*	Depot Medroxyprogesterone Acetate (DMPA)	AB	IM/90 days (13 weeks) Available as vial or syringe	DMPA 150 mg/mL	-	Depo Provera				

NOTES:

1. Drug names in GREEN are recently approved drugs with little to no DoD utilization data
2. "Brand Name" drug is for reference only; it may or may not be available on the market.
3. "Drug Name" identifies the currently available AB-rated generic equivalent products. If a generic is not available, the brand name is duplicated in this column as the sole available product.
4. "Branded NDC" indicates that there may be utilization data for a "Brand" drug. Consider dispensing a cost-effective AB-rated generic product if it is available at the Prime Vendor.
5. "Obsolete Drug" indicates that an NDC for a discontinued drug is still being used (primarily at the MTF); recommend switching to correct NDC to ensure accurate DoD utilization data.

B. Antifungals: Topical Lacquers

Background—The topical antifungal lacquers used for onychomycosis were reviewed for formulary placement, including ciclopirox 8% topical solution (Penlac, generic), efinaconazole 10% topical solution (Jublia), and tavaborole 5% topical solution (Kerydin). Comparisons to other treatment options used for onychomycosis (including oral terbinafine) were also reviewed by the P&T Committee but were not included in the formulary decision.

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

- The complete cure rates at one year with efinaconazole (Jublia) in the two pivotal trials were 17.8% and 15.2% for the active arms versus 3.3% and 5.5% in the vehicle arms, respectively. In comparison, complete cure rates at one year in the two pivotal trials with tavaborole (Kerydin) were 6.5% and 9.1% for the active arms versus 0.5% and 1.5% in the vehicle arms, respectively. Efficacy data with ciclopirox supports complete cure rates ranging from 5.5% to 8.5%. The variations in the complete cure rates achieved with Jublia, Kerydin, and ciclopirox may be explained by differences in the maximum percentage of nail involvement allowed in the trials

- Oral terbinafine (Lamisil, generics) is more effective than the topical antifungal lacquers, with complete cure rates ranging from 38% to greater than 50%.

- There is only minimal follow-up data beyond one year for Jublia and Kerydin, which limits the ability to assess recurrence rates with the newer agents, compared to other onychomycosis treatments. Data with ciclopirox show a 40% relapse rate at three months while terbinafine has a five-year relapse rate of 20%.

- The safety profiles for the topical antifungal lacquers appear similar and do not differ significantly from placebo vehicle. Both Jublia and Kerydin contain a warning regarding flammability, due to high alcohol content.

- Differences among the medication dispensers for the newer agents may result in product wastage. While tavaborole uses a simple dropper method, efinaconazole uses a brush applicator method. Ciclopirox requires removal after each continuous week of application and, unlike the newer agents, creates a tacky effect after application.

Overall Relative Clinical Effectiveness Conclusion: The treatment effect of the topical antifungals is modest at best, with complete cure rate failures exceeding 80%. The topical agents ciclopirox, efinaconazole, and tavaborole are not as effective as oral terbinafine. Overall, the newer entrants Jublia and Kerydin have a benign safety profile, but their modest clinical effectiveness should limit their use to patients who are unable to tolerate oral antifungal agents and who fail topical ciclopirox.

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 that oral terbinafine was the most cost-effective antifungal agent for onychomycosis, followed by ciclopirox 8% topical solution (Penlac; generic), and lastly followed by efinaconazole 10% topical solution (Jublia) and tavaborole 5% topical solution (Kerydin).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. Designating efinaconazole (Jublia) and tavaborole (Kerydin) as NF resulted in cost avoidance for the Military Health Service (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following:
   - UF:
     - Ciclopirox 8% topical solution (Penlac; generic)
   - NF:
     - Efinaconazole10% topical solution (Jublia)
     - Tavaborole 5% topical solution (Kerydin)

   Jublia and Kerydin were selected for NF status due to their minimal clinical advantages over ciclopirox, overall modest clinical effectiveness, and lack of cost effectiveness, particularly when compared to the clinically superior oral antifungal agent terbinafine.

   Note that as part of this recommendation, a topical lacquer was not added to the BCF. The BCF selection for the Antifungals includes clotrimazole cream (Topical Antifungals Subclass).

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

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) modifying the current PA criteria for efinaconazole (Jublia) and tavaborole (Kerydin) originally recommended at the February 2015 P&T Committee meeting (and implemented August 19, 2015). PA criteria revisions were made to ensure a trial of both a topical antifungal agent and an oral antifungal agent, prior to utilization of Jublia or Kerydin. See Appendix C for the full criteria.

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 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 August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

C. Ophthalmic Anti-Inflammatory/Immunomodulatory Agents—Ophthalmic Immunomodulatory Agents Subclass: Cyclosporine 0.05% Ophthalmic Emulsion (Restasis)

Background—The ophthalmic immunomodulatory agents have not previously been reviewed for UF placement. Restasis is the only drug currently in this subclass. There are several pipeline products in this subclass, which will be reviewed upon FDA approval. Over-the-counter (OTC) ophthalmic wetting products (artificial tears) including carboxy- and hydroxypropyl-methylcellulose (Refresh, Celluvisc); polyvinyl alcohol (Hypotears), and high viscosity formulations (Systane, glycerin, and Refresh Endura) are used for mild to moderate dry eye symptoms, but were only reviewed for cost comparisons, and are not part of the UF decision.

Restasis is FDA-approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. In 2013, the American Academy of Ophthalmology stated that cyclosporine is appropriate for use in patients who have moderate to severe dry eye disease. In two clinical studies, Restasis 0.05% demonstrated efficacy in the treatment of moderate to severe dry eye disease, showing improvements in both objective and subjective measures. Restasis is safe in the treatment of moderate to severe dry eye diseases, with ocular burning and stinging occurring most commonly.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) that Restasis demonstrated improvements in both signs and symptoms of dry eye disease.

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 that OTC ophthalmic wetting agents are the most cost effective, followed by cyclosporine 0.05% ophthalmic emulsion (Restasis).
- BIA was performed to evaluate the potential impact of designating cyclosporine 0.05% ophthalmic emulsion (Restasis) as formulary or NF on the UF. BIA results showed that designating Restasis as formulary demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 1 opposed, 0 abstained, 0 absent) cyclosporine 0.05% ophthalmic emulsion (Restasis) be designated UF.

   Note that the BCF drugs will remain Pred Forte and Pred Mild in the Ophthalmic Anti-Inflammatory/Immunomodulatory Agents—Ophthalmic Steroids Subclass.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) PA criteria for Restasis to ensure appropriate use. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD*** The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. INNOVATOR DRUGS

Background—Section 702 of the FY15 National Defense Authorization Act (NDAA) established new authority for the P&T Committee's review process of FDA newly-approved innovator drugs. The P&T Committee is provided up to 120 days to recommend tier placement for innovator drugs on the UF. During this period, innovator drugs will be assigned a classification pending status; they will be available under terms comparable to NF drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs. For additional information, see the August 2015 DoD P&T Committee meeting minutes at http://www.health.mil/PandT.

Drugs subject to the Innovator Rule are defined as new drugs that are approved by the FDA under a Biologic License Application (BLA) or New Drug Application (NDA). The NDA innovator drugs will be further defined by their chemical types to include, but not limited to, new molecular entities, new active ingredients, new dosage formulations, and new combinations.

A. Newly-Approved Innovator Drugs

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost effectiveness analysis presented for the innovator drugs. For the complete list of innovator drugs reviewed at the February 2016 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, see Appendix E.

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

   - UF:
     - Asfotase alfa injection (Strensiq)
     - Elvitegravir/cobicistat/emtricitabine/tenofovir/alafenamide (Genvoya)
     - Naloxone nasal spray (Narcan Nasal)
     - Selexipag (Uptravi)
     - Patiromer (Veltassa)
     - Cobimetinib (Cotellic)
     - Ixazomib (Ninlaro)
     - Osimertinib (Tagrisso)
     - Alectinib (Alecensa)
     - Coagulation Factor X injection (Coagadex)
     - Antihemophilic factor, recombinant (rFVIII) injection (Adynovate)

   - NF:
     - Aspirin ER 162.5 mg (Durlaza)
     - Meloxicam low dose 5 mg and 10 mg (Vivlodex)
     - Rolapitant (Varubi)
     - Insulin degludec (Tresiba)
     - Amphetamine ER oral suspension (Dyanavel XR)
     - Glycopyrrolate oral inhaler (Seebri Neohaler)
     - Indacaterol/glycopyrrolate oral inhaler (Utibron Neohaler)

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) MN criteria for aspirin ER 162.5 mg (Durlaza), meloxicam low dose 5 mg and 10 mg (Vivlodex), rolapitant (Varubi), insulin degludec (Tresiba), amphetamine ER oral suspension (Dyanavel XR), glycopyrrolate oral inhaler (Seebri Neohaler), and indacaterol/glycopyrrolate oral inhaler (Utibron Neohaler). See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) PA criteria for asfotase alfa injection (Strensiq). Strensiq is an orphan drug indicated for treatment of perinatal/infantile and juvenile-onset hypophosphatasia (HPP). This rare disease has a 50% mortality rate in infants who manifest within six months. No formulary alternative is available. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) an effective date upon signing of the minutes in all points of service.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

B. Newly-Approved Innovator Drugs—Program Updates

Two administrative function updates were proposed for the innovator drug process, as outlined below.

1. **INNOVATOR DRUGS WITH NO FORMULARY ALTERNATIVE TO ADJUDICATE AS UF**—Currently, the DHA's Pharmacy Operations Division (POD) defines drug classes and assigns drugs to a UF class as part of the administrative processes required for the day-to-day operation of the UF. When a drug is assigned to a specific UF drug class, the formulary alternatives for the drug are also identified. A formulary agent is defined as a drug from the same drug class or used for the same indication as the NF drug.

   Innovator drugs are designated as NF (Tier 3 copayment) upon market entry. All NF medications, including innovator drugs, have MN criteria that establish clinical necessity based on 32 CFR Sec. 199.2. One of the criteria for MN approval is that there is no alternative pharmaceutical agent on the formulary. Some innovator drugs may have no UF alternatives, and a provider must document clinical necessity to obtain the drug when clinically necessary for each individual patient. The recommended authority below removes this requirement and the associated NF copayments when no alternative pharmaceutical agent exists on the UF.

   a) ***COMMITTEE ACTION: INNOVATOR DRUGS WITH NO FORMULARY ALTERNATIVE TO ADJUDICATE AS UF***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent):

      (1) The DHA POD, after consultation with a physician who is a DoD P&T Committee member or MHS specialist, may direct innovator products with no formulary alternative be made available under Tier 2 terms of the TRICARE pharmacy benefit, prior to a formal vote from the P&T Committee; and,

      (2) All innovator products, including those that the POD has determined have no formulary alternative, be reviewed by the P&T Committee at the next available meeting.

2. **DESIGNATION OF TEMPORARY SPECIFIC MN AND PA CRITERIA FOR INNOVATOR DRUGS**—General MN criteria for the Innovator program were approved at the August 2015 DoD P&T Committee meeting. While the general MN criteria are applicable to many of the innovator drugs, in certain cases more specific MN criteria are needed. Current DoD P&T processes may result in lengthy implementation periods for both MN and PA criteria for innovator drugs when they are formally reviewed by the DoD P&T Committee. The recommended authority below will allow the DHA POD to develop specific MN criteria (and PA criteria, if needed) for certain innovator drugs immediately after FDA approval and prior to market launch.

   a) ***COMMITTEE ACTION: DESIGNATION OF TEMPORARY SPECIFIC MN AND PA CRITERIA FOR INNOVATOR DRUGS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent):

      (1) The DHA POD has authority to administratively implement temporary specific MN/PA criteria on select innovator drugs at the time of product launch, using information available from the FDA (e.g., product labeling, FDA advisory committee recommendations, FDA drug safety board), from peer-reviewed national guidelines, or from the manufacturer.

      (2) Physicians who are P&T Committee members or MHS specialists will be consulted prior to implementation.

      (3) The temporary specific MN/PA criteria will only be active until the formal P&T Committee review process is complete (i.e., P&T Committee recommendations made during the next available meeting are implemented after approval by the DHA Director).

      (4) Implementation of permanent criteria will become effective upon signing of the minutes. All users who have established temporary specific MN/PA criteria will be grandfathered when the permanent criteria become effective, unless directed otherwise.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Gastrointestinal-2 (GI-2) Miscellaneous Drugs: Eluxadoline (Viberzi) Manual PA Criteria**—The GI-2 Miscellaneous Drug Class was reviewed by the P&T Committee in

November 2015. At the time of the November 2015 meeting, eluxadoline (Viberzi) was approved by the FDA but not yet commercially available.

Eluxadoline is a mixed mu-opioid receptor agonist that is FDA-approved for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). Because of the mechanism of action, several contraindications and warnings exist for the product, in addition to the potential for abuse. PA criteria was recommended for Viberzi due to the safety issues. Additionally, PA criteria also apply for rifaximin for treatment of IBS-D.

a) ***COMMITTEE ACTION: ELUXADOLINE (VIBERZI) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Viberzi in all new patients, consistent with the new FDA-approved product labeling and safety warnings. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: ELUXADOLINE (VIBERZI) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

2. **Atypical Antipsychotics (AAPs): Brexpiprazole (Rexulti) Manual PA Criteria**
The AAPs, also known as the second generation antipsychotics, were reviewed by the P&T Committee in May 2011. Brexpiprazole is a new entrant to the class, and is FDA-approved for treating schizophrenia and as adjunct to antidepressant therapy for major depressive disorder. Brexpiprazole has serotonergic and dopaminergic effects similar to other AAPs.

   Manual PA criteria were recommended for Rexulti due to the similar mechanism of action and FDA labeling as aripiprazole (Abilify), which recently became available in generic formulations. The AAPs will be re-reviewed for formulary status at the May 2016 DoD P&T Committee meeting.

   a) ***COMMITTEE ACTION: BREXPIPRAZOLE (REXULTI) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for brexpiprazole (Rexulti) in all new patients. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: BREXPIPRAZOLE (REXULTI) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

3. **Anticonvulsants: Lacosamide (Vimpat) Manual PA Criteria**—Lacosamide (Vimpat) was approved in 2008 and only has one FDA-approved indication for treating partial onset seizures. Because of the concern for off-label use, PA criteria were recommended. The Anticonvulsant Drug Class has not been previously reviewed by the P&T Committee, but will be reviewed for formulary placement at the May 2016 DoD P&T Committee meeting.

    a) ***COMMITTEE ACTION: LACOSAMIDE (VIMPAT) MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for lacosamide (Vimpat) in all new patients, consistent with the new FDA-approved product labeling. See Appendix C for the full criteria.

    b) ***COMMITTEE ACTION: LACOSAMIDE (VIMPAT) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

4. **Renin-Angiotensin-Antihypertensive Agents (RAAs): Sacubitril/Valsartan (Entresto) Automated and Manual PA Criteria**—The RAAs class was previously reviewed by the P&T Committee in May 2010. Automated (step therapy) criteria apply, requiring a generic angiotensin converting enzyme (ACE) inhibitor or preferred angiotensin receptor blocker (ARB), prior to use of a non-step preferred ACE inhibitor or ARB.

    Entresto is a new fixed-dose combination product containing the ARB valsartan (Diovan) and sacubitril, a neprilysin inhibitor. Sacubitril is a prodrug that inhibits neprilysin (neutral endopeptidase) through the active metabolite, leading to increased levels of peptides, including natriuretic peptides.

    Entresto is FDA-approved to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (New York Heart Association [NYHA] class II-IV) and a decreased left ventricular ejection fraction (LVEF). Several ACE inhibitors and the ARBs valsartan and candesartan (Atacand, generic) are indicated for patients with heart failure due to decreased LVEF.

    a) ***COMMITTEE ACTION: SACUBITRIL/VALSARTAN (ENTRESTO) AUTOMATED AND MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) automated and manual PA for Entresto in all new and current users, consistent with the current step therapy requirements for the RAAs class, and FDA labeling for Entresto. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: SACUBITRIL/ VALSARTAN (ENTRESTO) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is August 10, 2016.

5. **Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx) 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 (implemented on December 17, 2014). Secukinumab (Cosentyx) was reviewed by the P&T Committee in February 2015; automated and manual PA criteria were recommended (and implemented on May 4, 2015). In August 2015, Cosentyx was reviewed as a newly-approved drug for treating plaque psoriasis and was recommended for formulary status on the UF, requiring a trial of adalimumab (Humira), the step-preferred TIB, first.

   Secukinumab (Cosentyx) received a new FDA indication in January 2016 for treatment of psoriatic arthritis and ankylosing spondylitis in adults. The PA criteria were updated for Cosentyx to reflect the new FDA indication.

   a) ***COMMITTEE ACTION: SECUKINUMAB (COSENTYX) PA CRITERIA*** The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) revised manual PA criteria for secukinumab (Cosentyx) in new patients, consistent with the new FDA-approved product labeling for psoriatic arthritis and ankylosing spondylitis. See Appendix C for the full criteria.

   b) ***COMMITTEE ACTION: SECUKINUMAB (COSENTYX) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) implementation of the PA for secukinumab (Cosentyx) become effective upon signing of the minutes.

B. Quantity Limits (QLs)

Quantity limits were reviewed for eight drugs: cobimetinib (Cotellic) for unresectable or metastatic melanoma, osimertinib (Tagrisso) and alectinib (Alecensa) for non-small cell lung cancer (NSCLC), ixazomib (Ninlaro) for relapsed or refractory multiple myeloma, and four inhalers for COPD including glycopyrrolate oral inhaler (Seebri Neohaler), glycopyrrolate/indacaterol oral inhaler (Utibron Neohaler), tiotropium bromide (Spiriva Respimat), and fluticasone/vilanterol (Breo Ellipta Institutional Pack).

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) QLs for cobimetinib (Cotellic), osimertinib (Tagrisso), alectinib (Alecensa), ixazomib (Ninlaro), glycopyrrolate oral inhaler (Seebri Neohaler), glycopyrrolate/indacaterol oral inhaler (Utibron Neohaler),

tiotropium bromide (Spiriva Respimat), and fluticasone/vilanterol (Breo Ellipta Institutional Pack). See Appendix D for the QLs.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. 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 the 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 require pre-authorization prior to use in the retail point of service (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 maintaining the current NF status for the following two products:
   - 13 for, 0 opposed, 0 abstained, 2 absent: Sebela Pharmaceuticals: calcitonin-salmon (Miacalcin), 200 International Units (3.7 mL) nasal spray. Note that Miacalcin nasal spray was designated NF when the osteoporosis drugs were reviewed at the June 2008 DoD P&T Committee meeting. Miacalcin will now require pre-authorization at the retail POS.
   - 14 for, 0 opposed, 0 abstained, 1 absent: Vanda Pharmaceuticals: tasimelteon (Hetlioz), 20 mg capsule. Note that Hetlioz was designated as NF at the February 2015 DoD P&T Committee meeting, with manual PA criteria and MN criteria.

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA FOR MIACALCIN NASAL SPRAY***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) the following pre-authorization criteria for Miacalcin 200 International Units (3.7 mL) nasal spray.

   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.

C. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA FOR HETLIOZ***
Note that tasimelteon (Hetlioz) will not be available in the Mail Order Pharmacy, as it

is only available in the Retail Network via a restricted distribution process, thus pre-authorization criteria do not apply.

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 1 absent) to maintain the existing PA criteria and MN criteria for tasimelteon (Hetlioz) from the February 2015 DoD P&T Committee meeting. See the February 2015 P&T Committee meeting minutes at http://www.health.mil/PandT.

D. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA FOR MIACALCIN***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday after a 30-day implementation period in the Retail Network for Miacalcin nasal spray; and 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation the effective date is June 8, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

IX. OTC DRUG REVIEW

A. Doxylamine

Section 702 of the FY13 NDAA provides legislative authority for the OTC Drug Program. The Final Rule published in the Federal Register on July 27, 2015, establishes the process for identifying OTC products for coverage under the TRICARE pharmacy benefit and the rules for making these products available to eligible DoD beneficiaries. The Final Rule can be found at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy.

The approved OTC drugs will comply with the mandatory generic policy stated in 32 CFR 99.21(j)(2) and be available under terms similar for generic drugs, except that the need for a prescription and/or a copayment may be waived in some circumstances. No cost-sharing for OTC drugs is required at any of the three POS for a uniformed service member on active duty.

Background—The P&T Committee evaluated the relative clinical and cost effectiveness and patient access considerations of adding doxylamine 25 mg (Unisom, generic) to the UF via the OTC Drug Program. Doxylamine has not previously been covered as a TRICARE pharmacy benefit under the OTC Demonstration Project; it is the first OTC drug to be considered under the new legislation.

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

- Doxylamine 25 mg (Unisom, generics) is available OTC as a sleep aid but is frequently used for treating nausea and vomiting of pregnancy (NVP), along with pyridoxine (vitamin B6). A prescription product, Bendectin, containing doxylamine and pyridoxine was discontinued from the market in the 1980s.
- In May 2015, the P&T Committee recommended NF status for Diclegis, a prescription product containing delayed release doxylamine succinate and pyridoxine, based on clinical and cost effectiveness. Manual PA criteria were also recommended, requiring a trial of nonpharmacologic interventions and OTC pyridoxine, and consideration of alternate antiemetics.
- The May 2015 P&T Committee also found the OTC ingredients of doxylamine with or without pyridoxine were therapeutically equivalent to Diclegis.
- Input from MTF obstetrics and gynecology providers voiced concern regarding worldwide availability of OTC doxylamine at all MTFs, and the potential for confusion due to the various OTC formulations of the product available in the retail setting (other products with the name "sleep aid" contain diphenhydramine).
- A trial conducted by the manufacturer of Bendectin in 1975 showed doxylamine monotherapy to be as effective and, in some endpoints, more effective than any other combination or monotherapy agent (e.g., doxylamine/pyridoxine, pyridoxine) for treating NVP.
- The September 2015 American College of Obstetrics and Gynecology (ACOG) Practice Bulletin also supports doxylamine for first-line use in the treatment of nausea and vomiting of pregnancy.
- Advantages of OTC doxylamine include its pregnancy category A rating, and the long history of efficacy and safety in both the OTC and prescription setting for treating NVP. Disadvantages include the sedating effects and need for multiple daily dosing, which may be a significant concern for some patients in setting of NVP.
- Providing doxylamine as an OTC TRICARE pharmacy benefit allows uniform availability of the product, and would enhance obstetric care and be consistent with the recently updated ACOG guidelines.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) OTC doxylamine 25 mg was less costly than the NF product Diclegis.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) adding OTC doxylamine 25 mg to the UF, based on clinical and cost effectiveness. As part of this recommendation, a prescription will be required for OTC doxylamine. Additionally, an age limit of patients less than 65 years of age was also recommended, to ensure appropriate use in accordance with Beers Criteria (a list of medications considered inappropriate for use in patients older than 65 years, due to the risk of adverse effects).

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) adding OTC doxylamine 25 mg to the BCF to ensure uniform patient access at all MTFs.

3. ***COMMITTEE ACTION: COPAYMENT WAIVER***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) waiving the copayment requirement for OTC doxylamine 25 mg. The copayment waiver was recommended because doxylamine is considered an acute use drug, with the majority of utilization expected at the MTFs and Retail Network pharmacies. Additionally, waiving the copayment would encourage use of the most cost-effective option for NVP and potentially shift utilization from agents with concerning safety profiles.

4. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 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 July 6, 2016

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

X. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM (EXPANDED MTF/MAIL PHARMACY INITIATIVE), AND NF (TIER 3) PHARMACEUTICALS AT MAIL ORDER

The P&T Committee was briefed on the initial implementation of the Expanded MTF/Mail Pharmacy Initiative, which began October 1, 2015, as well as ongoing implementation of the requirement that NF pharmaceutical agents be generally not available at MTFs or the Retail Network, but available in the Mail Order program.

For more information on these two programs, refer to the August 2015 and November 2015 DoD P&T Committee meeting minutes, available at http://www.health.mil/PandT. Page 10 also discusses the recommended exception to the latter requirement for NF contraceptives that would allow their continued availability at the retail POS.

The P&T Committee reviewed four drugs and agreed that the branded agents gabapentin (Gralise) and ibuprofen/famotidine (Duexis) are suitable for mail order dispensing (the acute use exception does not apply), and that tasimelteon (Hetlioz) and V-Go (a disposable insulin delivery device) are unable to be dispensed at mail order due to availability limitations.

XI. ITEMS FOR INFORMATION

The P&T Committee was briefed on the draft DoD/Veterans Affairs (VA) Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715.

XII. ADJOURNMENT

The meeting adjourned at 1145 hours on February 11, 2016. The next meeting will be in May 2016.

Appendix A—Attendance: February 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—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary

Appendix G—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.

R.C. Bono
VADM, MC, USN
Director

160505
Date

Appendix A—Attendance: February 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, M.S.	Chief, DHA Operations Management Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
COL Jack Lewi, MC	Army, Internal Medicine Physician
Col William Hannah, MC	Air Force, Internal Medicine Physician
CDR Brian King, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ John Poulin, MC	Army, Physician at Large
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
Mr. Bruce Mitterer	DHA Contract Operations Division
Ms. Tammera Cardinal	DHA Contract Operations Division
MAJ Randall Sweeney	Defense Logistics Agency Troop
Ms. Amanda Doherty	Defense Logistics Agency Troop
CAPT Matt Baker	Indian Health Service
Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch
MAJ Aparna Raizada, MS	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

Appendix A—Attendance (continued)

Others Present	
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
David Meade, PharmD via DCS	DHA Integrated Utilization Branch
Robert Conrad, PharmD via DCS	DHA Operations Management Branch
LT Teisha Robertson via DCS	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Diana Loffgren	University of Texas Pharmacy Student
Caroline Kim	University of Maryland Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• Inhaled human insulin (Afrezza) **Non-Basal Insulins**	• Patient has experienced significant adverse effects from the formulary alternatives that are not expected to occur with Afrezza **Formulary Alternatives:** insulin aspart (NovoLog), insulin aspart 70/30 (NovoLog Mix), insulin lispro (Humalog), and insulin glulisine (Apidra),
• **Indomethacin low Dose 20 mg and 40 mg Capsules (Tivorbex)** • **Meloxicam Low Dose 5 mg and 10 mg Capsules (Vivlodex)** • Diclofenac potassium liquid filled capsules 25 mg (Zipsor) • Diclofenac potassium powder packets 50 mg (Cambia) • Naproxen sodium ER 375-, 500, & 750 mg (Naprelan CR, generics) • Mefenamic acid 250 mg (Ponstel, generic) • Ketorolac nasal spray (Sprix) • Famotidine/ibuprofen (Duexis) • Diclofenac low dose 18 mg and 35 mg capsules (Zorvolex) **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**	• Patient has experienced significant adverse effects from at least three formulary NSAIDs **Formulary Alternatives:** ibuprofen 400, 600 & 800 mg tablets and 125 mg/5 mL suspension (generic), indomethacin 25 & 50 mg (generic), meloxicam 7.5 mg & 15 mg (generic), naproxen 250 mg & 500 mg (generic), celecoxib (Celebrex generics), diclofenac potassium tablets (Cataflam generic), diclofenac sodium tablets (Voltaren generic), diclofenac/misoprostol (Arthrotec), naproxen sodium 275 mg & 550 mg (Anaprox, generic), naproxen/esomeprazole (Vimovo), diflunisal, etodolac, fenoprofen, flurbiprofen, ketoprofen, ketorolac, meclofenamate, nabumetone, oxaprozin, piroxicam, sulindac, tolmetin
• Olopatadine 0.7% ophthalmic solution (Pazeo) **Ophthalmic-1 Class: Ophthalmic Antihistamines/ Mast Cell Stabilizers**	• Use of formulary ophthalmic antihistamine/mast cell stabilizers are contraindicated • Use of formulary ophthalmic antihistamine/mast cell stabilizers have resulted in therapeutic failure **Formulary Alternatives:** olopatadine 0.1% (Patanol, generic), olopatadine 0.2% (Pataday), azelastine (Optivar), bepotastine (Bepreve), emedastine (Emadine), epinastine (Elestat)
• Efinaconazole 10% topical solution (Jublia) • Tavaborole 5% topical solution (Kerydin) **Antifungals: Topical Lacquers**	• Use of formulary agents is contraindicated **Formulary Alternatives:** ciclopirox 8% topical solution (Penlac, generic), oral terbinafine (Lamisil)
• Aspirin extended release 162.5 mg (Durlaza) **Antiplatelets**	• Patient cannot take over the counter (OTC) aspirin, clopidogrel, prasugrel (Effient), or ticagrelor (Brilinta) due to the following reasons: (Prescriber must supply a reason on the Medical Necessity Form.) **Formulary Alternatives:** OTC aspirin 325 mg and 81 mg, OTC enteric coated aspirin (Ecotrin, generic), OTC buffered aspirin (Bufferin, generic), clopidogrel (Plavix, generic), prasugrel (Effient), ticagrelor (Brilinta); aspirin 25 mg/dipyridamole 200 mg (Aggrenox); persantine

Drug / Drug Class	Medical Necessity Criteria
• Rolapitant (Varubi) **Antiemetic-Antivertigo Agents**	• Patient has experienced or is likely to experience significant adverse effects from the formulary agent. • Use of formulary agent has resulted in therapeutic failure. • Patient previously responded to Varubi and changing to a formulary agent would incur unacceptable risk. **Formulary Alternatives:** aprepitant (Emend)
• Insulin degludec (Tresiba) **Basal Insulins**	• Use of all the formulary long-acting (basal) insulins have resulted in therapeutic failure. **Formulary Alternatives:** insulin glargine (Lantus), insulin detemir (Levemir), Novolin N, Humulin N
• Amphetamine ER oral suspension (Dynavel XR) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	• Use of formulary ADHD stimulants is contraindicated • Patient has experienced significant adverse effects from formulary ADHD stimulants • Use of the formulary stimulants has resulted in therapeutic failure **Formulary Alternatives:** mixed amphetamine salts XR (Adderall XR, generic), methylphenidate ER oral suspension (Quillivant XR)
• Glycopyrrolate oral inhaler (Seebri Neohaler) **Long-Acting Muscarinic Antagonist (LAMAs)**	• The patient has experienced significant adverse effects from formulary drugs. **Formulary Alternatives:** tiotropium (Spiriva), aclidinium (Tudorza), umeclidinium (Incruse Ellipta)
• Indacaterol/Glycopyrrolate oral inhaler (Utibron Neohaler) **Long-Acting Beta Agonist (LABA)/LAMA**	• The patient has experienced significant adverse effects from formulary drugs. **Formulary Alternatives:** vilanterol/umeclidinium (Anoro Ellipta), olodaterol (Incruse Ellipta) used with tiotropium (Spiriva), olodaterol/tiotropium (Stiolto Respimat)
• Norethindrone acetate 1mg/ EE 20 mcg (Minastrin 24 Fe chewable) **Oral Contraceptive Products**	• No alternative formulary agent—Patient requires the nonformulary chewable contraceptive due to established swallowing difficulties. **Formulary Alternatives:** See Table 1 on pages 11–14 for the list of other contraceptive products available on the Uniform Formulary containing EE 20 mcg.
• Norethindrone acetate 0.8 mg/ EE 25 mcg (Generess Fe chewable, generics) **Oral Contraceptive Products**	• No alternative formulary agent—Patient requires the nonformulary chewable contraceptive due to established swallowing difficulties. • No alternate formulary agent—Patient's needs cannot be met with either a monophasic contraceptive with EE 20 mcg or EE 30 mcg, OR a multiphasic with EE 25 mcg. **Formulary Alternatives:** **Monophasic + EE 20 mcg**—norethindrone acetate 1 mg/EE 20 mcg (Microgestin Fe 1/20, generics; Microgestin 1/20, generics); levonorgestrel 0.1 mg/EE 20 mcg (Sronyx, Lutera, generics); drospirenone 3 mg/EE 20 mcg (Yaz, generics)

Drug / Drug Class	Medical Necessity Criteria
	Formulary Alternatives: (continued) **Monophasic + EE 30 mcg**—norethindrone acetate1.5 mg/EE 30 mcg (Microgestin Fe 1.5/30, generics; Microgestin 1.5/30, generics); levonorgestrel 0.15mg/EE 30 mcg (Levora-28, generics); drospirenone 3 mg/EE 30mcg (Yasmin, generics); norgestrel 0.3 mg/EE 30 mcg (Low-Ogestrel, generics); desogestrel 0.15 mg/EE 30 mcg (Reclipsen, Ortho Cept, generics) **Multiphasic + EE 25 mcg**—desogestrel 0.1/0.125/0.15 mg/EE 25 mcg (Velivet, generics); norgestimate 0.18/0.215/0.25 mg/EE 25 mcg (Ortho Tri-Cyclen Lo, Tri-Lo-Sprintec, generics)
• Norethindrone 0.4 mg/EE 35 mcg (Wymzya Fe chewable, generics) **Oral Contraceptive Products**	• No alternative formulary agent—Patient requires the nonformulary chewable contraceptive due to established swallowing difficulties. • No alternate formulary agent—Patient's needs cannot be met with either a monophasic contraceptive with EE 35 mcg OR a multiphasic with EE 35 mcg **Formulary Alternatives:** **Monophasic + EE 35 mcg**—norethindrone 0.5 mg/EE 35 mcg (Nortrel, 0.5/35, generics); norethindrone 1 mg/EE 35 mcg (Norinyl 1+35, generics); norgestimate 0.25 mg/EE 35 mcg (Mononessa, generics); ethynodiol diacetate 1 mg/EE 35 mcg (Zovia 1-35E, generics) **Multiphasic + EE 35 mcg**—norethindrone 0.5/1/0.5 mg/EE 35mcg (Leena and generics); norethindrone 0.5/0.75/1 mg/EE 35 mcg (Necon 7/7/7, Ortho-Novum 7/7/7, generics); norgestimate 0.18/0.215/0.25 mg/EE 35 mcg (TriNessa, Tri-Sprintec, generics)
• Drospirenone 3 mg/EE 20 mcg (Beyaz) • Norethindrone acetate 1 mg/EE 20 mcg (Lomedia 24 Fe; generics) • Drospirenone 3 mg/EE 30 mcg (Safyral) • Norethindrone 0.4 mg/EE 35 mcg (Balziva; generics) • Levonorgestrel 0.09 mg/EE 20 mcg (Amethyst; generics) • Levonorgestrel 0.15 mg/EE 30/10 mcg (Camrese; generics) • Levonorgestrel 0.1 mg/EE 20/10 mcg (Camrese Lo; generics) • Norethindrone acetate 1 mg/EE 10 mcg (Lo Loestrin Fe) • Norethindrone acetate 1 mg/EE 20/30/35 mcg (Tri-Legest Fe; generics) • Dienogest 2/3 mg and estradiol valerate 3/2/2/1 mg (Natazia) **Oral Contraceptive Products**	• The patient cannot be treated with formulary oral contraceptives due to the following reasons: (Prescriber must supply a reason on the Medical Necessity Form.) **Formulary Alternatives:** See Table 1 on pages 11–14 for the list of other contraceptive products available on the Uniform Formulary

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Inhaled insulin (Afrezza) **Insulins**	Manual PA criteria apply to all new and current users of Afrezza. Coverage is approved for non-smoking patients with either: **Type 1 Diabetes Mellitus (diagnosed)** • Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting subcutaneous (SC) insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin • Afrezza is used as adjunctive treatment to current basal insulin therapy • Spirometry testing [baseline forced expiratory volume in the first second (FEV_1) upon initiation with repeated FEV_1 at 6 months after initiation and repeated annually thereafter] has been performed **Type 2 Diabetes Mellitus (diagnosed)** • Failure to achieve hemoglobin A1C ≤ 7 % in 90 days of use of a rapid or short-acting SC insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin • Failure of or clinically significant adverse effect to two oral anti-diabetic agents (i.e., sulfonylurea, TZD, or DPP-4 inhibitor) if metformin is contraindicated • Spirometry testing (baseline FEV_1 upon initiation with repeated FEV_1 at 6 months after initiation and repeated annually thereafter) has been performed. Contraindications to the use of Afrezza: hypoglycemia, chronic lung disease [asthma, chronic obstructive pulmonary disease (COPD)], hypersensitivity to regular human insulin, or any Afrezza excipients PA does not expire.
• Efinaconazole 10% (Jublia) and tavaborole 5% (Kerydin) topical solutions **Topical Antifungals**	PA criteria apply to all new and current users of efinaconazole (Jublia) and tavaborole (Kerydin). (Updates are bolded.) Manual PA criteria: Jublia and Kerydin are approved if all of the following criteria apply: 1. The patient must have diagnostically confirmed onychomycosis by either potassium hydroxide (KOH) preparation, fungal culture, nail biopsy, or other assessment to confirm diagnosis. 2. The patient is immunocompromised, has diabetes mellitus or peripheral vascular disease and has swelling and/or redness in the surrounding nail tissue or pain in affected nail(s). 3. **The patient must have tried ciclopirox (Penlac) and had therapeutic failure AND** 4. **The patient must have tried one of the following oral agents: itraconazole (Sporonax) or terbinafine (Lamisil) and had therapeutic failure OR** • the patient has a contraindication (renal impairment, pre-existing liver disease, or evidence of ventricular dysfunction such as CHF) to one of the above antifungal agents, OR • the patient has had an adverse event/intolerance to one of the above antifungal agents 5. Treatment is requested due to a medical condition and not for cosmetic

Drug / Drug Class	Prior Authorization Criteria
	purposes. Examples include the following: • patients with history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis • diabetic patients with additional risk factors for cellulitis • patients who experience pain/discomfort associated with the infected nail 6. The patient's condition is causing debility or a disruption in their activities of daily living. 7. . Have Jublia or Kerydin been used in the previous 24 months? If no, PA not approved. If yes, then proceed to next question. 8. Have Jublia or Kerydin been used in the past 30 days? If no, PA not approved; if yes, then PA is approved. PA expires after 1 year.
• Norethindrone acetate 1mg/ EE 20 mcg (Minastrin 24 Fe chewable) **Oral Contraceptive Products**	Manual PA criteria apply to all new users of Minastrin 24 Fe chewable tablets. Manual PA criteria: Coverage is approved for Minastrin 24 Fe chewable tablets if: • The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty. PA does not expire.
• Norethindrone acetate 0.8 mg/ EE 25 mcg (Generess Fe chewable, generics) **Oral Contraceptive Products**	Manual PA criteria apply to all new users of Generess Fe chewable tablets and generics. Manual PA criteria: Coverage is approved for Generess Fe chewable and generics if: • The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty. OR • Patient's needs cannot be met with either (1) a monophasic contraceptive containing ethinyl estradiol (EE) 20 mcg or EE 30 mcg, OR (2) a multiphasic contraceptive containing EE 25 mcg. PA does not expire.
• Norethindrone 0.4 mg/ EE 35 mcg (Wymzya Fe chewable, generics) **Oral Contraceptive Products**	Manual PA criteria apply to all new users of Wymzya Fe chewable tablets and generics. Manual PA criteria: Coverage is approved for Wymzya Fe chewable generics if: • The patient is unable to tolerate a non-chewable oral contraceptive due to an established swallowing difficulty. OR • The patient's needs cannot be met with either (1) a monophasic contraceptive containing EE 35 mcg OR (2) a multiphasic with containing 35 mcg. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Cyclosporine 0.05% ophthalmic emulsion (Restasis) **Ophthalmic Anti-Inflammatory/ Immunomodulatory Agents—Ophthalmic Immunomodulatory Agents**	<u>PA criteria apply to all new users of Restasis.</u> • 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. <u>Manual PA Criteria</u>: • Coverage is approved if one of the following is fulfilled: o Patient has diagnosis of Keratoconjunctivitis Sicca (KCS) with lack of therapeutic response to at least two OTC artificial tears agents o Patient has ocular graft vs. host disease o Patient has corneal transplant rejection o Patient has experienced documented corneal surface damage while using frequent artificial tears • Coverage is not approved for off-label uses such as, but not limited to: o Atopic keratoconjunctivitis (AKC)/vernal keratoconjunctivitis (VKC) o Pterygia o Blepharitis o Ocular rosacea o LASIK associated dry eye 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.
• Eluxadoline (Viberzi) **GI-2 Miscellaneous Drugs**	All new users of eluxadoline (Viberzi) are required to undergo manual prior authorization criteria. <u>Manual PA criteria</u>: Coverage will be approved if: • The patient is ≥ 18 years; AND • Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink ≤ 3 alcoholic beverages per day; AND • Patient has no history of marijuana use or illicit drug use in the previous 6 months; AND • Patient does not have severe hepatic impairment (Child-Pugh C); AND • Patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D); AND o The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium) AND o The patient has had failure, intolerance, or contraindication to at least one tricyclic antidepressant (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline • Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Brexpiprazole (Rexulti) **Atypical Antipsychotics (AAPs)**	All new users of brexpiprazole (Rexulti) are required to undergo manual prior authorization criteria. Manual PA criteria: Coverage will be approved if: • Diagnosis of Major Depressive Disorder o The patient is ≥ 18 years; AND o The patient has had treatment failure of at least two other antidepressant augmentation therapies (one of which must be aripiprazole); OR o Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) AND o Patient has concurrent use of an antidepressant • Diagnosis of schizophrenia o The patient is ≥ 18 years; AND o The patient has had treatment failure of at least two other atypical antipsychotics (one of which must be aripiprazole); OR o Patient has had an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti) • Non-FDA approved uses are not approved. • Prior Authorization does not expire.
• Lacosamide (Vimpat) **Anticonvulsants**	All new users of lacosamide (Vimpat) are required to undergo manual prior authorization criteria. Manual PA criteria: • Coverage will be approved if the patient has a diagnosis of Seizure Disorder and Vimpat is used as monotherapy or adjunctive therapy in the treatment of partial-onset seizure in patients ≥ 17 years of age. • Coverage is not approved for the following: o Non-FDA approved indications o Diabetic neuropathic pain o Essential tremor • Prior Authorization does not expire.
• Sacubitril/valsartan (Entresto) **Renin-Angiotensin-Antihypertensive Agents (RAAs)**	Automated or manual PA criteria apply to all new and current users of Entresto. Automated PA criteria: • The patient has filled a prescription for a step-preferred RAA drug at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. • Step-preferred RAAs include lisinopril +/- hydrochlorothiazide (HCTZ), captopril +/- HCTZ, ramipril, losartan +/- HCTZ, valsartan +/- HCTZ, benazepril +/- HCTZ, enalapril +/- HCTZ, fosinopril +/- HCTZ, moexipril +/- HCTZ, perindopril, quinapril +/- HCTZ, telmisartan +/- HCTZ, telmisartan/amlodipine, valsartan/amlodipine, valsartan/amlodipine/HCTZ. Note that a history of candesartan +/- HCTZ also qualifies as meeting the step therapy criteria. Manual PA criteria: if automated PA criteria are not met, Entresto is approved if: • The patient has a documented diagnosis of chronic heart failure (New York Heart Association class II-IV heart failure) with left ventricular ejection fraction ≤40%. AND • The patient is receiving concomitant treatment with a beta blocker, or the patient has a contraindication to a beta blocker. AND • The patient is intolerant to an ACE inhibitor AND • The patient does not have a history of angioedema to ACE inhibitors or ARBs. • Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Secukinumab (Cosentyx) **Targeted Immunomodulatory Biologics (TIBs)**	Prior Authorization criteria originally approved February 2015 and implemented May 4, 2015. February 2016 changes to PA criteria in bold. Manual PA criteria for psoriatic arthritis and ankylosing spondylitis applies to new patients. Manual PA Criteria applies to all new users of secukinumab (Cosentyx). 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 Cosentyx if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • AND Coverage approved for patients > 18 years with: • Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy OR • **Psoriatic arthritis (February 2016) OR** • **Ankylosing spondylitis (February 2016)** Coverage is NOT provided for concomitant use with other TIBs. Prior Authorization does not expire.
• Asfotase alfa injection (Strensiq) **Metabolic Replacement Agents Miscellaneous**	Prior Authorization applies to all new and current users of Strensiq. Automated PA criteria • Strensiq will be approved for patients younger than one year of age Manual PA criteria—applies if patient is older than one year of age • Strensiq will be approved if: o The patient has the FDA-approved indication of perinatal/infantile and juvenile-onset hypophosphatasia (HPP) AND o The diagnosis is supported by confirmatory testing o Off-label uses are NOT approved Prior Authorization does not expire.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Cobimetinib (Cotellic) **Oncologic Agents: Melanoma**	▪ Retail Network: 63 tablets per 21 days ▪ MTF and Mail Order Pharmacy: 126 tablets per 42 days
• Osimertinib (Tagrisso) **Oncologic Agents: Non-small Cell Lung Cancer**	▪ Retail Network: 30 tabs per 30 days ▪ MTF and Mail Order Pharmacy: 45 tabs per 45 days
• Ixazomib (Ninlaro) **Oncologic Agents: Multiple Myeloma**	▪ Retail Network: 3 tabs per 21 days ▪ MTF and Mail Order Pharmacy: 6 tabs per 42 days
• Alectinib (Alecensa) **Oncologic Agents: Non-small Cell Lung Cancer**	▪ Retail Network: 240 caps per 30 days ▪ MTF and Mail Order Pharmacy: 360 caps per 45 days
• Glycopyrrolate oral inhaler (Seebri Neohaler) **Pulmonary II Agents—LAMA**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ MTF and Mail Order Pharmacy: 3 inhalers (180 actuations) per 90 days
• Glycopyrrolate/indacaterol oral inhaler (Utibron Neohaler) **Pulmonary II Agents—LAMA/LABA**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ MTF and Mail Order Pharmacy: 3 inhalers (180 actuations) per 90 days
• Tiotropium (Spiriva Respimat) **Pulmonary II Agents—LAMA**	▪ Retail Network: 1 inhaler (60 actuations) per 30 days ▪ MTF and Mail: 3 inhalers (180 actuations) per 90 days
• Fluticasone/ vilanterol (Breo Ellipta) 200 25 mcg Institutional Pack **Pulmonary I Agents—ICS/LABAs**	▪ Retail Network, MTF and Mail Order Pharmacy: 1 Institutional Pack (14 inhalations) per 14 days

Appendix E—Table of Innovator Drugs: Formulary Recommendations

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Alectinib (Alecensa)	• Oral Oncology • Subclass: Lung Cancer • Not previously reviewed	• crizotinib (Xalkori)	• Advanced anaplastic lymphoma kinase positive non-small cell lung cancer (NSCLC) failing crizotinib	• ALK+ accounts for 2-7% of NSCLC • Few oral options after crizotinib failure • Approval based on tumor size reduction, requires additional studies to verify benefit • Approved with documented ALK+ FDA test • Pending Ph III study comparing as 1st line therapy	• UF
Amphetamine ER oral suspension (Dyanavel XR)	• Attention Deficit Hyperactivity Disorder • Subclass: Stimulants • Reviewed Nov 2015	• amphetamine sulfate (Evekeo) • methylphenidate ER suspension (Quillivant XR) • mixed amphetamine salts (Adderall IR and XR generics)	• ADHD	• The first amphetamine XR oral suspension • Other ADHD stimulant agents with a liquid dosage form on the UF	• NF
Antihemophilic factor recombinant (rFVIII) injection (Adynovate)	• Antihemophilic Factor • Subclass: Factor VIII • Reviewed Feb 2010	• Eloctate (extended half-life) • Kogenate FS, Recombinant	• Hemophilia A, Factor VIII deficiency	• New category of longer acting recombinant Factor VIII products • Pegylated FVIII allows extended half-life (14.3 hours with Adynovate vs. 10.4 hours with Advate) • Extended half- life allows for 1 less infusion/week • Uses most popular FVIII, Advate • Used for on demand treatment and prophylaxis	• UF
Asfotase alfa injection (Strensiq)	• Metabolic replacement agents miscellaneous • Not previously reviewed	• None –orphan drug	• Perinatal/infantile and juvenile-onset hypophosphatasia (HPP)	• 1st FDA-approved treatment for HPP • Tissue non-specific alkaline phosphatase (biologic) • In HPP, calcium and phosphate build up in the body causing damage to bones and organs • 50% mortality rate in infants • Strensiq showed statistical improvement in survival (infant/perinatal); and, in radiological scores, mobility, growth, and height (juveniles)	• UF

Aspirin extended release 162.5 mg (Durlaza; New Haven Pharma)	• Antiplatelets • Reviewed Feb 2012	• OTC ASA • clopidogrel	• Secondary Prevention • CV events (MI, unstable angina, chronic angina) • Stroke, TIA	• 505(b)(2) approval using aspirin data • Durlaza Tmax at 2 hours vs. 1 hour with Aspirin • No clinical studies • 1st low-dose prescription ER ASA • Several OTC aspirin (81 mg/325 mg) and prescription antiplatelets are available	• NF
Coagulation Factor X injection (Coagadex)	• Antihemophilic Factor • Subclass: Factor X • Reviewed Feb 2010	• fresh frozen plasma • Bebulin VH, Profilnine SD	• Hereditary Factor X deficiency	• Rare disease, 1 in 1 million • 1st purified Factor X in US/world, but not new practice as fresh frozen plasma (FFP) contains significant amounts of Factor X and provides current treatment choice • Human plasma-derived Factor X concentrate • Used for on-demand treatment and perioperative management of bleeding	• UF
Cobimetinib (Cotellic)	• Oncological Agent • Subclass: metastatic melanoma • Not previously reviewed	• vemurafenib (Zelboraf) • dabrafenib (Tafinlar) • trametinib (Mekinist)	• Unresectable or metastatic melanoma with the BRAF V600E or V600K mutation (combination with Zelboraf)	• Another approved BRAF/MEK inhibitor combination • Others include trametinib (Mekinist)/dabrafenib (Tafinlar) • Cotellic is not indicated for use in patients with wild-type BRAF melanoma	• UF
Elvitegravir,cobicistat, emtricitabine, tenofovir, alafenamide (Genvoya)	• Anti-retrovirals • Not previously reviewed	• Stribild	• HIV-1 in ≥12 years old antiretroviral naïve or to replace regimen in stable virologically-suppressed • Only for patients with pre-antiretroviral therapy CrCl >70 mL/min • No dose adjustment CrCl ≥ 30mL/min	• One of 5 recommended regimens for naïve patients (rating strong based on randomized controlled trial) with increased safety margin over similar combination	• UF

Glycopyrrolate oral inhaler (Seebri Neohaler)	• Pulmonary II • Subclass: LAMA • Reviewed May 2013	• tiotropium (Spiriva) • aclidinium (Tudorza) • umeclidinium (Incruse Ellipta)	• Long-term, maintenance treatment of COPD	• Seebri: Fourth LAMA to reach market. • Utibron: Third combination LAMA/LABA • There is no evidence to suggest that Seebri or Utibron is superior or inferior in safety or efficacy to the LAMAs or LABA/LAMA combinations currently available • Neohaler device requires BID dosing and a higher peak inspiratory flow rate compared to other devices • Seebri and Utibron offer no clinically compelling advantages over existing UF agents used in the long-term maintenance treatment of COPD	• NF
Glycopyrrolate Indacaterol oral inhaler (Utibron Neohaler)	• Pulmonary II • Subclass: LAMA/LABA • Reviewed May 2013	• olodaterol/tiotropium (Stiolto Respimat) • vilanterol/ umeclidinium(Anoro Ellipta)	• Long-term, maintenance treatment of airflow obstruction in COPD		• NF
Insulin degludec (Tresiba)	• Basal Insulins • Reviewed Feb 2010	• glargine (Lantus) • glargine (Basalgar) • detemir (Levemir) • Novolin N • Humulin N	• Diabetes mellitus	• The 1st "ultra-long-acting" basal insulin with a distinct, slow absorption which results in a flat and stable action profile • Dosed subcutaneously daily at any time • Degludec non-inferior to both glargine and detemir in improvement of glycemic control	• NF
Ixazomib (Ninlaro)	• Oral Oncology-Multiple Myeloma • Not previously reviewed	• lenalidomide (Revlimid) • bortezomib (Velcade) IV	• Multiple Myeloma	• 1st oral proteasome inhibitor; all oral regimen • Requires ≥ 1 prior therapy failure • Give in combo with lenalidomide plus steroid • Overall survival benefit yet to be demonstrated • Multiple combination regimens utilized IV/PO	• UF
Meloxicam low dose 5 and 10 mg (Vivlodex)	• NSAIDs • Reviewed May 2014	• meloxicam (Mobic) • celecoxib (Celebrex) • Ibuprofen (Motrin)	• Osteoarthritis pain	• 505(b)(2) approval using meloxicam (Mobic) data • The 3rd "SoluMatrix" NSAID allowing for faster dissolution resulting in similar Cmax and 20% lower AUC at a lower dose • Not interchangeable with other meloxicam (20% lower dose) • FDA review does not support manufacturer claim of improved pharmacokinetic profile	• NF

Naloxone nasal spray (Narcan Nasal)	• Alcohol deterrants-narcotic antagonists • Not previously reviewed	• naloxone hydrochloride IV/IM • naloxone IM/SQ Auto-injector (Evzio)	• Treatment of opioid overdose	• First non-injectable form of naloxone • Eliminates risk for contaminated needle stick	• UF
Osimertinib (Tagrisso)	• Oral Oncology • Subclass: NSCLC • Not previously reviewed	• erlotinib (Tarceva) • gefitinib (Iressa) • afatinib (Gilotrif)	• Advanced epidermal growth factor receptor (EGFR)-positive T790 mutation NSCLC failing EFGR therapy	• EGFR+ accounts for ~15% of NSCLC cases • No other agent approved for T790M mutation • Approved based on tumor size reduction; requires additional studies to verify benefit • Approved with documented T790M test	• UF
Patiromer (Veltassa)	• Binders-chelators-antidotes-overdose agents • Not previously reviewed	• sodium polystyrene sulfonate (Kayexalate)	• Treatment of hyperkalemia	• Can be used in patients with obstructive bowel disease (which is contraindicated with Kayexalate) • May be tolerated for long-term use, no report of GI tract ulceration or necrosis (which has been associated with Kayexalate) • Potential for chronic hyperkalemia management	• UF
Rolapitant (Varubi)	• Anti-Nausea • Reviewed May 2006	• aprepitant (Emend)	• Prevention of delayed nausea and vomiting associated with emetogenic cancer chemotherapy	• The second approved NK1 antagonist after aprepitant (Emend) • Half-life is approximately 7 days (Emend half-life is 9-13 hours) • Varubi only indicated for delayed chemotherapy-induced nausea and vomiting (CINV), whereas Emend is indicated for both acute and delayed CINV	• NF
Selexipag (Uptravi)	• PAH agents • Subclass: Prostacyclins • Reviewed Feb 2015	• treprostinil oral tab (Orenitram ER)	• Pulmonary arterial hypertension	• Selexipag is the 2nd available oral prostacyclin	• UF

Appendix F—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
Feb 2016	**Contraceptives: Oral Contraceptives and**	UF class review (previously reviewed Aug 2011)	▪ EE 20 mcg; 0.1 mg levonorgestrel (Lutera, Sronyx or equiv) ▪ EE 20 mcg; 3 mg drospirenone (Yaz or equiv) ▪ EE 30 mcg; 3 mg drospirenone (Yasmin or equiv) ▪ EE 30 mcg; 0.15 mg levonorgestrel (Levora-28, or equiv) ▪ EE 35 mcg; 0.25 mg norgestimate (Mononessa, or equiv) ▪ EE 35 mcg; 1.0 mg norethindrone (Norinyl 1+35, or equiv) ▪ EE 35 mcg; 0.18/0.215/0.25 mg norgestimate (TriNessa, or equiv) ▪ 0.35 mg norethindrone (Nor-QD, Jolivette or equiv) ▪ EE 30 mcg; 0.15 mg levonorgestrel extended cycle **(Jolessa only)**	▪ EE 20 mcg; 1.0 mg norethindrone (Microgestin 1/20 or equiv) ▪ EE 20 mcg; 1.0 mg norethindrone; ferrous fumarate (Microgestin Fe 1/20 or equiv) ▪ EE 30 mcg; 0.3 mg norgestrel (Low-Ogestrel or equiv) ▪ EE 30 mcg; 1.5 mg norethindrone (Microgestin 1.5/30 or equiv) ▪ EE 30 mcg; 1.5 mg norethindrone; ferrous fumarate (Microgestin Fe1.5/30 or equiv) ▪ EE 30 mcg; 0.15 mg desogestrel (Reclipsen or equiv) ▪ EE 35 mcg; 1.0 mg ethynodiol diacetate (Zovia 1-35E; or equiv) ▪ EE 35 mcg; 0.5 mg norethindrone (Nortrel 0.5/35 or equiv) ▪ EE 50 mcg; mestranol 50 mcg; 1 mg norethindrone (Norinyl 1+50 or equiv) ▪ EE 50 mcg; 1 mg ethynodiol diacetate (Zovia 1-50E or equiv) ▪ EE 50 mcg; 0.5 mg norgestrel (Ogestrel or equiv)	▪ EE 20 mcg; 1.0 mg norethindrone acetate ferrous fumarate (Minastrin 24 FE chew) ▪ EE 20 mcg; 3 mg drospirenone; levomefolate calcium 0.451mg (Beyaz) ▪ EE 20 mcg/norethindrone acetate 1 mg ferrous fumarate – 24 day regimen (Loestrin 24 Fe or equiv) ▪ EE 10 mcg; 1.0 mg norethindrone; ferrous fumarate (Lo Loestrin Fe) ▪ EE 25 mcg; 0.8 mg norethindrone acetate ferrous fumarate (Generess Fe chew) ▪ EE 30 mcg; 3 mg drospirenone; levomefolate calcium 0.451mg (Safyral) ▪ EE 35 mcg; 0.4 mg norethindrone (Balziva or equiv) ▪ EE 35 mcg; 0.4 mg norethindrone	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪PA now applies to Minastrin Fe 24 chew, Generess FE chew, and Wymzya Fe chew tablets – See Appendix C	▪No changes made to BCF choices ▪Minastrin Fe 24 and Generess Fe chewables now NF ▪Jolessa generics now UF; Jolessa remains BCF

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
			▪ Norethindrone 0.35 mg (Nor-Q-D or equiv)	▪ EE 30 mcg; 0.15 mg levonorgestrel extended cycle (Quasense, Introvale, Setlakin or equiv); Jolessa only is BCF ▪ EE 35 mcg; 0.5/1.0 mg norethindrone (Necon 10/11) ▪ EE 20/10 mcg; 0.15 mg desogestrel (Azurette or equiv) ▪ EE 25 mcg; 0.18/0.215/0.25 mg norgestimate (Ortho Tri-Cyclen Lo or equiv) ▪ EE 35 mcg; 0.18/0.15/0.25 mg norgestimate (TriNessa or equiv) ▪ EE 35 mcg; 0.5/0.75/1 mg norethindrone (Necon 7/7/7 or equiv) ▪ EE 35 mcg; 0.5/1/0.5 mg norethindrone (Leena or equiv) ▪ EE 30/40/30 mcg; 0.05/0.075/0.125 mg levonorgestrel (Trivora-28 or equiv) ▪ EE 25 mcg; 0.1/0.125/0.15 mg desogestrel (Velivet or equiv) ▪ EE 20/25/30/10 mcg/levonorgestrel 0.15 mg (Quartette)	acetate ferrous fumarate (Wymzya Fe chew or equiv) ▪ EE 20 mcg/levonorgestrel 0.9 mg – 28 day continuous regimen (Amethyst or equiv) ▪ EE 30/10 mcg; 0.15 mg levonorgestrel (Camrese or equiv ▪ EE 20/10 mcg; 0.10 mg levonorgestrel (Camrese Lo or equiv) ▪ EE 20/30/35 mcg; norethindrone 1 mg ferrous fumarate (Tri-Legest Fe or equiv) ▪ Estradiol valerate 3/2/2/1 mg; dienogest 2/3 mg (Natazia)			

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
Feb 2016	**Contraceptives: Miscellaneous Contraceptives**	UF class review (previously reviewed Aug 2011)	Miscellaneous Contraceptives (None)	▪ norelgestromin 150 mcg + EE 35 mcg transdermal (Xulane, equiv to discontinued Ortho-Evra) ▪ etonogestrel 0.12 mg +EE 15 mcg vaginal ring (NuvaRing) ▪ 104 mg/0.65mL depot medroxyprogesterone acetate injection (Depo-Subq Provera 104) ▪ 150 mg/mL depot medroxyprogesterone acetate injection IM and SC (Depo-Provera; generics)	▪ None	Pending signing of the minutes / 90 days The effective date is August 10, 2016.		
Feb 2016	**Antifungals Topical Lacquers Subclass**	UF class review	BCF: None (BCF selections from the Antifungals Drug Class include clotrimazole)	▪ ciclopirox 8% topical solution (Penlac, generic)	▪ efinaconazole 10% topical solution (Jublia) ▪ tavaborole 5% topical solution (Kerydin)	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪Prior authorization applies for Jublia and Kerydin (revised from Feb 2015) – See Appendix C	
Feb 2016	**Ophthalmic Anti-Inflammatory/ Immuno-modulatory Agents: Ophthalmic Immuno-modulatory Agents Subclass**	UF class review	BCF: None (BCF Ophthalmic Anti-Inflammatory Drugs include Pred Mild and Pred Forte)	▪ cyclosporine 0.05% ophthalmic emulsion (Restasis)	▪ None	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪Prior authorization applies for Restasis – 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
Feb 2016	**Non-Basal Insulins**	New Drug Class previously reviewed in 1999 and Aug 2003 (Pre-UF Rule decision)	**August 2003** ▪ insulin aspart (NovoLog vials) ▪ 70% insulin aspart protamine suspension/30% insulin aspart (NovoLog Mix vials) **May 2010** ▪ insulin aspart pen and cartridges (NovoLog FlexPen; NovoLog PenFill cartridges) ▪ 70% insulin aspart protamine suspension/30% insulin aspart pen injection device (NovoLog Mix 70/30 FlexPen)	Aug 2003 Pre-UF Rule decision ▪ Insulin lispro (Humalog)	**Feb 2016** ▪ **Inhaled insulin (Afrezza)**	Pending signing of the minutes / 90 days The effective date is August 10, 2016.	▪Afrezza PA applies from May 2015 – 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
Feb 2016	**NSAIDs**	New Drug Class previously reviewed Aug 2011	▪ ibuprofen 400 mg, 600 mg & 800 mg tablets & 125 mg/5 mL susp (generic) ▪ 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)	**Feb 2016** ▪ **indomethacin low dose 20 and 40 mg capsules (Tivorbex)** ▪ **meloxicam low dose 5 and 10 mg capsules (Vivlodex)** May 2014 ▪ diclofenac low dose 18 and 35 mg capsules (Zorvolex) Aug 2011 ▪ 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 The effective date is August 10, 2016.	N/A	▪ New MN Criteria applies to all NF NSAIDs. See Appendix B.

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
Feb 2016	**Ophthalmic-1s – Dual Action Ophthalmic Antihistamines and Mast Cell Stabilizers**	New Drug Class previously reviewed Aug 2010	▪ olopatadine 0.1% (Patanol; generics)	▪ bepotastine (Bepreve) ▪ olopatadine 0.2% (Pataday) ▪ azelastine (Optivar, generics) ▪ Epinastine (Elestat)	**Feb 2016** ▪ **olopatadine 0.7% (Pazeo)** **Feb 2012** ▪ alcaftadine (Lastacaft)	Pending signing of the minutes / 90 days The effective date is August 10, 2016.		
Feb 2016	**Long-Acting Beta Agonists (LABAs)**	New Drug Class previously reviewed Feb 2009	▪ Salmeterol (Serevent Diskus)	**Feb 2016** ▪ **olodaterol (Striverdi Respimat)** **Feb 2009** ▪ formoterol (Foradil) ▪ arformoterol nebulized solution (Brovana)	**May 2014** ▪ formoterol nebulized solution (Arcapta Neohaler) **Feb 2009** ▪ formoterol nebulized solution (Perforomist)	N/A	▪QL apply	

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

BCF: Basic Core Formulary
ECF: Extended Core Formulary
ER: extended release
IR: immediate release

Appendix G—Table of Abbreviations

AAPs	atypical antipsychotics
AC	allergic conjunctivitis
ACE	angiotensin converting enzyme
ARB	angiotensin receptor blocker
ACOG	American College of Obstetrics and Gynecology
ADHD	attention deficit hyperactivity disorder
AH/MCS	antihistamine/mast cell stabilizer
AKC	atopic keratoconjunctivitis
AUC	area under the curve
BAP	Beneficiary Advisory Panel
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CD	controlled delivery
CFR	Code of Federal Regulations
CINV	chemotherapy-induced nausea and vomiting
CMA	cost minimization analysis
Cmax	maximum (peak) plasma concentration
COPD	chronic obstructive pulmonary disease
CrCl	creatinine clearance
CV	cardiovascular
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DoD	Department of Defense
DPP4	dipeptidyl peptidase-4 inhibitor
ECF	Extended Core Formulary
EE	ethinyl estradiol
EGFR	epidermal growth factor receptor
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
Fe	iron
FEV_1	forced expiratory volume in one second
FFP	fresh frozen plasma
FY	fiscal year
GCN	generic code number
GI-2	Gastrointestinal-2 Miscellaneous Drugs
HCTZ	hydrochlorothiazide
HF	heart failure
HPP	hypophosphatasia
IBS	irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
IM	intramuscular
IR	immediate release
KCS	keratoconjunctivitis sicca

KOH	potassium hydroxide
LABA	long-acting beta agonist
LAMA	long-acting muscarinic antagonists
LVEF	left ventricular ejection fraction
MHS	Military Health System
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
NVP	nausea and vomiting of pregnancy
NYHA	New York Heart Association
OCPs	oral contraceptive products
OTC	over-the-counter
ODT	orally dissolving tablet
P&T	Pharmacy and Therapeutics
PA	prior authorization
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
RAAs	Renin Angiotensin-Antihypertensives Drug Class
QD	once daily
QLs	quantity limits
SC	subcutaneous
Tmax	time to reach maximum (peak) plasma concentration
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs
VKC	vernal keratoconjunctivitis