DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

November 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 15 and 16, 2017, 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 2017 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the August 2017 DoD P&T Committee meeting on October 20, 2017, and signed the first and second addenda to the minutes on September 27 and October 19, 2017, respectively.

2. **Clarification to the August 2017 Minutes Implementation Dates:** The implementation dates for updated prior authorization criteria, quantity limits, line extensions, and the formulary status and prior authorizations for the newly-approved drugs per 32 CFR 199.21(g)(5) was changed to November 1, 2017.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 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. Weight Loss Agents

Background—Prior to the National Defense Authorization Act (NDAA) 2017, weight loss agents were excluded from the TRICARE pharmacy benefit. An Interim Final Rule published on September 29, 2017, (DOD-2017-HA-RIN 0720) "authorizes coverage under TRICARE

Prime and TRICARE Select for medically necessary treatment of obesity, even if it is the sole or major condition treated." Therefore, the P&T Committee evaluated the weight loss agents.

The medications approved for weight loss include both generic and branded products. The older generic drugs are phentermine (Adipex-P, generics), phendimetrazine immediate release (IR) and sustained release (SR) (Bontril, Bontril Slow Release, generics), benzphetamine (Didrex, generics), and diethylpropion (Tenuate, Tandil, generics). A branded, low-dose formulation of phentermine 8 mg (Lomaira) is now available. These older drugs are approved for up to 12 weeks of treatment. The clinical review focused on the newer branded drugs approved for long-term treatment of weight loss beyond 12 weeks.

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

- Professional treatment guidelines from several organizations differ with respect to recommendations for weight loss. However, there is agreement among all the guidelines that comprehensive lifestyle intervention is the foundation of weight loss treatment. Pharmacotherapy may be offered to patients with a body mass index (BMI) ≥ 30 and to those with a BMI ≥ 27 who have obesity-associated comorbidities.
- The weight loss agents were primarily studied in placebo-controlled trials and vary significantly in their reported efficacy and safety. The individual trials also varied in the requirements for concurrent lifestyle interventions. All the trials included the percentage of patients who achieved a 5% reduction in weight from baseline over a 12- to 16-week period. For all the drugs, approximately 33% to 75% of patients achieved this endpoint, compared to 25% of patients receiving placebo.
- Phentermine/topiramate extended release (ER) (Qsymia) is a fixed-dose combination product that suppresses appetite. The safety concerns with Qsymia include the risk of congenital malformations, and cautions in patients with hypertension, elevated heart rate, or renal dysfunction.
- The fixed-dose combination of naltrexone SR/bupropion SR (Contrave) reduces cravings. Product labeling includes a black box warning advising against use in patients with major depression or psychiatric disorders. Contrave is not recommended in patients with a history of seizures, or uncontrolled hypertension, and in those taking opioids.
- Lorcaserin is available in two formulations, immediate release (Belviq) and sustained release (Belviq XR). The mechanism by which lorcaserin induces weight loss is unknown. Patients with cardiac conditions, including congestive heart failure, bradycardia, heart valve problems, and second or third degree heart block, require close monitoring.
- Orlistat (Xenical) is a lipase inhibitor administered with high-fat meals. It is the only weight loss drug approved for pediatric patients as young as 12 years of age. Xenical should be avoided in patients with gallbladder disease or malabsorption syndromes.

- Liraglutide (Saxenda) is a glucagon-like peptide-1 receptor agonist (GLP1RA) that is administered subcutaneously (SC) once daily in a 3 mg dosage. It causes weight loss by increasing satiety. Liraglutide is also available in a 1.8 mg formulation (Victoza) for treating type 2 diabetes. In a two-year dose comparison study, the two dosages of liraglutide, 1.8 mg and 3 mg, were comparable in efficacy for weight loss.
- Other GLP1RAs, including exenatide once weekly (Bydureon), have shown a decrease in weight from baseline when evaluated in type 2 diabetic patients. In the 26-week DURATION-6 trial, Bydureon reduced baseline weight by 2.7 kg, compared to 3.6 kg with Victoza; these differences between the drugs are statistically significant but not clinically relevant.
- Qsymia is the only weight loss drug shown to cause a significant reduction in blood pressure. Reductions in hemoglobin A1c in type 2 diabetic patients have been reported with Contrave, Belviq, and Saxenda. In one trial, Qsymia showed a slowed rate of progression to type 2 diabetes compared to placebo.
- Due to the lack of head-to-head trials with the weight loss agents, systematic reviews were evaluated to determine comparative clinical efficacy. The Institute for Clinical & Economic Review in 2015 evaluated 17 placebo-controlled trials. Qsymia and Saxenda had the highest proportion of patients achieving a > 5% weight loss, followed by Contrave, and then Belviq. Discontinuations due to adverse drug reactions occurred most commonly with Qsymia (1.3%–16%) and Contrave (19%–29%). Xenical was not included in the analysis.
- A 2016 Journal of the American Medical Association (JAMA) systematic review included 28 studies with the newer weight loss drugs. Qsymia and Saxenda had the highest odds of achieving a 5% weight loss followed by Contrave. Saxenda and Contrave had the highest discontinuation rate from adverse events.
- Varied results were found when Military Health System (MHS) providers were asked their opinions on prescribing weight loss drugs. The respondents were divided on whether a weight loss drug was needed on the formulary, with 43% responding "yes" versus 40% saying "no". More than half of providers (59%) stated a willingness to prescribe two agents separately in lieu of fixed-dose combinations.
- Overall, these drugs have a modest effect on weight loss, and evidence for sustained weight loss beyond one to two years is minimal. Clinical comparisons between the individual drugs are difficult due to the differing mechanisms of action, lack of head-to-head trials, lack of long-term cardiovascular outcomes studies, and widely varying adverse event profiles. Discontinuations due to adverse events can be of concern.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA), cost-effectiveness analysis (CEA), and budget impact analysis (BIA) were performed to evaluate the weight loss agents. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA and CEA results found that the generic agents including phentermine, phendimetrazine, benzphetamine, and diethylpropion were the most cost effective,

followed by phentermine 8 mg tablets (Lomaira), phentermine/topiramate ER (Qsymia), lorcaserin (Belviq and Belviq XR), naltrexone SR/bupropion SR (Contrave), orlistat (Xenical), and liraglutide 3 mg injection (Saxenda).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating the generic agents benzphetamine, diethylpropion, phendimetrazine, and phentermine as formulary, with liraglutide 3 mg injection (Saxenda), lorcaserin (Belviq and Belviq XR), naltrexone SR/bupropion SR (Contrave), phentermine 8 mg tablets (Lomaira), phentermine/topiramate ER (Qsymia), and orlistat (Xenical) as NF, demonstrated significant cost avoidance for the MHS.

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

    - UF
        - benzphetamine (Didrex, generics)
        - diethylpropion (Tenuate, Tandil, generics)
        - phendimetrazine IR and SR (Bontril, Bontril SR, generics)
        - phentermine (Adipex-P, generics)

    - NF
        - liraglutide 3 mg injection (Saxenda)
        - lorcaserin (Belviq, Belviq XR)
        - naltrexone SR/bupropion SR (Contrave)
        - orlistat (Xenical)
        - phentermine 8 mg tablets (Lomaira)
        - phentermine/topiramate ER (Qsymia)

    - A weight loss drug was not added to the BCF.

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for all the weight loss drugs, including the generic products, in new and current users. In general, lifestyle intervention for at least six months is required prior to use of a weight loss drug, and is required throughout treatment. Additionally, a trial of phentermine is required prior to use of the branded agents, unless the patient has significant cardiovascular disease or other contraindications to a stimulant.

    Renewal PA criteria are required after 12 weeks for the generic products, and after four months for the products approved for long-term use (Belviq, Belviq XR, Contrave, Qsymia, Saxenda, and Xenical). See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Belviq, Belviq XR, Contrave, Lomaira, Qsymia, Saxenda, and Xenical. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) excluding the weight loss drugs from the EMMPI list, as it is not yet clear to what degree these products are maintenance medications. See Appendix G.

5. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR WEIGHT LOSS AGENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) excluding the weight loss agents from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation in all points of service. Based on the P&T Committee's recommendation, the effective date is May 2, 2018.

B. Oncologic Agents: Multiple Myeloma Subclass

Background—The P&T Committee evaluated the oral therapies for multiple myeloma; the subclass has not previously been reviewed for formulary status. Multiple myeloma is the 14th most common cancer, but represents only 1.8% of all new cancers diagnosed in the United States. The median age of diagnosis is 69 years, and there is a 50% 5-year mortality rate. The disease is characterized by a series of remissions and relapses, eventually progressing to treatment-refractory disease, and ultimately, patient demise.

The multiple myeloma drug class consists of five products: three immunomodulators, thalidomide (Thalomid), lenalidomide (Revlimid), and pomalidomide (Pomalyst); one proteasome inhibitor, ixazomib (Ninlaro); and, the histone deacetylase inhibitor panobinostat (Farydak). No generic alternatives exist for these branded agents, with the earliest patent or orphan drug expiration expected in 2027.

Despite the fact that multiple myeloma impacts only a small fraction of the MHS population, (<2,000 patients), the drugs account for $136 million in yearly expenditures. Expenditures are primarily driven by one product, Revlimid, which has increased in price by 39% within the last 5 years, exceeding more than $100 million per year in expenditures.

Complexities in determining the relative clinical effectiveness of the multiple myeloma drugs include the use of concomitant intravenous chemotherapies that are not part of the TRICARE

pharmacy benefit [e.g., bortezomib (Velcade), carfilzomib (Kyprolis)], the practice of combining therapies when patients relapse rather than replacing therapies, and the significant toxicities of the drugs.

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

- Multiple Myeloma is a complex and rapidly evolving field with management decisions based on several factors, including staging and grading of disease, cytogenetic profiles, patient response to previous therapy, and adverse event profiles. Treatment is not curative.
- The National Comprehensive Cancer Network (NCCN) guidelines support that the backbone of multiple myeloma therapy includes regimens comprised of triplet therapies (lenalidomide with Velcade and dexamethasone), proteasome inhibition, and immunomodulatory agents.
- Lenalidomide (Revlimid) is the preferred immunomodulatory agent across the full spectrum of disease course, from frontline therapy to the multi-relapsed or refractory state. Lenalidomide is also FDA-approved for treating mantle cell lymphoma and myelodysplastic syndrome.
- Thalidomide (Thalomid) is reserved for very specific circumstances, largely related to its increased toxicity relative to lenalidomide. Thalidomide has a wide range of FDA-approved and off-label indications.
- Pomalidomide (Pomalyst) is reserved as an alternative regimen in relapsed/refractory disease that has not responded to treatment with lenalidomide.
- Ixazomib (Ninlaro) and panobinostat (Farydak) are indicated for relapsed/refractory disease after at least one previous therapy and demonstrate only modest efficacy. Panobinostat lacks an overall survival benefit and is poorly tolerated.
- Each of the multiple myeloma drugs is associated with significant toxicities that can be life threatening and frequently result in dosage reductions. The immunomodulators are well-known teratogens, with FDA requirements for a Risk Evaluation and Mitigation Strategies (REMS) program; they also increase the risk for venous thromboembolism (VTE). Ninlaro and Pomalyst both cause thrombocytopenia and diarrhea. Finally, Farydak increases the risk of death via hemorrhagic, arrhythmogenic, and ischemic cardiac events.

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

- CMA results showed thalidomide (Thalomid) was the most cost-effective multiple myeloma drug, followed by ixazomib (Ninlaro), panobinostat (Farydak), lenalidomide (Revlimid), and pomalidomide (Pomalyst).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) the following, based on clinical and cost effectiveness:
    - **UF:**
        - ixazomib (Ninlaro)
        - lenalidomide (Revlimid)
        - panobinostat (Farydak)
        - pomalidomide (Pomalyst)
        - thalidomide (Thalomid)
    - **NF:** None
    - Note that a BCF product was not selected for the Multiple Myeloma drug subclass.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new users of Revlimid, Pomalyst, Ninlaro, and Farydak. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—QLs for the multiple myeloma drugs have previously been in place due to the likelihood of dosage reductions required due to toxicity. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for Revlimid, Pomalyst, and Thalomid, and revising the QL for Ninlaro and Fardyak based on FDA dosing guidelines and treatment courses. See Appendix D for the QLs.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is April 4, 2018.

C. Vitamins: Prenatal Vitamins Subclass

Background—At the August 2017 meeting, the P&T Committee discussed the planned transition of multiple National Drug Codes (NDCs), including all legend prenatal vitamins, from prescription to non-prescription status in the First DataBank drug database. Actions recommended by the P&T Committee in response to this change were approved by the Director, DHA, on October 20, 2017, but are on hold due to recent litigation between outside parties concerning the change in status for these products. Therefore, prenatal vitamins currently listed as legend drugs remain a covered TRICARE pharmacy benefit, and thus were considered for formulary status. A total of 152 different prenatal vitamins (by brand name) were dispensed at any DoD point of service during Fiscal Year 2017 (see Appendix E).

Relative Clinical Effectiveness Analysis and Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- Prenatal vitamins are a low-cost intervention known to improve outcomes by preventing neural tube defects and providing adequate iron stores to prevent anemia and decrease nausea and vomiting during pregnancy.
- U.S. Preventive Services Task Force (USPSTF) guidelines recommend that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg of folic acid (Grade A recommendation).
- Continued TRICARE coverage of prenatal vitamins is highly desirable in order to ensure uninterrupted access to essential care.
- Provision of prenatal vitamins as part of the TRICARE pharmacy benefit is even more important for the MHS than civilian health plans, given worldwide assignment of female service members and beneficiaries to countries with variable availability of food products fortified with folic acid.
- In addition to iron and folic acid, prenatal vitamins may also contain additional components, including fatty acids [e.g., docosahexaenoic acid (DHA), omega-3, and eicosapentaenoic acid (EPA)] and calcium.
- Prenatal vitamins that provide alternative dosage forms (gummies, chewable, smaller capsule or tablet size, etc.), are available due to patient preference or marketing issues.
- Prenatal vitamins exhibit a high degree of therapeutic interchangeability.

Relative Cost-Effectiveness Analysis and Conclusion—The relative cost-effectiveness analysis included identifying the highest volume, most cost-effective options that would provide a variety of formulations to meet the clinical needs of beneficiaries, based on ingredient cost and usage at each point of service (MTF, TRICARE Mail Order Pharmacy, Retail Network pharmacies). The Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following products (listed by brand name) typically comprise the highest volume, lowest cost options at all three points of service: Prenatal Vitamins Plus Low I, Prenatal Vitamin + Low Iron, Prenatal Plus, Preplus, Prenatal (OTC), Prenatal Vitamins (OTC), Prenatal Multi + DHA (OTC) and Prenatal Formula (OTC).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing the following legend products on the UF, with all other legend prenatal vitamins designated NF:

    - **UF**:
        - Prenatal Vitamins Plus Low I
        - Prenatal Vitamin + Low Iron
        - Prenatal Plus
        - Preplus

- **NF**: All other legend prenatal vitamins listed in Appendix E other than those listed above.
- Note that the products recommended for UF placement, listed above, include approximately 90% of the 30-day equivalent prescriptions dispensed for prenatal vitamins.
- The products recommended for UF placement is different from, and thus supersedes, the list of agents identified as highest value in the August 2017 DoD P&T Committee minutes (available at https://health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Meeting-Minutes).
- Selecting these agents facilitates the standardization of available agents in the Prenatal Vitamin subclass across DoD points of service.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to make no BCF selection in the Prenatal Vitamin subclass, or in the overall Vitamin Class, given uncertainty regarding potential future changes in legend status. The P&T Committee also noted the possibility of establishing a joint national contract with the U.S. Department of Veterans Affairs (VA) for prenatal vitamins.

3. ***COMMITTEE ACTION: MTF OTC TEST LIST RECOMMENDATION*** The P&T Committee also agreed that prenatal vitamins currently listed as OTC products should be considered for addition to the MTF OTC Test List (see "Aligning OTC Formularies" on page 52 of the May 2017 DoD P&T Committee meeting minutes).

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) placing the following OTC prenatal vitamins on the MTF OTC Test List: Prenatal, Prenatal Vitamins, Prenatal Multi+DHA, Prenatal Formula. Note that items not included on the MTF OTC Test List will reject at MTF sites under the new electronic health record system (MHS Genesis).

4. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for the prenatal vitamins. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: AGE AND GENDER EDIT***—Prenatal vitamins are not currently covered for male patients, and female patients older than 45 years of age, consistent with TRICARE coverage of legend prenatal vitamins for pregnancy-related use only. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current age and gender requirements for prenatal vitamins. The P&T Committee noted expert opinion stating that pregnancy was very rare past the age of 45, but agreed that the requirement should be overridden in such cases.

6. ***COMMITTEE ACTION: EMMPI REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to not add the legend prenatal vitamins to the EMMPI program, and that the NF prenatal vitamins should be exempted from the NF mail order requirement due to feasibility issues related to the sheer number of products involved.

7. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service 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 2, 2018.

V. NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5)

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions***—**The P&T Committee agreed (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix F for the complete list of newly-approved drugs reviewed at the November 2017 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations, and see Appendix G for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

- **UF**:
    - abemaciclib (Verzenio) – Oral Oncology Agents for Breast Cancer
    - belimumab (Benlysta) – Immunosuppressive Agents – Systemic Lupus Erythematosus
    - plasma-derived human C1 esterase inhibitor SQ injection (Haegarda)– Hereditary Angioedema (HAE)
    - enasidenib (Idhifa) – Oral Oncology Agents for Acute Myelogenous Leukemia
    - fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta) – Pulmonary II Combination Agents – Chronic Obstructive Pulmonary Disease (COPD)
    - glecaprevir/pibrentasvir (Mavyret) – Hepatitis C Virus Direct Acting Antivirals (HCV DAAs)
    - L-glutamine (Endari) – Dietary Supplements
    - naldemedine (Symproic) – Gastrointestinal-2 Agents – Opioid Induced Constipation (OIC) Drugs
    - neratinib (Nerlynx) – Oral Oncology Agents for Breast Cancer
    - nitisinone (Nityr) – Metabolic Replacement Agents
    - perampanel (Fycompa oral solution) – Anticonvulsants/Anti-Mania Agents

- sofosbuvir/velpatasvir/voxilaprevir (Vosevi) – HCV DAAs

- **NF:**
  - amantadine ER (Gocovri) – Parkinson's Disease Drugs
  - betrixaban (Bevyxxa) – Oral Anticoagulants
  - delafloxacin (Baxdela) – Antibiotics – Quinolones
  - fluticasone propionate (ArmonAir RespiClick) – Pulmonary I Agents – Inhaled Corticosteroids
  - guselkumab (Tremfya) injection – Targeted Immunomodulatory Biologics (TIBs)
  - insulin aspart (Fiasp) – Insulins – Short-Acting Agents
  - lesinurad/allopurinol (Duzallo) – Antigout Agents – Chronic
  - methylphenidate ER orally dissolving tablet (Cotempla XR ODT) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
  - simvastatin oral suspension (FloLipid) – Antilipidemic-1s

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Gocovri, Bevyxxa, Baxdela, ArmonAir RespiClick, Tremfya, Fiasp, Duzallo, Cotempla XR ODT, and Flolipid. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) the following:

- Applying the same manual PA criteria for Tremfya in new users, as is currently in place for the other non step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Tremfya, a trial of both secukinumab (Cosentyx) and ustekinumab (Stelara) is required if the patient cannot be treated with Humira.

- Applying the same manual PA criteria to new users of Vosevi and Mavyret as is currently in place for the other non step-preferred DAAs for chronic hepatitis C infection. Harvoni is the preferred agent.

- Revising the manual PA criteria for Haegarda in new users to not allow concomitant use with another C1 esterase inhibitor product.

- Applying manual PA criteria to new users of Verzenio, Gocovri, Idhifa, Endari, Nerlynx, and Fycompa.

- Applying PA criteria to new and current users of Benlysta, ArmonAir RespiClick, Fiasp, Duzallo, Cotempla XR ODT, and FloLipid.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained, 0 absent; Day 2: 16 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service, on February 14, 2018.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. **New Manual PA Criteria: Antidepressants and Non-Opioid Pain Syndrome Agents—Bupropion Hydrobromide (Aplenzin)**

   Aplenzin is a branded formulation of bupropion ER approved for treating major depressive disorder and seasonal affective disorder. It was designated NF at the November 2009 meeting. Aplenzin contains a hydrobromide (HBr) salt, compared to the hydrochloride salt in Wellbutrin XL. The two formulations are bioequivalent. Cost-effective generic formulations of Wellbutrin are available and on the UF.

   a) ***COMMITTEE ACTION: BUPROPION HBr MANUAL PA CRITERIA*** The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for Aplenzin, due to the significant cost differences and lack of clinically compelling benefits between Aplenzin and generic bupropion ER. New and current users of Aplenzin are required to try generic bupropion ER and a second antidepressant first. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria, Step Therapy, and MN Criteria**—Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications. The updated manual PA outlined below will apply to new users.

   a) **Oral Oncological Agents: Dabrafenib (Tafinlar) and Trametinib (Mekinist)**—Tafinlar and Mekinist were reviewed in August 2014 with manual PA criteria recommended. Criteria were updated to add the additional indication for non-small cell lung cancer (NSCLC).

   b) **Oral Oncological Agents: Vemurafenib (Zelboraf)**—Zelboraf was reviewed in February 2012 with manual PA criteria recommended. Criteria were updated to add the additional indication for Erdheim-Chester Disease with BRAF V600 mutation.

   c) **TIBs—Ustekinumab (Stelara)**—Stelara was reviewed in August 2014 with manual PA criteria recommended. Criteria were updated to add the additional indication for severe plaque psoriasis in patients 12 to 18 years old.

   d) **Corticosteroids—Immune Modulators—Atopic Dermatitis Subclass: Crisaborole (Eucrisa)**—Eucrisa was reviewed in May 2017 with manual PA criteria recommended. Several atopic dermatitis agents are now available in

generic formulations. Due to the significant cost differences between Eucrisa and formulary alternatives, the PA criteria were updated to include a two-week trial of at least two formulary medium to high potency topical steroids or a topical calcineurin inhibitor (e.g., tacrolimus, Elidel) prior to use of Eucrisa.

e) **Corticosteroids—Immune Modulators—Hereditary Angioedema (HAE) Subclass: Plasma-derived human C1 Esterase Inhibitor IV (Cinryze)**—The HAE drugs were reviewed for formulary status in August 2017, and Haegarda was reviewed as a new drug during the November 2017 P&T Committee meeting (see pages 10-11). Both Haegarda and Cinryze are indicated for prophylaxis of HAE episodes. The manual PA criteria were updated to prohibit concomitant use of Cinryze and Haegarda.

f) **Gastrointestinal-2 (GI-2) Agents—Miscellaneous Subclass: Rifaximin (Xifaxan)**—The GI-2 drugs were reviewed for formulary status in November 2015. Manual PA criteria apply for rifaximin for diarrhea predominant irritable bowel syndrome (IBS-D), requiring a trial of antispasmodic and tricyclic antidepressant first. The evidence for rifaximin for treating IBS-D was reviewed thoroughly for any new guideline updates and for new published clinical trials. PA criteria from other commercial health plans were also reviewed. No changes to the current rifaximin PA criteria were recommended at this time.

g) **Non-Insulin Diabetes Drugs: GLP1RAs—Step Therapy, Manual PA Criteria, and MN Criteria**—The NF and non step-preferred GLP1RAs [lixisenatide (Adlyxin), liraglutide (Victoza), insulin degludec (Xultophy), insulin glargine/lixisenatide (Soliqua), exenatide microspheres BID (Byetta), and dulaglutide (Trulicity)] all require a trial of exenatide weekly (Bydureon) and albiglutide (Tanzeum). Tanzeum manufacturing will cease in June 2018. The step therapy, manual PA criteria, and MN criteria for the GLP1RAs were updated to remove the requirement of a trial of Tanzeum. Additionally, the manual PA criteria for the UF and step-preferred products (Bydureon and Tanzeum) were updated to reflect the market discontinuation of Tanzeum, and to advise prescribers of this issue.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY AND MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the manual PA criteria for Tafinlar, Mekinist, Zelboraf, Stelara, Cinryze, and Eucrisa, and updates to the step therapy, manual PA criteria, and MN criteria for the GLP1RAs. All updated criteria apply to new users of these agents. See Appendix C for the full criteria.

3. **Default Step Therapy Rules**

Step therapy requirements are in place for several drugs classes, where clinically effective (formulary alternatives) and cost-effective medications (the "step-preferred"

products) are required first, before the use of the "non step-preferred products." The P&T Committee meets on a quarterly interval; however, new products are approved on a routine basis by the FDA, leading to a potential delay in responding appropriately when there are new entrants to a class with existing step therapy requirements.

a) ***COMMITTEE ACTION: DEFAULT STEP THERAPY RULES***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that in the drugs classes where there are existing step therapy requirements (listed below), the DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB), through administrative authority, will direct Express Scripts, Inc. to proactively identify and immediately implement step therapy requirements for the newly-approved drug. The new drug will follow the respective step therapy and manual PA requirements as the other non step-preferred products in their respective drug class. Any actions taken of this type will be reviewed at the next P&T Committee meeting. The specific drug classes are as follows: TIBs, HCV DAAs, branded tetracycline antibiotics, inhaled corticosteroids (ICS), ICS/long-acting beta agonists (LABAs), dipeptidyl peptidase 4 inhibitors (DPP-4s), GLP1RAs, sodium-glucose co-transporter 2 (SGLT2) inhibitors, basal insulins, idiopathic pulmonary fibrosis (IPF) drugs, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, and gout drugs.

B. Quantity Limits (QLs)

1. **General QLs—**QLs were reviewed for 10 drugs from drug classes where there are existing QLs, including the oncologic agents, HCV DAAs, oral inhalers, iron overload, and for 4 new drugs where QLs are not currently in place.

   a) ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) QLs for Nerlynx, Idhifa, olaparib tabs and caps (Lynparza), Verzenio, Mavyret, Vosevi, deferasirox sprinkles (Jadenu), tiotropium/olodaterol (Stiolto Respimat), ArmonAir RespiClick, Trelegy Ellipta, Benlysta, Bevyxxa, Endari, and topical doxepin (Zonalon, Prudoxin) for pruritus. See Appendix D for the QLs.

C. PA, Default Step Therapy, MN, and QLs Implementation Periods

1. ***COMMITTEE ACTION: PA, DEFAULT STEP THERAPY, MN, AND QLs IMPLEMENTATION PERIODS—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following implementation periods:

   - The new manual PA for Aplenzin become effective on the first Wednesday after a 90-day implementation period in all points of service. Additionally, the P&T Committee recommended DHA send letters to the beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is May 2, 2018.

- Updates to the current PAs for Tafinlar, Mekinist, Zelboraf, Stelara, Eucrisa, and Cinryze become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.
- The default step therapy rules for the TIBs, HCV DAAs, branded tetracycline antibiotics, ICS, ICS/LABA, DPP-4s, GLP1RAs, SGLT2s, basal insulins, IPF drugs, PCSK9 inhibitors, and gout drugs become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.
- The QLs for the 14 drugs listed in section VI, B, above, and in Appendix D become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.

VII. BRAND OVER GENERIC AUTHORIZATION FOR MESALAMINE DELAYED RELEASE (LIALDA)

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Lialda product is more cost effective than the AB-rated generic formulations for mesalamine delayed release (DR), which were launched in June 2017. The manufacturer of Lialda has offered a Blanket Purchase Agreement (BPA). Therefore, the branded Lialda product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Lialda. The "brand over generic" requirement for Lialda will be removed administratively when it is no longer cost effective compared to the AB-rated generics.

A. ***COMMITTEE ACTION: LIALDA BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA—***The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 4 absent) implementing the requirement to prefer the branded Lialda product over generic formulations. Manual PA criteria are required for generic mesalamine ER in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Lialda product cannot be used. (See Appendix C).

B. ***COMMITTEE ACTION: LIALDA BRAND COPAYMENT CHANGE—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) that the brand (Tier 2) formulary cost share for Lialda in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share.

The authority for the last recommendation is codified in 32 CFR 199.21(j)(3):

> [W]hen 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.

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for four product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) clarifying the formulary status of the following four products to reflect the current formulary status, and applicable step therapy, PA criteria, MN criteria, and QLs for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- GI-2 Miscellaneous Agents: linaclotide (Linzess) 72 mcg tablet is designated formulary on the UF, which is the same as Linzess 145 mcg.

- Oral Oncologic Agents: olaparib (Lynparza) 100 mg and 150 mg tablets are designated formulary on the UF, which is the same as Lynparza capsules. Additionally, QLs will also apply. See Section VI, B, above, on page 14, and Appendix D for the QLs.

- Neurological Agents/Miscellaneous—Movement Disorders: valbenazine (Ingrezza) 80 mg is designated NF with the same PA criteria as Ingrezza 40 mg. (See the August 2017 DoD P&T Committee minutes for the Ingrezza PA criteria.)

- TIBs: etanercept (Enbrel Mini single-dose prefilled cartridge) is designated NF and non step-preferred, with the same PA criteria and QLs as Enbrel SQ injection. (See the August 2014 and November 2014 DoD P&T Committee minutes for the PA criteria and QLs for Enbrel SQ.)

IX. FORMULARY STATUS UPDATE FOR TAPENTADOL IR (NUCYNTA)

The Committee received an MTF request to consider changing the formulary status of the narcotic analgesic tapentadol IR (Nucynta). Tapentadol IR was originally designated NF at the November 2009 meeting, while tapentadol ER (Nucynta ER) was most recently reviewed in August 2015 and designated with UF status. The formulary status change was requested in order to assist with local MTF recapture efforts.

The was no new pertinent clinical information to change the clinical conclusion from November 2009 that there is insufficient evidence to suggest a clinically meaningful therapeutic advantage in patient outcomes, in terms of efficacy and safety, with tapentadol IR compared to the other narcotic analgesics already on the UF. A cost analysis, including an assessment of the overall costs to the MHS and MTF recapture rates, and a CMA comparing selected narcotic analgesics that are competitors to Nucynta IR, found that costs to the MHS will increase with a formulary change from NF to formulary on the UF.

A. ***COMMITTEE ACTION: NUCYNTA IR FORMULARY CHANGE REQUEST***
The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) maintaining tapentadol IR (Nucynta) as NF on the UF.

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

See Appendix G for the mail order status of medications designated NF during the November 2017 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the November 2017 meeting, including the newly-approved drugs affected by the EMMPI, will be effective on the first Wednesday two weeks after the signing of the minutes, on February 14, 2018.

A. **Newly-Approved Drugs per 32 CFR 199.21(g)(5)**

1. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF STATUS***

   The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained 0 absent; Day 2: 16 for, 0 opposed, 0 abstained 1 absent):

   a) **Add:** Trelegy Ellipta

   b) **Do Not Add:**

   - Not available at Mail Order: Nerlynx, Idhifa, Verzenio, Haegarda, Benlysta, and Nityr
   - Not currently required to go to Mail Order (e.g., not on the EMMPI list): Vosevi and Mavyret (HCV DAAs), and Fycompa oral solution (anticonvulsant)
   - Requires additional information regarding relative prices at Retail versus the Mail Order Pharmacy: Endari
   - Pending class review: Symproic

2. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR NF STATUS***

   The P&T Committee recommended (Day 1: 17 for, 0 opposed, 0 abstained 0 absent; Day 2: 16 for, 0 opposed, 0 abstained 1 absent)::

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: Tremfya, ArmonAir RespiClick, Fiasp, Duzallo, and FloLipid.

   b) **Do Not Add:** The previously established exception from the mail order requirement for acute use agents applies to Baxdela (antibiotic) and Bevyxxa (anticoagulant). The previously

established exception from the mail order requirement for C-II controlled substances applies to methylphenidate extended release orally dissolving tablets (Cotempla XR ODT). The following agent may not be feasible to provide through mail order and should be exempted pending further information: amantadine extended release (Gocovri).

XI. RE-EVALUATION OF NF GENERICS

Background—The DHA POD FMB monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, TMA, on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes.

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 generically available NF agents in four previously reviewed drug classes: the ADHD/wakefulness promoting agents, benign prostatic hyperplasia (BPH) drugs, topical antifungals, and renin-angiotensin antihypertensive agents (RAAs). Existing step therapy and manual PA requirements, and BCF designation were also discussed when pertinent.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—For the topical antifungals, BPH agents, and RAAs, the P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) that there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusions from when the classes were originally reviewed for UF placement. The P&T Committee took into account new information for wakefulness-promoting agents. Specific comments, including the results of comparative cost reviews, are below:

A. ADHD/Wakefulness: Wakefulness Promoting Subclass

- *armodafinil (Nuvigil, generics); modafinil (Provigil, generics)*—Currently, armodafinil is NF (Tier 3) and modafinil is UF. The two drugs are now generically available from multiple manufacturers, with the same unit cost based on weighted average cost across all points of service. The unit cost for both products has dropped significantly from the previous brand cost.

  Clinically, there was no new data to change the conclusion that there are no compelling differences in efficacy or safety between the products. Both products are classified as C-IV controlled substances, which provides a potential barrier to inappropriate use. Current PA requirements are based primarily on the likelihood of their use for non-FDA approved indications that cannot be supported based on available evidence.

The P&T Committee reviewed an updated analysis of International Classification of Disease (ICD) 9/10 diagnosis codes for patients starting treatment with modafinil or armodafinil. A total of 67% of all patients have an ICD 9/10 code for an FDA-approved indication, which is a much lower rate of off-label use than in a 2012 MHS analysis.

- *sodium oxybate (Xyrem)*—There are no generic equivalents for sodium oxybate (Xyrem). Due to the significant abuse potential, Xyrem is only available under stringent restricted distribution requirements from a single pharmacy. The current manual PA restricts use to its two FDA-approved indications: excessive sleepiness associated with narcolepsy without cataplexy (which requires a trial of modafinil first) or treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. An analysis of MHS utilization by diagnostic codes suggests continued off-label use of sodium oxybate.

B. Topical Antifungals

The nonformulary generic topical antifungals are still not cost effective relative to the generic formulary products. However, utilization of BCF clotrimazole cream and solution was much lower than ketoconazole cream and ketoconazole solution, respectively, while unit costs were similar or lower for the UF ketoconazole products.

C. BPH Agents: 5-Alpha Reductase Inhibitors (5-ARI) Subclass

Dutasteride (Avodart, generics) and dutasteride/tamsulosin (Jalyn, generics) are NF and non step-preferred, requiring a trial of finasteride (Proscar, generics) first. The P&T Committee noted that finasteride and dutasteride are highly therapeutically interchangeable for the treatment of BPH, and the combination product Jalyn offers no additional benefit compared to either of the individual components, or finasteride plus tamsulosin.

The weighted average cost per unit for Jalyn was substantially higher than that for finasteride, finasteride plus tamsulosin, or dutasteride plus tamsulosin as individual components. The weighted average cost per unit for generic dutasteride was slightly higher than that for finasteride.

D. RAAs

The NF generic antihypertensive agents are still not cost effective relative to the generic formulary products. However, several products currently designated as UF and non step-preferred were considered for UF and step-preferred status, given several factors, including the cost difference by points of service.

1. ***COMMITTEE ACTION: NF GENERIC PRODUCT, UF, BCF, PA RECOMMENDATIONS AND IMPLEMENTATION—***The P&T

Committee recommended the following, effective the first Wednesday two weeks after the signing of the minutes:

a) Returning the following product to UF status (16 for, 0 opposed, 0 abstained, 1 absent): *ADHD/Wakefulness*—armodafinil (Nuvigil, generics)

b) Removing the PA requirements for the following products, with reassessment in one year (12 for, 3 opposed, 0 abstained, 2 absent): *ADHD/Wakefulness*—armodafinil (Nuvigil, generics), modafinil (Provigil, generics)

c) Revising the PA criteria for the following product in new users (16 for, 0 opposed, 0 abstained, 1 absent): *ADHD/Wakefulness*—sodium oxybate (Xyrem). See Appendix C for the full criteria.

d) Making the following changes to the BCF (16 for, 0 opposed, 0 abstained, 1 absent):
   - Add to the BCF: *Topical Antifungals*—ketoconazole cream and shampoo
   - Remove from the BCF: *Topical Antifungals*—clotrimazole solution

e) Returning the following product to the UF, with step therapy requirements and PA criteria remaining unchanged (16 for, 0 opposed, 0 abstained, 1 absent): *BPH Agents*—dutasteride (Avodart, generics)

f) Designating the following products as UF and step-preferred, with pertinent updates made to the PA criteria for the non step-preferred RAAs (16 for, 0 opposed, 0 abstained, 1 absent): *RAAs*—irbesartan (Avapro, generics), irbesartan/HCTZ (Avalide, generics)

XII. ITEMS FOR INFORMATION

A. MHS PRESCRIBING AND COST TRENDS

The Committee was briefed on various aspects of MHS prescribing and cost trends, including overall trends and spends, specialty spend, top 25 drug classes, and opioid dispensing patterns.

B. SELF-MONITORING BLOOD GLUCOSE TEST STRIPS: PRECISION XTRA GLUCOMETERS

Manufacturing of the Precision Xtra glucometers will cease in mid-2018; manufacturing of the Precision Xtra test strips will continue indefinitely. A passive conversion to the FreeStyle Lite glucometers is recommended; MTFs should dispense FreeStyle Lite glucometers to patients newly diagnosed with diabetes, or those with a malfunctioning Precision Xtra glucometer.

C. UF DRUG CLASS OVERVIEW

An overview of the Ophthalmic Immunomodulatory Agents subclass was presented to the Committee. Clinical information was provided to assist with determining the most appropriate scenario for solicitation purposes. The clinical and economic analyses of this drug class will be completed at an upcoming DoD P&T Committee meeting.

D. QUANTITY LIMITS AT THE MTFs:

The February 2005 DoD P&T Committee meeting was the first meeting under the new Uniform Formulary Rule. 10 U.S.C. §1074g requires the establishment of an effective, efficient, integrated pharmacy benefit program under chapter 55 of title 10, United States Code, which applies to MTFs as well as to the purchased care system. The DoD P&T Committee makes recommendations to the Director, TMA (now DHA), not only on formulary/non-formulary status for pharmaceutical agents in a class, but also on prior authorizations, quantity limits, and medical necessity criteria. Therefore, prior authorizations, quantity limits, and medical necessity criteria established by the DoD P&T Committee will apply to all three points of service.

As shown in Appendix D, quantity limits are listed for the MTFs, along with the Mail Order and Retail points of service. In general up to a 90-day supply of medication is allowed at the MTFs, similar to the Mail Order. Unless specifically directed otherwise by the DoD P&T Committee, QLs at the MTFs are to be processed in the same manner as in the Mail Order.

XIII. ADJOURNMENT

The meeting adjourned at 1545 hours on November 16, 2017. The next meeting will be in February 2018.

Appendix A—Attendance: November 2017 DoD 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 Legend Prenatal Vitamins in the Class

Appendix F—Table of Formulary Recommendations for Newly-Approved Drugs per 32 CFR 199.21(g)(5)

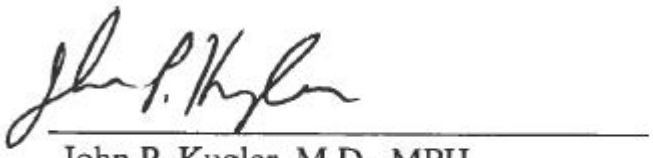
Appendix G—Mail Order Status of Medications Designated Nonformulary during the November 2017 DoD P&T Committee Meeting

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

Appendix I—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



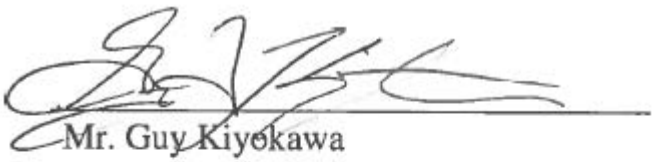
John P. Kugler, M.D., MPH
DoD P&T Committee Chair

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:



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

31 JAN 18

Date

Appendix A—Attendance: November 2017 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood for Mr. David Bobb	Chief of Staff, DHA Pharmacy Operations Division
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
LTC John Poulin, MC	Army Physician at Large
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Col Angela Mysliwiec, MC	TRICARE Regional Office Representative
Voting Members Absent	
Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
Ms. Catherine Gilbert	Defense Logistics Agency Troop Support
Lt Col Derek Underhill	Defense Logistics Agency Troop Support
Mr. Dwight Bonham via phone	DHA Contract Operations Division
Mr. Evan Zaslow via phone	DHA Contract Operations Division
Ms. Kim Wood	DHA Contract Operations Division
LCDR Matthew Miller	Indian Health Service
CDR Marisol Martinez	Centers for Disease Control and Prevention

Appendix A—Attendance (continued)

Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, 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
David Folmar, PharmD	DHA Formulary Management Branch
Robert Conrad, PharmD	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
LCDR Christina Andrade	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
CPT Zachary Leftwich, MSC	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Brian Beck, PharmD	DHA Purchased Care Branch
Lt Col Ellen Roska, BSC	DHA Integrated Utilization Branch
Libby Hearin, PharmD	DHA Informatics Integration Branch

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	• Use of formulary agents and nonformulary agents (Qsymia, Contrave, Xenical, Belviq/Belviq XR) are contraindicated • Use of formulary agents and nonformulary agents (Qsymia, Contrave, Xenical, Belviq/Belviq XR) have resulted in therapeutic failure **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• lorcaserin (Belviq, Belviq XR) • naltrexone SR/bupropion SR (Contrave) **Weight Loss Agents**	• Use of formulary agents is contraindicated • Use of formulary agent resulted in therapeutic failure **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• orlistat (Xenical) **Weight Loss Agents**	• Use of formulary agents and nonformulary agents (Qsymia, Contrave, Belviq/ Belviq XR) is contraindicated • Use of formulary agents and nonformulary agents (Qsymia, Contrave, Belviq/ Belviq XR) have resulted in therapeutic failure • No alternative formulary agent: The patient is between 12 and 18 years of age **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• phentermine 8 mg tabs (Lomaira) **Weight Loss Agents**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• phentermine/topiramate ER (Qsymia) **Weight Loss Agents**	• Use of phentermine has resulted in therapeutic failure **Formulary Alternatives:** phentermine, diethylpropion, benzphetamine, phendimetrazine
• amantadine ER tablets (Gocovri) **Parkinson's Disease Drugs**	• The patient has experienced significant adverse effects to the formulary alternative amantadine IR that are not expected to occur with Gocovri. **Formulary Alternative:** amantadine immediate release
• betrixaban (Bevyxxa) **Oral Anticoagulants**	• No formulary alternative: The patient requires extended duration venous thromboembolism prophylaxis and cannot take SQ enoxaparin or SQ heparin due to adverse effects or therapeutic failure **Formulary Alternatives:** enoxaparin (Lovenox), SQ heparin
• delafloxacin (Baxdela) **Antibiotics: Quinolones**	• Use of formulary agents is contraindicated • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** ciprofloxacin and clindamycin, trimethoprim-sulfamethoxazole, linezolid, or any culture-sensitive agent(s)

Drug / Drug Class	Medical Necessity Criteria
• fluticasone propionate (ArmonAir RespiClick) **Pulmonary I Agents: Inhaled Corticosteroids**	• No formulary alternative: The patient requires fluticasone and cannot manipulate BOTH the Diskus or the hydrofluoroalkane (HFA) metered-dose inhaler device. **Formulary Alternatives:** fluticasone propionate (Flovent Diskus, Flovent HFA)
• guselkumab (Tremfya) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) are contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) • Adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) have resulted in therapeutic failure **Formulary Alternatives:** adalimumab (Humira), secukinumab (Cosentyx), ustekinumab (Stelara), and apremilast (Otezla)
• insulin aspart (Fiasp) **Insulins: Short-Acting Agents**	• Use of Novolog and Humalog has resulted in therapeutic failure **Formulary Alternatives:** insulin aspart (Novolog), insulin lispro (Humalog), insulin glulisine (Apidra)
• lesinurad/allopurinol (Duzallo) **Antigout Agents: Chronic**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents resulted or are likely to result in therapeutic failure **Formulary Alternatives:** probenecid
• methylphenidate extended release orally disintegrating tablets (Cotempla XR ODT) **Attention Deficit Hyperactivity Disorder (ADHD) Drugs**	• Use of Adderall XR and Concerta OROS (and generics) AND Quillivant XR or Aptensio XR have resulted in therapeutic failure **Formulary Alternatives:** mixed amphetamine salts ER (Adderall XR, generics), extended-release methylphenidate (Concerta, generics), methylphenidate extended release oral suspension or chewable tablets (Quillivant XR),methylphenidate extended release capsules (Aptensio XR)
• simvastatin oral suspension (FloLipid) **Antilipidemic-1s**	• No alternative formulary agent: The patients requires a statin and cannot swallow simvastatin tablets. **Formulary Alternatives**: atorvastatin, lovastatin, pravastatin, simvastatin, rosuvastatin
• Nonformulary legend prenatal vitamins **Prenatal Vitamins Subclass**	• Patient has experienced significant adverse effects from formulary agents • No formulary alternative: the patient has swallowing difficulties Formulary Alternatives: Prenatal Vitamin Plus Low I, Prenatal Vitamin + Low Iron, Prenatal Plus, Preplus

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• benzphetamine • diethylpropion • phendimetrazine IR and SR • phentermine **Weight Loss Agents**	Manual PA criteria apply to all new and current users of phentermine, phendimetrazine, benzphetamine, and diethylpropion. Manual PA criteria—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy • Patient is not pregnant • If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin Off-label uses are not approved Prior Authorization expires after 3 months Renewal PA Criteria: PA will be renewed for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication. • The patient is not pregnant. • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• phentermine 8 mg tablets (Lomaira) **Weight Loss Agents**	Manual PA criteria apply to all new and current users of phentermine 8 mg tablets (Lomaira) Manual PA criteria—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • The patient requires a dose of phentermine less than 15 mg due to elevated baseline heart rate. • Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents. • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy.

Drug / Drug Class	Prior Authorization Criteria
	• For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. • If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin. Off-label uses are not approved Prior Authorization expires after 3 months. Renewal PA Criteria: Lomaira will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • The patient is not pregnant. • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• phentermine/topiramate ER (Qsymia) **Weight Loss Agents**	Manual PA criteria apply to all new and current users of Qsymia. Manual PA criteria—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agents. • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. • If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin. Off-label uses are not approved Prior Authorization expires after 4 months. Renewal PA Criteria: Qsymia will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • For patients initially receiving Qsymia 7.5mg/46mg: discontinue Qsymia, or escalate to 15mg/92mg if a 3% reduction in baseline body weight is not achieved at after 12 weeks • For patients receiving Qsymia 15mg/92mg: discontinue if a 5% reduction in baseline body weight is not achieved at 12 weeks • The patient is not pregnant.

Drug / Drug Class	Prior Authorization Criteria
	• Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• naltrexone SR/ bupropion SR (Contrave) **Weight Loss Agents**	Manual PA criteria apply to all new and current users of Contrave <u>Manual PA criteria</u>—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • Patient has tried and failed to achieve a 5% reduction in baseline weight after a 12 week course of phentermine unless there is a history of cardiovascular disease (e.g. arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or significant contraindication to phentermine) • Patient is not on concurrent opioid therapy and does not have a seizure disorder or uncontrolled hypertension • Patient is not currently on an monoamine oxidase inhibitor (e.g., Emsam, Marplan, Nardil), or another formulation of bupropion or naltrexone • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. • If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin. Off-label uses are not approved Prior Authorization expires after 4 months. Renewal PA Criteria: Contrave will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • The patient is not pregnant. • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• lorcaserin (Belviq, Belviq XR) **Weight Loss Agents**	Manual PA criteria apply to all new and current users of Belviq or Belviq XR <u>Manual PA criteria</u>—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • Patient has tried and failed to achieve a 5% reduction in baseline weight after a 12 week course of phentermine unless there is a history of cardiovascular disease (e.g. arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or significant contraindication to phentermine) • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)

Drug / Drug Class	Prior Authorization Criteria
	• Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. • If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin. Off-label uses are not approved Prior Authorization expires after 4 months. Renewal PA Criteria: Belviq or Belviq XR will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • The patient is not pregnant • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• orlistat (Xenical) Adults ≥18 Years of Age **Weight Loss Agents**	Manual PA criteria apply to all new and current users of Xenical Manual PA criteria—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • The patient has tried and failed or has a contraindication to ALL of the following: Qsymia, Contrave, and Belviq/Belviq XR • The patient does not have chronic malabsorption syndrome or cholestasis • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. • If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin. Off-label uses are not approved, including nonalcoholic steatohepatitis (NASH) Prior Authorization expires after 4 months and then annually Renewal PA Criteria: Xenical will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • The patient is not pregnant

Drug / Drug Class	Prior Authorization Criteria
	• Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• orlistat (Xenical) Pediatric Patients 12 to 17 Years of Age **Weight Loss Agents**	Manual PA criteria apply to all new and current users of Xenical Manual PA criteria—Agent approved if ALL of the following criteria are met: • Patient is between the ages of 12 and 17 years old • The patient currently has a BMI of ≥ 95th percentile for age and sex, OR if in ≥ 85th percentile but < 95th percentile for age and sex and has at least one severe co-morbidity (type 2 diabetes mellitus, premature cardiovascular disease) or has a strong family history of diabetes or premature cardiovascular disease (CVD) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • Patient is not pregnant. Off-label uses are not approved Prior Authorization expires after 4 months and then annually Renewal PA Criteria: Xenical will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient's current BMI percentile has decreased for age and weight (considering the patient is increasing in height and will have a different normative BMI from when Xenical was started) OR • The patient currently has a BMI >85th percentile • The patient is not pregnant
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	Manual PA criteria apply to all new and current users of Saxenda Manual PA criteria—Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • Patient has tried and failed or has a contraindication to all of the following agents: Qsymia, Xenical, Contrave, and Belviq or Belviq XR • If the patient is diabetic, must have tried and failed metformin and the preferred GLP1-RA (Bydureon) • Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer, or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. Off-label uses are not approved, including Diabetes Mellitus Prior Authorization expires after 4 months and then annually

Drug / Drug Class	Prior Authorization Criteria
	Renewal PA Criteria: Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.
• ixazomib (Ninlaro) **Multiple Myeloma Subclass**	Manual PA criteria apply to all new users of Ninlaro Manual PA criteria—Ninlaro is approved if **all** of the following apply: • Patient is > 18 years old • Must be prescribed by or in consultation with a hematologist or oncologist • Patient is diagnosed with multiple myeloma • Patient must not have had disease progression with a bortezomib (Velcade) or carfilzomib (Kyprolis)–containing regimen • One or more of the following must apply: o Patient must have failed or not be candidate for bortezomib AND carfilzomib o Patient has failed or is not a candidate for carfilzomib and has high risk cytogenetics o Patient will be starting Ninlaro as third (or higher) line of therapy • Must be used in combination with lenalidomide (Revlimid), pomalildomide (Pomalyst), OR thalidomide (Thalomid) • Must be used in combination with dexamethasone • Must not be used concurrently with bortezomib or carfilzomib Off-label uses are not approved Prior Authorization does not expire
• lenalidomide (Revlimid) **Multiple Myeloma Subclass**	Manual PA criteria apply to all new users of lenalidomide. Manual PA criteria—Lenalidomide is approved if all of the following apply: • Patient is > 18 years old • Must be prescribed by or in consultation with a hematologist or oncologist • Patient has one of the following diagnoses: o Multiple myeloma o Mantle Cell Lymphoma refractory to at least 2 prior treatment regimens, one of which contains bortezomib (Velcade) OR at least 1 prior treatment regimen and has failed or has a contraindication to bortezomib o Myelodysplastic syndrome w/5q deletion with one or more of the following: symptomatic anemia, transfusion-dependent anemia, or anemia not controlled with an erythroid stimulating agent • Patient is not on concurrent pomalidomide (Pomalyst) or thalidomide (Thalomid) • PA will be approved for the following non-FDA approved indications: o Relapsed/refractory multi-centric Castleman Disease not responding to non-lenalidomide management o Diffuse large B-cell lymphoma (Non-Hodgkin Lymphoma) as second-line (or subsequent) therapy relapsed/refractory to non-lenalidomide management o Follicular lymphoma (Non-Hodgkin Lymphoma) o Relapsed/refractory classical Hodgkin's lymphoma o Myelofibrosis refractory to or with contraindications to alternative therapies o Systemic light chain amyloidosis with organ involvement Off-label uses other than those listed above are not approved Prior Authorization does not expire

Drug / Drug Class	Prior Authorization Criteria
• panobinostat (Farydak) **Multiple Myeloma Subclass**	Manual PA criteria apply to all new users of Farydak Manual PA criteria—Farydak is approved if **all** of the following apply: • Must be prescribed by or in consultation with a hematologist or oncologist • Patient is > 18 years old • Patient is diagnosed with multiple myeloma that is relapsed or refractory • Patient's disease is NOT refractory to all of the following drugs: bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro) • Patient will be starting Farydak as the third (or higher) line of therapy • Patient's previous regimens include at least one regimen with bortezomib, carfilzomib OR ixazomib, AND at least one regimen with lenalidomide, pomalidomide, OR thalidomide • Must be used in conjunction with dexamethasone • Must be used in conjunction with a bortezomib, carfilzomib, OR Ninlaro-containing regimen • Must meet ALL of the following requirements: o Platelet count > $100x10^9$/L o QTc < 450 msec o Patient has no evidence of acute or chronic ischemic disease on EKG and no history of MI or unstable angina within the last 6 months • Patient must have access to anti-diarrheal therapy Off-label uses are not approved Prior Authorization expires after 12 months Renewal PA Criteria: PA will be re-approved for an additional 6 months, if the patient has not yet completed 16 cycles of treatment.
• pomalidomide (Pomalyst) **Multiple Myeloma Subclass**	Manual PA criteria apply to all new users of Pomalyst Manual PA criteria—Pomalyst is approved if: • Patient is > 18 years old • Must be prescribed by or in consultation with a hematologist or oncologist • Patient is diagnosed with relapsed/refractory multiple myeloma that is refractory to lenalidomide AND all of the following must apply: o Patient has previously had a trial of a bortezomib, carfilzomib, OR Ninlaro-containing regimen o Patient will be starting Pomalyst as third (or higher) line of therapy o Must be used in combination with dexamethasone • Patient is not using concurrent lenalidomide or thalidomide • PA will be approved for the following non-FDA approved indications: o Myelofibrosis refractory to or with contraindications to alternative therapies (including lenalidomide) and erythropoietin levels > 500 mU/ml o Systemic light chain amyloidosis with organ involvement refractory to or with contraindications to alternative therapies including lenalidomide Off-label uses other than those listed above are not approved Prior Authorization does not expire

Drug / Drug Class	Prior Authorization Criteria
• abemaciclib (Verzenio) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Verzenio. Manual PA criteria—Verzenio is approved if: • The patient has a diagnosis of HR+, HER2 negative advanced or metastatic breast cancer • Breast cancer has progressed during or after endocrine therapy • The patient is using Verzenio and meets ALL of the following: o Patient is postmenopausal and will use Verzenio in combination with fulvestrant OR o The patient is premenopausal or perimenopausal and is receiving ovarian suppression with GnRH agonist AND Verzenio will be used in combination with fulvestrant OR o Verzenio will be used as monotherapy and the patient has had prior chemotherapy for treatment of metastatic breast cancer Off-label uses are not approved Prior Authorization does not expire
• amantadine ER tabs (Gocovri) **Parkinson's Disease Drugs**	Manual PA criteria apply to all new users of Gocovri Manual PA Criteria—Gocovri is approved if: • The patient is ≥18 years old AND • Has a diagnosis of Parkinson's Disease AND • Has had therapeutic failure of a trial of amantadine 200 mg immediate release tablets administered twice daily Off label uses are not approved Prior Authorization does not expire
• belimumab (Benlysta) **Targeted Immunomodulatory Biologics (TIBs)**	Manual PA Criteria apply to all new and current users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta. Manual PA criteria: Coverage is approved for Benlysta if all of the following are met: • Benlysta is prescribed by or in consultation with a specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist • The patient is ≥18 years old • The patient has a documented diagnosis of active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE • The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) • The patient does not have severe active lupus nephritis or severe active central nervous system lupus • The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide Off-label uses are not approved Prior Authorization expires in one year. Renewal PA Criteria: Benlysta will be approved on a yearly basis if all of the following are met: • Treatment with Benlysta has shown documented clinical benefit (i.e. improvement in number/frequency of flares, improvement in in Safety of

Drug / Drug Class	Prior Authorization Criteria
	Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.) • The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) • The patient does not have severe active lupus nephritis or severe active central nervous system lupus The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide
• plasma-derived human C1 esterase inhibitor IV (Cinryze) • plasma-derived human C1 esterase inhibitor SQ (Haegarda) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	**Updates from the November 2017 meeting are bolded** Manual PA criteria apply to all new users of Cinryze and Haegarda. <u>Manual PA criteria</u>—Cinryze or Haegarda is approved if: • The patient is ≥13 years old (Cinryze) or ≥12 years old (Haegarda) AND • The patient must be diagnosed with hereditary angioedema (HAE) Type I, II, or III (HAE with normal C1-esterase inhibitor) AND • The drug is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist AND • The patient must experience ≥2 HAE attacks per month AND • **The patient is not receiving Haegarda and Cinryze concomitantly.** • The patient has tried and failed an attenuated androgen (danazol) OR o Patient has experienced or is expected to experience serious adverse effects from the use of an androgen (e.g., virilization of women, stroke, or myocardial infarction, venous thromboembolism) OR o Patient is female of childbearing age • Cinryze or Haegarda are not approved for any indication other than HAE. Off label uses are not approved Prior Authorization does not expire.
• enasidenib (Idhifa) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Idhifa. <u>Manual PA criteria</u>—Idhifa is approved if all the following criteria are met: • The patient is ≥18 years old and has a diagnosis of relapsed refractory acute myelogenous leukemia (AML) • Patient exhibits the IDH2 mutation as determined by an FDA approved test • Must be prescribed by or in consultation with hematologist or oncologist • Idhifa is used in combination with standard chemotherapy protocols Off-label uses are not approved Prior Authorization expires at one year. Renewal criteria: Idhifa will be approved for one year if the patient has not had disease progression.

Drug / Drug Class	Prior Authorization Criteria
• fluticasone propionate (ArmonAir RespiClick) **Pulmonary I Agents: Inhaled Corticosteroids (ICS)**	PA criteria apply to all new and current users of ArmonAir RespiClick who are older than 12 years of age. Manual PA criteria—ArmonAir RespiClick is approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if: • The patient has experienced any of the following issues with either Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred ICS drug: • The patient requires fluticasone and cannot manipulate BOTH the Flovent Diskus (active inhalation) or Flovent HFA MDI (passive inhalation) Off-label uses are not approved Prior Authorization does not expire.
• glecaprevir/pibrentasvir (Mavyret) **Hepatitis C Virus – Direct Acting Antiviral Agent Subclass (HCV DAAs)**	Manual PA criteria apply to new users of Mavyret. Manual PA criteria: • Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for glecaprevir/pibrentasvir (Mavyret) if: • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3) AND Coverage approve for patients ≥18 years of age with • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 2, 3, 4, 5 or 6 • The patient does not have severe cirrhosis Off-label uses are not approved PA expires after 365 days
• sofosbuvir/velpatasvir/ voxilaprevir (Vosevi) **Hepatitis C Virus – Direct Acting Antiviral Agent Subclass (HCV DAAs)**	Manual PA criteria apply to new users of Vosevi. Manual PA criteria: • Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir / velpatasvir /voxilaprevir (Vosevi)) if: • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA

Drug / Drug Class	Prior Authorization Criteria
	• There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3) Coverage approve for patients ≥18 years of age with • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C • Document HCV RNA viral loadThe patient has HCV genotype 1, 2, 3, 4, 5, or 6 AND has tried and failed treatment with a regimen containing a NS5A Inhibitor (e.g.,,Epclusa, Harvoni, Technivie, Viekira, Viekira XR, Zepatier, Daklinza) OR • The patient has HCV genotype 1a or 3 AND has tried and failed treatment with Sovaldi without a NS5A Inhibitor. • AND the patient does not have any of the following: o Decompensated cirrhosis o Moderate or severe hepatic impairment (Child-Pugh Class B or C) o Severe renal impairment (eGFR <30 mL/min or End Stage Renal Disease) Off-label uses are not approved PA expires after 365 days
• guselkumab (Tremfya) **Targeted Immunomodulatory Biologics (TIBs)**	**Changes made from the November 2017 meeting are in bold.** Step therapy and Manual PA Criteria apply to all new users of guselkumab (Tremfya). 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 Tremfya if: • Contraindications exist to Humira **and Cosentyx, and Stelara** • Inadequate response to Humira **and Cosentyx, and Stelara** (need for different anti-tumor necrosis factor [TNF] or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic congestive heart failure (CHF) • Adverse reactions to Humira **and Cosentyx, and Stelara** not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy **and have failed to respond to or lost response to other systemic therapies** Off-label uses are not approved Prior Authorization does not expire 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), ustekinumab (Stelara), apremilast (Otezla), rituximab (Rituxan), secukinumab (Cosentyx), or ixekizumab (Taltz).

Drug / Drug Class	Prior Authorization Criteria
• insulin aspart (Fiasp) **Insulins Short acting Agents**	Manual PA criteria apply to all new and current users of Fiasp. Manual PA criteria: Coverage will be approved if all criteria are met: • Patient has type 1 diabetes • Patient has tried and failed insulin aspart (Novolog) • Patient has tried and failed or is intolerant to insulin lispro (Humalog) • Prescribed by or in consultation with an endocrinologist Off-label uses are not approved Prior authorization does not expire.
• L-glutamine oral powder (Endari) **Dietary Supplements**	Manual PA criteria apply to new users of Endari. Manual PA Criteria: coverage will be approved if ALL of the following criteria are met: • Patient has a diagnosis of sickle cell anemia or Sickle ß thalassemia • Age ≥ 5 years old • Patient has had ≥ 2 sickle cell crises in the last 12 months • Patient has had an inadequate treatment response to a 3 month trial of both hydroxyurea and blood transfusion therapy Off-label uses are not approved Prior Authorization does not expire.
• lesinurad/allopurinol (Duzallo) **Antigout Agents: Chronic**	Manual PA criteria apply to all new and current users of Duzallo. Manual PA criteria: Coverage will be approved if all criteria are met: • The patient is ≥ 18 years of age • The patient has chronic or tophaceous gout • The patient has a creatinine clearance (CrCl) >45 mL/min • The gout patient has not achieved target serum uric acid level despite maximally-tolerated therapy with allopurinol Off-label uses are not approved Prior authorization does not expire
• methylphenidate ER orally dissolving tablets (Cotempla XR ODT) **Attention Deficit Hyperactivity Disorder (ADHD Drugs)**	Manual PA criteria apply to all new and current users of Cotempla XR ODT. Manual PA criteria: Coverage will be approved if ALL of the following criteria are met: • Patient is between the ages of 6-17 years of age and has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient Must have tried and failed or has a contraindication to Adderall XR (generic) • Patient must have tried and failed or has a contraindication to Concerta OROS (generic) • Patient must have tried and failed or has a contraindication to methylphenidate ER oral suspension (Quillivant XR), or methylphenidate ER cap (Aptensio XR) Off-label uses are not approved Prior Authorization does not expire

Drug / Drug Class	Prior Authorization Criteria
• neratinib (Nerlynx) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Nerlynx Manual PA criteria—Nerlynx is approved if meets all of the following: • The patient is an adult ≥18 years of age with early stage HER2-overexpressed/amplified breast cancer • Nerlynx is used following adjuvant trastuzumab-based therapy (preferably less than 1 year, but no more than 2 years after completion of trastuzumab (Herceptin)-based therapy. • The patient has been counseled on significant adverse event profile • Nerlynx is co-prescribed with an antidiarrheal to mitigate adverse events for at a minimum 2 months • Patient has been counseled on the possibility of an unproven survival benefit gain with Nerlynx Off-label uses are not approved Prior Authorization expires after 18 months No renewal allowed, patient should not take more than a 365-day lifetime supply
• perampanel oral solution (Fycompa O/S) • **Anticonvulsants – Antimania Agents**	Manual PA criteria apply to all new users of Fycompa O/S ≥18 years of age. Manual PA criteria—Fycompa O/S is approved if: • The patient cannot swallow perampanel tablets AND • The patient has a diagnosis of epilepsy with partial-onset seizures with or without secondarily generalized seizures OR • The patient has a diagnosis of epilepsy with primary generalized tonic-clonic seizures Off-label uses are not approved Prior authorization does not expire
• simvastatin oral suspension (FloLipid) **Antilipidemic-1s**	PA criteria apply to all new and current users of FloLipid Manual PA criteria—FloLipid is approved (e.g., trial of generic simvastatin, atorvastatin, pravastatin, lovastatin, or rosuvastatin tablets) is not required if: • The provider writes in why the patient requires liquid simvastatin and cannot take simvastatin, atorvastatin, pravastatin, lovastatin, rosuvastatin tablets • Acceptable responses include that the patient requires simvastatin and cannot swallow the statin tablets due to some documented medical condition , including dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience Off-label uses are not approved Prior Authorization does not expire

Drug / Drug Class	Prior Authorization Criteria
• Bupropion HBr (Aplenzin) **Antidepressants and Non-Opioid Pain Syndrome Agents – Norepinephrine-Dopamine Reuptake Inhibitors Subclass**	**Manual PA criteria apply to all new and current users of Aplenzin. Note that PA is not required for generic bupropion (Wellbutrin, Wellbutrin SR or Wellbutrin XL); providers are encouraged to consider changing the prescription to generic Wellbutrin XL.** Manual PA criteria: Coverage for Aplenzin is approved if ALL of the following apply: • The patient is ≥18 years old • The patient has clinically diagnosed major depressive disorder or seasonal affective disorder • The patient must have tried and failed both of the following: o generic bupropion ER (e.g., patient cannot take more than one tablet of generic bupropion) AND o at least one generic selective serotonin reuptake inhibitor (SSRI) or other antidepressant • Patient does not have a history of seizure disorder or bulimia Off label uses are not approved (e.g., smoking cessation) Prior Authorization expires after 1 year. • Renewal PA criteria for continuation of therapy: PA is approved for an additional year if the patient has had an adequate clinical response and continues to be unable to take multiple tablets of generic bupropion. • Renewal PA criteria is limited to one year.
• Dabrafenib (Tafinlar) **Oncological Agents**	**Changes from the November 2017 meeting are in BOLD** Manual PA Criteria: • Coverage will be approved if: o Utilized as a single agent for treatment of unresectable or metastatic melanoma with BRAF V600E mutation o Combination use with Mekinist in the treatment of unresectable or metastatic melanoma with BRAF V600E or V600K mutations OR o **In combination with trametinib (Mekinist), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation** Off-**label uses are not approved** Prior Authorization does not expire
• Trametinib (Mekinist) **Oncological Agents**	**Changes from the November 2017 meeting are in BOLD** Manual PA Criteria: • Coverage will be approved if: o Treatment (alone or in combination with dabrafenib (Tafinlar)) of unresectable or metastatic melanoma with BRAF V600E or V600K OR o **In combination with dabrafenib (Tafinlar), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation** • Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy **Off-label uses are not approved**

Drug / Drug Class	Prior Authorization Criteria
	Prior Authorization does not expire
• Vemurafenib (Zelboraf) **Oncological Agents**	**Changes from the November 2017 meeting are in BOLD** Manual PA Criteria: • Coverage will be approved if: o Documented diagnosis of unresectable or metastatic melanoma with BRAFV600E mutation AND o Detected by an FDA-approved test (Cobas 4800) OR o **Patient has Erdheim-Chester Disease with BRAF V600 mutation** **Off-label uses are not approved** Prior Authorization does not expire
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics**	**Changes from the November 2017 meeting are in BOLD** Manual PA Criteria: coverage will be approved if: • Patients **~~≥ 18~~ ≥12** years with o Mod to severe plaque psoriasis who are candidates for phototherapy or systemic therapy OR • Patients ≥18 years with o Active psoriatic arthritis (PsA) alone or in combination with methotrexate o Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids or TNF blockers • Coverage NOT provided for concomitant use with other TIBs Off-label uses are not approved Prior Authorization does not expire
• Crisaborole (Eucrisa) **Corticosteroids-Immune Modulators – Atopic Dermatitis Subclass**	**Changes from the November 2017 meeting are in BOLD** Manual PA criteria apply to all new users of Eucrisa. Manual PA Criteria: Coverage approved if all criteria are met: • Patient has mild to moderate atopic dermatitis • Prescribed by a dermatologist, allergist, immunologist • Patient has a contraindication to, intolerability to, or failed treatment with **a two week trial of** at least one medium to high potency topical corticosteroid AND • **Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of a second agent including** • An additional medium - high potency topical corticosteroid OR • Topical calcineurin inhibitor (i.e. tacrolimus, Elidel) Off-label uses are not approved Prior Authorization does not expire.
• mesalamine delayed release generic for Lialda **GI-1 Agents: Aminosalicylates Subclass**	Manual PA criteria apply to all new users of generic Lialda. Note that brand Lialda is the preferred mesalamine delayed release product in DoD. Manual PA Criteria: Coverage for generic mesalamine delayed release is approved if the following criteria is met: • The provider has provided patient-specific justification as to why the brand Lialda product cannot be used. • Acceptable reasons include the following, which have occurred or are likely to occur with the branded Lialda product: allergy to the branded Lialda;

Drug / Drug Class	Prior Authorization Criteria
	contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues.
• sodium oxybate (Xyrem) **ADHD/Wakefulness-Promoting Agents**	**Changes from the November 2017 meeting are in BOLD** Manual PA criteria apply to all new users of Xyrem. Manual PA Criteria: Coverage of Xyrem is approved if the following criteria are met: • **The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND** • **Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND** • Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. o Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing **OR** • Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy **AND** o **the patient has history of failure, contraindication, or intolerance of both of the following, modafinil, or armodafinil, AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND** • **Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders)** **Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.** **PA expires after 1 year** **PA Renewal criteria: Xyrem will be renewed on a yearly basis if:** • **There is documentation demonstrating the patient has had a reduction in frequency of cataplexy attacks associated with Xyrem therapy OR** • **There is documentation demonstrating the patient has had a reduction in the symptoms of excessive daytime sleepiness associated with Xyrem therapy AND** • **Patient is not receiving a concomitant CNS depressant**

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• ixazomib (Ninlaro) **Multiple Myeloma Subclass**	Note: revised from February 2016 meeting ▪ MTF/Mail: 56-day supply ▪ Retail: 28-day supply
• panobinostat (Farydak) **Multiple Myeloma Subclass**	Note: revised from May 2017 meeting ▪ MTF/Mail/Retail: 21-day supply
• lenalidomide (Revlimid) • pomalidomide (Pomalyst) • thalidomide (Thalomid) **Multiple Myeloma Subclass**	Maintain current QLs due to REMS requirements ▪ MTF/Mail/Retail: 28-day supply
• neratinib (Nerlynx) **Oncologic Agents**	▪ MTF/Mail/Retail: 30-day supply
• enasidenib (Idhifa) **Oncologic Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• olaparib (Lynparza Tablets) **Oncologic Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• olaparib (Lynparza Capsules) **Oncologic Agents**	▪ MTF/Mail: 56-day supply ▪ Retail: 28-day supply
• abemaciclib (Verzenio) **Oncologic Agents**	▪ MTF/Mail: 56-day supply ▪ Retail: 28-day supply
• sofosbuvir/velpatasvir/voxilaprevir (Vosevi) **Hepatitis C Virus – Direct Acting Antiviral Agent Subclass (HCV DAAs)**	▪ MTF/Mail/Retail: 28-day supply
• glecaprevir/pibrentasvir (Mavyret) **Hepatitis C Virus – Direct Acting Antiviral Agent Subclass (HCV DAAs)**	▪ MTF/Mail/Retail: 28-day supply

Drug / Drug Class	Quantity Limits
• deferasirox (Jadenu Sprinkles) **Endocrine Agents: Miscellaneous**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• tiotropium/olodaterol oral inhaler (Stiolto Respimat) **Pulmonary II Agents: Chronic Obstructive Pulmonary Disease (COPD) Subclass**	▪ MTF/Mail: 3 inhalers per 90-day supply ▪ Retail: 1 inhaler per 30-day supply
• fluticasone propionate (ArmonAir RespiClick) **Pulmonary I: Inhaled Corticosteroids (ICS)**	▪ MTF/Mail: 3 inhalers per 90-day supply ▪ Retail: 1 inhaler per 30-day supply
• fluticasone furoate/umeclidinium/vilanterol (Trelegy Ellipta) **Pulmonary I: Combination Subclass**	▪ MTF/Mail: 3 inhalers per 90-day supply ▪ Retail: 1 inhaler per 30-day supply
• betrixaban (Bevyxxa) **Anticoagulant Agents**	▪ MTF/Mail: 45-day supply ▪ Retail: 30-day supply
• belimumab (Benlysta) **Immunosuppressive Agents**	▪ MTF/Mail: 56-day supply ▪ Retail: 28-day supply
• doxepin topical agents (Zonalon, Prudoxin) **Eczema Agents**	▪ MTF/Mail/Retail: 45 gm for 30-day supply in all points of service
• l-glutamine oral powder (Endari) **Dietary Supplement**	▪ MTF/Mail: 60 day-supply ▪ Retail: 30-day supply

Appendix E—Table of Legend Prenatal Vitamins in the Subclass

ATABEX EC	NEEVODHA	PRENATA
BAL-CARE DHA	NESTABS	PRENATABS FA
BAL-CARE DHA ESSENTIAL	NESTABS ABC	PRENATABS RX
CADEAU DHA	NESTABS DHA	PRENATAL 19
CALCIUM PNV	NESTABS ONE	PRENATAL LOW IRON
CITRANATAL 90 DHA	NEWGEN	PRENATAL PLUS
CITRANATAL ASSURE	NEXA PLUS	PRENATAL PLUS-DHA
CITRANATAL B-CALM	NIVA-PLUS	PRENATAL VITAMIN PLUS LOW I
CITRANATAL DHA	OB COMPLETE	PRENATAL-U
CITRANATAL HARMONY	OB COMPLETE GOLD	PRENATE AM
CITRANATAL RX	OB COMPLETE ONE	PRENATE CHEWABLE
C-NATE DHA	OB COMPLETE PETITE	PRENATE DHA
COMPLETE NATAL DHA	OB COMPLETE PREMIER	PRENATE ELITE
COMPLETENATE	OB COMPLETE WITH DHA	PRENATE ENHANCE
CONCEPT DHA	OBSTETRIX DHA	PRENATE ESSENTIAL
CONCEPT OB	OBSTETRIX EC	PRENATE MINI
DOTHELLE DHA	OBSTETRIX ONE	PRENATE PIXIE
DUET DHA 400	OBTREX DHA	PRENATE RESTORE
DUET DHA BALANCED	O-CAL FA	PRENATE STAR
ELITE OB DHA	O-CAL PRENATAL	PREPLUS
ELITE-OB	PNV 29-1	PRETAB
ELITE-OB 400	PNV OB+DHA	PRIMACARE
ENBRACE HR	PNV-DHA	PROVIDA DHA
EXTRA-VIRT PLUS DHA	PNV-DHA + DOCUSATE	PROVIDA OB
FOCALGIN 90 DHA	PNV-FERROUS FUMARATE-DOCU-F	PUREFE OB PLUS
FOCALGIN CA	PNV-OMEGA	PUREFE PLUS
FOLET ONE	PNV-SELECT	RELNATE DHA
FOLIVANE-OB	PNV-VP-U	R-NATAL OB
HEMENATAL OB	PR NATAL 400	SELECT-OB
HEMENATAL OB + DHA	PR NATAL 400 EC	SELECT-OB + DHA
KOSHER PRENATAL PLUS IRON	PR NATAL 430	SE-NATAL 19
LEVOMEFOLATE DHA	PR NATAL 430 EC	TARON-C DHA
MARNATAL-F	PREFERA OB	TARON-PREX PRENATAL
MYNATAL	PREFERA-OB ONE	THRIVITE 19
MYNATAL ADVANCE	PREFERA-OB PLUS DHA	THRIVITE RX
MYNATAL PLUS	PRENA1 CHEW	TL-SELECT
MYNATAL-Z	PRENA1 PEARL	TRIADVANCE
MYNATE 90 PLUS	PRENA1 TRUE	TRICARE
NATACHEW	PRENAISSANCE	TRICARE PRENATAL
NATELLE ONE	PRENAISSANCE PLUS	TRICARE PRENATAL DHA ONE

Appendix F—Formulary Recommendations for Newly-Approved Drugs Per 32 CFR 199.21(g)(5)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
abemaciclib (Verzenio)	Oncologic Agents: Breast Cancer CDK4/6	▪ palbociclib (Ibrance) ▪ ribociclib (Kisqali)	With fulvestrant HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine tx Monotherapy HR+, HER2- advanced metastatic breast cancer with disease progression following endocrine tx and prior chemo in metastatic setting	• 3rd CDK4/6 inhibitor available for HR+, HER2- advanced breast cancer • Demonstrated progression-free survival (PFS) benefit as single therapy in advanced therapy and in combination with fulvestrant for patients with life-threatening incurable disease • No overall survival benefit shown to date • Failed to show benefit in overall survival for *KRAS* mutated NSCLC • More selective for CDK4 than CDK6 • Side effects of neutropenia less severe than comparators, while more severe than comparators in diarrhea • Antidiarrheals coadministered at first sign of adverse event • Reduced neutropenia allows for continuous dosing	• UF • Do not add to EMMPI list
amantadine ER (Gocovri)	Parkinson's Disease Drugs	▪ amantadine immediate release	Dyskinesia with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications	• Amantadine may be considered to reduce dyskinesia (Level C) • May be appropriate for reducing nocturnal side-effects in patients who experience benefit from the immediate release but have insomnia or agitation	• NF • Exempt from NF mail order requirement due to feasibility (unavailable at mail order)
belimumab (Benlysta) SC	Immuno-suppressive Agents	▪ Standard therapy only (e.g., NSAIDS, corticosteroids, antimalarials, immuno-suppressives)	B-lymphocyte stimulator-specific inhibitor for adults with active, autoantibody-+ systemic lupus erythematosus (SLE) receiving standard therapy	• 1st biologic approved to treat SLE in conjunction with standard therapy • New SC formulation allows for patient self-administration at home; previous approved formulation given as monthly IV infusion in the clinic/hospital • Dosed 200 mg SC injection (not weight-based) in the abdomen or thigh, given once weekly • Studies for IV and SC formulations demonstrated similar efficacy and safety profiles, and superiority over placebo • Advantage over infusion for convenience, but lower response rate in African American women than placebo	• UF • Do not add to EMMPI list
betrixaban (Bevyxxa)	Oral Anti-coagulants	▪ apixaban ▪ rivaroxaban ▪ enoxaparin	Venous thromboembolism (VTE) prophylaxis in acutely hospitalized adults at risk for thromboembolic complications from moderate or severely restricted mobility and other risk factors for VTE	• 5th available direct acting oral anticoagulant (DOAC) • Only oral agent approved for VTE prophylaxis in acutely hospitalized patients • CHEST guidelines do not recommend extended duration VTE prophylaxis beyond hospitalization or period of immobility • Significantly increases bleeding risk without significantly decreasing VTE risk • No compelling advantage over existing UF agents	• NF • Exempt from NF mail order requirement (acute use)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
plasma-derived human C1 esterase inhibitor injection (Haegarda)	Cortico-steroids-Immune Modulators: HAE	▪ Cinryze (C1 esterase inhibitor)	Hereditary Angioedema (HAE) routine prophylaxis	• 1st SQ drug for prophylaxis of HAE attacks • For patients who experience ≥ 4 HAE attacks per month • Study data shows decrease to 1.2 attacks per month • SQ formulation provides a convenience over Cinryze IV infusion	• UF • Do not add to EMMPI list
delafloxacin (Baxdela)	Antibiotics: Quinolones	▪ clindamycin + fluoroquinolone ▪ SMZ-TMP ▪ culture-sensitive agents	Acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria	• New fluoroquinolone antibiotic with a qualified infectious disease product (QIDP) designation indicated for the treatment of ABSSSIs • Fluoroquinolones are not first line agents for ABSSSIs • Provides an additional treatment option for MSSA and MRSA if designated susceptible bacteria • Cross-resistance can occur between delafloxacin and other fluoroquinolones • Well tolerated with nausea and diarrhea as the major AEs • No compelling advantage over existing UF agents	• NF • Exempt from NF mail order requirement (acute use)
enasidenib (Idhifa)	Oncologic Agents: Acute Myelogenous Leukemia (AML)	▪ None	Adult pts with relapsed or refractory AML with IDH2 mutation as detected by FDA-approved test	• 1st oral agent for relapsed or refractory acute myeloid leukemia with isocitrate dehydrogenase 2 mutation, approved with companion co-diagnostic • Differentiation syndrome has black box warning and can be life threatening; occurred in 14% of patients • 43% require dose interruption, 17% discontinued due to AEs • Effective in durable complete response or hematologic recovery and transfusion independence and provides meaningful benefit for patients	• UF • Do not add to EMMPI list
fluticasone furoate/ umeclidinium-vilanterol inhaler (Trelegy Ellipta)	Pulmonary II Drug Class: Combination/ COPD	▪ Spiriva/Advair ▪ Flovent/Anoro Ellipta	COPD airflow obstruction & reducing exacerbations in pts on fluticasone /vilanterol & need umeclidinium or on umeclidinium & need fluticasone /vilanterol	• 1st triple combination oral inhaler for COPD containing ICS/LAMA/LABA • Is labeled to reduce exacerbations • FDA approval does not match GOLD COPD guidelines for Group D • GOLD Group D to be used after trial of LAMA/LABA or ICS/LABA or LAMA	• UF • Add to EMMPI list
fluticasone propionate inhaler (ArmonAir RespiClick)	Pulmonary I Drug Class: Inhaled Cortico-	▪ Flovent HFA ▪ Flovent Diskus	Asthma in patients age ≥12 years	• 10th inhaled corticosteroid and 3rd fluticasone product • Breath-actuated device dosed twice daily • Flovent HFA and Diskus are the BCF step-preferred agents	• NF and non step-preferred • Add to mail list: NF mail order

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
	steroids (ICS)				requirement applies
glecaprevir/ pibrentasvir (Mavyret)	Hepatitis C Virus (HCV) Agents: Direct Acting Antivirals (DAAs)	▪ sofosbuvir/ velpatasvir (Epclusa)	• Chronic HCV genotype (GT) 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis AND • HCV GT 1 infection, previously tx with HCV NS5A inhibitor regimen or an NS3/4A protease inhibitor, but not both	• 3rd pangenomic DAA approved for the treatment of HCV • May be used in treatment-naïve and treatment-experienced patients • SURVEYOR studies showed sustained virologic response (SVR) rates ranged from 92%-100% • Provides an 8-week treatment option in patients both treatment-naïve and treatment-experienced to pegylated interferon, ribavirin, and/or sofosbuvir without cirrhosis • Dosed as three tablets once daily for 8-16 weeks • Advantages over other UF agents include treatment duration and once a day dosing	• UF and non step-preferred • Do not add to EMMPI list
guselkumab (Tremfya) injection	Targeted Immuno-modulatory Biologics (TIBs)	▪ adalimumab (Humira) ▪ etanercept (Enbrel) ▪ secukinumab (Cosentyx) ▪ ustekinumab (Stelara)	Tx of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	• Mechanism of Action: IL-23 inhibitor (similar to Stelara) • 8th TIB marketed for plaque psoriasis • Sole indication for plaque psoriasis (similar indication as Siliq and Taltz) • Showed superior efficacy to Humira in two Phase III randomized double-blind placebo controlled trials • IL-17 inhibitors (Cosentyx) in early trials show superiority over IL-23 • Adalimumab is the preferred TIB, with 9 indications; all others require trial of Humira first • Non step-preferred is the only formulary position available	• NF and non step-preferred • Add to mail list: NF mail order requirement applies
insulin aspart (Fiasp)	Insulins-Short Acting Agents	▪ insulin aspart (Novolog) ▪ insulin lispro (Humalog) ▪ insulin glulisine (Apidra)	Glycemic control in adults with diabetes mellitus	• Currently 3 other rapid-acting injectable insulin analogs are available • Novolog patent expiration expected Dec 2017 • Fiasp is a new formulation of insulin aspart (Novolog) • Differs from Novolog by the addition of L-arginine and niacinamide (vitamin B3), which the manufacturer claims makes the pharmacokinetic onset of action faster • No compelling advantage over existing UF agents	• NF • Add to mail list: NF mail order requirement applies
L-glutamine oral powder (Endari)	Dietary Supplements	▪ hydroxyurea	Reduce acute complications of sickle cell disease (SCD) in adult & pediatric patients ≥ 5 years	• 2nd approved medication for SCD; 1st new drug for SCD in 20 years; granted Organ Drug Designation • No head-to-head trials with hydroxyurea; 63% of patients in the phase 3 trial were also taking hydroxyurea • Benefits included longer median onset to first sickle cell crisis, lower occurrences of acute chest syndrome, and lower median number of hospitalizations for SCD pain • Generally highly tolerable adverse-effect profile, which includes constipation, nausea, headache, cough, and pain	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
				• Published literature lacking on drug interactions, use in hemoglobin SC, sickle β+-thalassemia, liver disease, or renal insufficiency • Provides an additional treatment option	
lesinurad-allopurinol (Duzallo)	Antigout Agents: Chronic	▪ allopurinol ▪ lesinurad (Zurampic) ▪ probenecid	Hyperuricemia associated with gout in patients unable to achieve target serum uric acid levels while on a therapeutic dose of allopurinol alone	• New fixed-dose combination of allopurinol and lesinurad • Lesinurad (Zurampic) previously reviewed Nov 2016; made NF with PA/MN • Efficacy of the combo was based on lesinurad studies • Must be used after failure of allopurinol therapy alone • Did not reduce gout flares over 12 months • Similar side effect profile as separate agents (Zurampic and allopurinol) • No compelling advantage over existing UF agents	• NF and non step-preferred • Add to mail list: NF mail order requirement applies
methyl-phenidate ER orally dissolving tablets (Cotempla XR ODT)	Attention Deficit Hyperactivity Disorder (ADHD) Drugs	▪ Aptensio XR ▪ Quillivant XR ▪ Adderall XR (generics) ▪ Concerta (generics)	ADHD in pediatric patients 6 to 17 years of age	• Cotempla XR ODT approved via 505(b)(2) pathway; only recommended in patients 6-17 years of age • Cotempla XR ODT is the 11th long-acting methylphenidate available (7 agents currently on the UF and 2 agents for those who cannot swallow Concerta: Quillivant XR, Aptensio XR) • Effects can last 12 hours, similar to other agents • All stimulants contain a black box warning for potential abuse and dependency • No compelling advantage over existing UF agents	• NF • Exempt from NF mail order requirement (C-II exception)
naldemedine (Symproic)	GI-2: Opioid-Induced Constipation (OIC) Drugs	▪ Naloxegol (Movantik) ▪ Methylnaltrexone (Relistor tabs) ▪ Lubiprostone (Amitiza)	OIC	• Naldemedine is 4th FDA-approved agent for OIC • Studied in 2 placebo-controlled trials • Significant placebo effect, no head-to-head trials, use of rescue laxative was not mentioned and length of study • Well tolerated with abdominal pain and diarrhea as the major adverse effects • May be taken with or without food • No compelling advantage over existing UF agents	• UF • Do not add to EMMPI list
neratinib (Nerlynx)	Oncologic Agents: Breast Cancer	▪ None	Extended adjuvant tx of adult pts with early stage HER2-overexpressed/ amplified breast cancer to follow adjuvant trastuzumab-based therapy	• Provides an extended adjuvant therapy option with a 2.3% absolute difference in invasive disease-free survival for HER2+ breast cancer at 2 years (94.2% versus 91.9% on placebo) • Yet to show any overall survival benefit • 25%-30% of pts discontinue due to AEs (mainly GI) • GI issues significant to necessitate co-administration with antidiarrheal at first dose • Give within 2 years of trastuzumab-based therapy	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
nitisinone (Nityr)	Metabolic Replacement Agents	▪ Nitisinone caps (Orfadin) ▪ Nitisinone suspension (Orfadin O/S)	Hereditary type 1 tyrosinemia (HT-1)	• New formulation of nitisinone (tablet) for treatment of HT-1 • Orfadin oral suspension reviewed August 2016 and made UF • All agents are equally efficacious; bioequivalent • Efficacy studies based on Orfadin suspension • Same contraindications and side effect profile b/w tab and suspension • Advantages of the tablet include lack of refrigeration and may be dissolved in liquids or applesauce	• UF • Do not add to EMMPI list
perampanel oral solution (Fycompa)	Anti-convulsants / Anti-Mania	▪ Fycompa tabs (perampanel)	Monotherapy for partial-onset seizures or adjunctive tx for primary generalized tonic-clonic seizures	• New oral solution formulation of perampanel for patients who cannot swallow tablets • Perampanel is 2nd or 3rd line option for partial-onset and primary generalized tonic-clonic seizures • Approved for patients 12 years and older	• UF • Do not add to EMMPI List
simvastatin oral suspension (FloLipid)	Anti-lipidemics-1 Drug Class (LIP-1s)	▪ atorvastatin ▪ pravastatin ▪ simvastatin tab	• Hyperlipidemia • Reduce CHD deaths, non-fatal MI, stroke, and revascularization • Ages 10-18 with HeFH after failing adequate trial of diet therapy	• Same indications as simvastatin tablets, including adolescents with heterozygous familial hypercholesterolemia (HeFH) • Approval based on bioequivalence studies with simvastatin tablets. • Limited role; FDA review showed very few adults (0.31%) and pediatric patients (0.20%) have swallowing difficulties • Formulation is purely for convenience; FDA concerned with potential overdosing in children. • No compelling advantages over existing UF agents	• NF and non step-preferred • Add to mail list: NF mail order requirement applies
sofosbuvir/ velpatasvir/ voxilaprevir (Vosevi)	HCV DAAs	▪ sofosbuvir/ velpatasvir (Epclusa)	Chronic HCV infection w/o cirrhosis or with compensated cirrhosis with genotype (GT) 1, 2, 3, 4, 5, or 6 infection and previous treatment with an NS5A inhibitor • GT 1a or 3 infection and previous treatment with sofosbuvir regimen without an NS5A inhibitor	• Vosevi is the 2nd pangenomic DAA approved for the treatment of HCV • Only approved for use in treatment-experienced patients • POLARIS study results showed the three-drug combo was superior (96%-98% SVR) to two-drug combo (85%-90% SVR) in genotype (GT)1b and GT3 • Vosevi is comparable to Epclusa in treatment of HCV 1b, 2, 4, 5, or 6 in patients previously treated with sofosbuvir without a NS5A inhibitor • Dosed as a single tablet once daily for 12 weeks in most patients • No clinically compelling advantage over existing UF agents for treatment-naïve patients; may benefit treatment-experienced patients	• UF and non step-preferred • Do not add to EMMPI List

Appendix G—Mail Order Status of Medications Designated Nonformulary During the November 2017 DoD P&T Committee Meeting

DoD P&T	ADD to the Mail Order Requirement	Exempted from Mail Order Requirement
Nov 2017	**Newly-Approved Drugs per 32 CFR 199.21(g)(5)** ▪ guselkumab (Tremfya) ▪ fluticasone propionate (ArmonAir RespiClick) ▪ insulin aspart (Fiasp) ▪ lesinurad/allopurinol (Duzallo) ▪ simvastatin oral suspension (FloLipid)	**Weight Loss Agents** ▪ liraglutide (Saxenda) ▪ lorcaserin, lorcaserin ER (Belviq, Belviq XR) ▪ naltrexone SR/bupropion SR (Contrave) ▪ orlistat (Xenical) ▪ phentermine/topiramate ER (Qsymia) ▪ phentermine 8 mg tabs (Lomaira) **Newly-Approved Drugs per 32 CFR 199.21(g)(5)** Acute use exception applies: ▪ betrixaban (Bevyxxa) ▪ delafloxacin (Baxdela) CII controlled substances exception applies: ▪ methylphenidate ER orally dissolving tablets (Cotempla XR ODT) Other: Feasibility exception applies (unavailable at mail order): ▪ amantadine ER (Gocovri)

Appendix H—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 2017	**Weight Loss Agents**	UF Class Review Class not previously reviewed; not previously a TRICARE pharmacy benefit	▪BCF: No weight loss product selected	▪ benzphetamine ▪ diethylpropion ▪ phendimetrazine IR and SR ▪ phentermine	▪ liraglutide 3 mg injection (Saxenda) ▪ lorcaserin (Belviq) ▪ lorcaserin ER (Belviq XR) ▪ naltrexone SR/ bupropion SR (Contrave) ▪ orlistat (Xenical) ▪ phentermine 8 mg tab (Lomaira) ▪ phentermine/ topiramate ER (Qsymia)	Pending signing of the minutes / 90 days The effective date is May 2, 2018	▪ Manual PAs required for all new and current users of all weight loss agents	▪ Must try phentermine first in all new users of Qsymia, Saxenda, Contrave, Belviq, Belviq XR, and Xenical unless a contraindication exists ▪ PA expires after 3 months for short-term drugs and 4 months for long-term drugs See Appendix C
Nov 2017	**Oncologic Drug Class: Multiple Myeloma Subclass**	UF Class review Class not previously reviewed	▪BCF: No multiple myeloma product selected	▪ ixazomib (Ninlaro) ▪ lenalidomide (Revlimid) ▪ panobinostat (Farydak) ▪ pomalidomide (Pomalyst) ▪ thalidomide (Thalomid)	None	Pending signing of the minutes / 60 days The effective date is April 4, 2018	Manual PA criteria apply to new users of Revlimid, Pomalyst, Ninlaro, and Farydak See Appendix C	▪ QLs apply. See Appendix D ▪ lenalidomide, pomalidomide, and panobinostat are part of REMS programs
Nov 2017	**Vitamins: Prenatal Vitamins Subclass**	UF Class Review Not previously reviewed	▪None	▪ Prenatal Vitamins Plus Low I ▪ Prenatal Vitamin + Low Iron ▪ Prenatal Plus ▪ Preplus	All products listed in Appendix E other than the products listed in the UF column	Pending signing of the minutes / 90 days The effective date is May 2, 2018	-	Coverage of prenatal vitamins limited to females younger than 45 years of age

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

Appendix I—Table of Abbreviations

5-ARI	5-alpha reductase inhibitors
A1c	hemoglobin A1c
ABSSSI	acute bacterial skin and skin structure infections
ADHD	attention deficit hyperactivity disorder
AE	adverse event
AML	acute myeloid leukemia
BCF	Basic Core Formulary
BIA	budget impact analysis
BMI	body mass index
BPA	blanket purchase agreement
BPH	benign prostatic hyperplasia
CEA	cost-effectiveness analysis
CFR	Code of Federal Regulations
CHD	coronary heart disease
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
CVD	cardiovascular disease
DHA	Defense Health Agency
DHA	docosahexaenoic acid
DOAC	direct acting oral anticoagulant
DoD	Department of Defense
DPP-4	dipeptidyl peptidase 4 inhibitors
DR	delayed release
ECF	Extended Core Formulary
EHR	electronic health record
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
EPA	eicosapentaenoic acid
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GI	gastrointestinal
GLP1RA	glucagon-like peptide-1 receptor agonist
GT	genotype
HAE	hereditary angioedema
HBr	hydrobromide
HCTZ	hydrochlorothiazide
HCV DAAs	hepatitis C virus/direct acting antivirals
HeFH	heterozygous familial hypercholesterolemia
HER2	human epidermal growth factor receptor-2
HFA/MDI	hydrofluoroalkane metered-dose inhaler
HR	hormone receptor
HT-1	hereditary type 1 tyrosinemia
IBS-D	diarrhea predominant irritable bowel syndrome
ICD	International Classification of Disease
ICS	inhaled corticosteroid
INSTIs	integrase strand transfer inhibitors

IPF	idiopathic pulmonary fibrosis
IR	immediate release
IV	intravenous
JAMA	Journal of the American Medical Association
LABA/LAMA	long-acting beta agonist/long-acting muscarinic antagonist
MHS	Military Health System
MI	myocardial infarction
MN	medical necessity
MRSA	methicillin-resistant staphylococcus aureus
MSLT	mean sleep latency time
MSSA	methicillin-sensitive staphylococcus aureus or staph aureus
MTF	Military Treatment Facility
NASH	Non alcoholic steatohepatitis
NCCN	National Comprehensive Cancer Network
NDAA	National Defense Authorization Act
NDC	National Drug Code
NF	nonformulary
NSAIDs	non-steroidal anti-inflammatory drugs
NSCLC	non-small cell lung cancer
OIC	opioid-induced constipation
ODT	orally dissolving tablet
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PCSK9	proprotein convertase subtilisin/kexin type 9
PFS	progression-free survival
POD	Defense Health Agency Pharmacy Operations Division
POS	point(s) of service
PPI	proton pump inhibitor
PsA	psoriatic arthritis
PT	patient
QIDP	qualified infectious disease product
QLs	quantity limits
RAAs	renin-angiotensin antihypertensive agents
REMS	Risk Evaluation and Mitigation Strategies
SC/SQ	subcutaneous
SCD	sickle cell disease
SCLC	non-small cell lung cancer
SGLT2	sodium glucose co-transporter 2
SLE	systemic lupus erythematosus
SSRI	selective serotonin reuptake inhibitor
SVR	sustained virologic response
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
TX	treatment
UF	Uniform Formulary

USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
VTE	venous thromboembolism
XR/SR	extended/sustained release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 9 and 10, 2017, 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 2017 Minutes—**RADM Colin Chinn, MC, USN, Acting Deputy Director, DHA, approved the minutes from the May 2017 DoD P&T Committee meeting on July 27, 2017.

2. **Clarification to the May 2017 Minutes**

   a) **Update to Deutetrabenazine (Austedo) Manual Prior Authorization (PA) Criteria:** Concomitant use with another vesicular membrane transport type 2 (VMAT-2) inhibitor is not allowed.

   b) **Section 703, National Defense Authorization Act for Fiscal Year 2008** Immediately following the May 2017 P&T Committee meeting, the manufacturer for crofelemer (Mytesi) complied with Section 703 and the drug was designated with formulary status on the Uniform Formulary.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 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. Basal Insulin Analogs

Background—The Basal Insulin Analogs were previously reviewed for UF status in February 2010. There are several new entrants to the class; however, there are no generic or biosimilar products available. The class is comprised of insulin glargine vials and pens (Lantus), insulin glargine 100 U/mL (Basaglar), insulin detemir vials and pen (Levemir), insulin degludec (Tresiba), and insulin glargine 300 U/mL (Toujeo). Manual prior authorizations (PAs) are currently in place for Toujeo and Tresiba.

Note that the combination products degludec/liraglutide (Xultophy) and degludec/lixisenatide (Soliqua) are part of the glucagon-like peptide-1 receptor agonists (GLP1RA) subclass, and were not included in the review. The formulary recommendations do not apply to neutral protamine Hagedorn (NPH) or 70/30 insulin preparations.

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

- Basal insulin analogs are dosed subcutaneously (SQ) once daily, and have similar initial dosing.
    - Insulin glargine (Lantus) was marketed in 2000, and was designated as BCF in 2010.
    - Insulin detemir (Levemir) may be dosed once or twice daily and has been marketed since 2005.
    - Insulin degludec (Tresiba) has a long duration of action of up to 42 hours, versus 24 hours for the other products. It also has flexibility with regard to time of administration, and is available in two concentrations (100 U/mL, 200 U/mL).
    - Basaglar is another insulin glargine identical to Lantus in terms of amino acid sequence and pH. It was approved using the FDA 505(b)(2) pathway, since it is a similar biologic version of Lantus.
    - Toujeo is a more concentrated version of Lantus containing 300 U/mL, and has an onset of action developing over 6 hours, compared to Lantus at 3 to 4 hours.
- Although the basal insulin analogs differ in their pharmacokinetic profiles, this variance does not translate into differences in glycemic control or hemoglobin A1c improvements when comparing one product to one another.
- When compared in head-to-head trials, there were no clinically relevant differences reported between the basal insulin analogs and their effect on glycemic control. Lantus was the active comparator in the majority of the non-inferiority trials.
- A 2016 meta-analysis from the Institute of Clinical and Economic Review evaluated eight trials comparing insulin degludec (Tresiba) with insulin glargine (Lantus) or insulin detemir (Levemir). For all eight trials, insulin degludec was non-inferior to the other insulins based on A1c results.

- Regarding hypoglycemia, it is difficult to conclude emphatically that one basal insulin analog is less likely to cause clinically relevant severe or nocturnal hypoglycemia events. This is due to the differences in the definitions of hypoglycemia used in the individual clinical trials, the open label study designs, and the different primary endpoints.
- For special populations, Lantus, Levemir, and Tresiba are approved for use in pediatrics. The basal insulin analogs are rated as pregnancy category C, with the exception of Levemir, which is rated as pregnancy category B.
- A survey of Military Health System (MHS) providers found that the majority of respondents (90%) stated a preference for Lantus in their clinical setting and that it should remain on the BCF, due to their familiarity with the product. Additionally, most clinicians responded that two basal insulins were required on the formulary. After Lantus, most providers stated a preference for Levemir, followed by Tresiba as a second available agent.
- The majority of MHS patients can be treated with Lantus, based on the lack of compelling advantages of the newer basal insulin analogs, existing MHS utilization patterns, and MHS provider opinion.

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

- CMA results showed that glargine pens and vials (Lantus) were the most cost-effective basal insulin analogs followed by glargine 300 U/mL (Toujeo), detemir vial (Levemir), glargine 100 U/mL (Basaglar), detemir pen (Levemir), and degludec (Tresiba).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating glargine pens and vials (Lantus) as BCF and step-preferred, and designating detemir vials (Levemir) and glargine 300 U/mL (Toujeo) as UF and non step-preferred, with glargine 100 U/mL (Basaglar), detemir pen (Levemir), and degludec (Tresiba) as NF and non step-preferred, demonstrated a significant estimated cost avoidance for the MHS.

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

    - **UF and Step-Preferred:**
        - insulin glargine pen and vial (Lantus)
    - **UF and Non Step-Preferred**
        - insulin detemir vial (Levemir)
        - insulin glargine 300 U/mL (Toujeo)
    - **NF and Non Step-Preferred:**
        - insulin detemir pen (Levemir)

- insulin degludec (Tresiba)
- insulin glargine 100 U/mL (Basaglar)

Note that as part of this recommendation, all new users of a basal insulin analog are required to try Lantus first.

2. ***COMMITTEE ACTION: BCF***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) maintaining insulin glargine pens and vials (Lantus) on the BCF, due to provider opinion and clinical and cost effectiveness.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) step therapy for the basal insulin analogs, requiring a trial of Lantus in all new users, prior to use of the non step-preferred products (Basaglar, Levemir, Tresiba, and Toujeo). The step therapy requirement will be included in the manual PAs.

   The existing PAs for Tresiba and Toujeo currently include the requirement for a trial of Lantus first. The Tresiba PA criteria were updated to include use in pediatrics. New PA criteria for Levemir pens and vials, and Basaglar were recommended to incorporate the step therapy. In general, the non step-preferred product will only be allowed if the patient has tried and failed or is intolerant to Lantus, or in the pregnant population, if the patient cannot be treated with Lantus. 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) maintaining the current MN criteria for insulin degludec (Tresiba), and insulin glargine 100 U/mL (Basaglar), and new criteria for insulin detemir pen (Levemir). See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) maintaining the basal insulins on the EMMPI list. See Appendix F.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
   The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation. Based on the P&T Committee's recommendation, the effective date is November 22, 2017.

B. Corticosteroids – Immune Modulators Drug Class: Hereditary Angioedema (HAE) Agents Subclass

Background—HAE is a rare disease characterized by lack of or dysfunction of C1 esterase inhibitor. The disease presents as frequent edema episodes affecting the gastrointestinal (GI) tract, extremities, face, and airway. HAE is mediated by bradykinin, and is unresponsive to typical therapy of steroids, epinephrine, and antihistamines.

The drugs in the HAE subclass include the C1 esterase inhibitors and the bradykinin B2 receptor antagonist icatibant (Firazyr). The C1 esterase inhibitors all contain the same active ingredient, but differ in manufacturing and source (plasma derived versus recombinant), FDA indications (treatment versus prophylaxis), and dosing (weight-based versus fixed dosing).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 1 absent) the following for the HAE drugs:

- Treatment
    - Berinert, Ruconest, and icatibant (Firazyr) are indicated for treatment of acute angioedema episodes, based on placebo-controlled trials. The C1 esterase inhibitors are self-administered via intravenous (IV) infusion, while Firazyr is administered by SQ injection. Berinert and icatibant (Firazyr) have FDA approval for treatment of laryngeal attacks, but clinical trial data is available with Ruconest.
    - There are no direct comparative studies between the products for treatment of HAE. However, indirect comparison shows that Berinert, Ruconest, and Firazyr start relieving symptoms within 30 to 90 minutes following administration.
- Prophylaxis
    - For long-term prophylaxis of HAE, guidelines recommend Cinryze and the attenuated androgen Danazol. Factors to consider for initiation of prophylaxis include attack frequency and severity, comorbid conditions, access to emergent treatment, patient experience and preference, and risk factors for adverse effects.
    - Evidence for efficacy of Danazol from a retrospective study showed a 94% response rate, with a decrease from 33.3 attacks per year pre-treatment to 5.4 attacks following Danazol administration.
- Safety
    - The C1 esterase inhibitors all contain warnings for thrombosis. The plasma-derived products (Berinert, Cinryze) carry a risk of blood-borne pathogens, while the recombinant product (Ruconest) has a risk for hypersensitivity reactions in patients allergic to rabbits. Differences between the products regarding the long-term risks of viral transmission and thrombosis remain to be determined.

- Attenuated androgens are rated Pregnancy Category X. Well-known risks of using androgens include virilization in females, stroke, myocardial infarction (MI), and venous thromboembolism.

- Other Factors
  - A survey of MTF and network providers who treat HAE patients commented that Danazol is recommended for prophylaxis but should be avoided in patients with contraindications and women of childbearing age.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 1 absent) the following:

- CMA results showed that Berinert, Cinryze, Ruconest, and icatibant (Firazyr) were cost-effective agents.
- 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 four HAE agents (Berinert, Cinryze, Ruconest, and icatibant [Firazyr]) as formulary on the UF demonstrated the largest estimated cost avoidance for the MHS.

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

   - **UF:**
     - plasma-derived human C1 esterase inhibitor IV (Cinryze)
     - plasma-derived human C1 esterase inhibitor IV (Berinert)
     - recombinant C1 esterase inhibitor IV (Ruconest)
     - icatibant SQ (Firazyr)

   - **NF:** None
   - A new SQ-administered product, plasma-derived human C1 esterase inhibitor SQ (Haegarda) was recently approved for HAE prophylaxis. Haegarda will remain in pending NF status until the November DoD P&T Committee review.
   - Note that BCF selection for the Corticosteroids – Immune Modulator Class include prednisone.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the HAE prophylaxis product Cinryze, requiring a trial of Danazol in new users. The PA will also apply to Haegarda upon market launch. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—QLs for the HAE products were recommended in August 2016. The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) maintaining the current QLs for Berinert, Ruconest, Cinryze, and icatibant (Firazyr), and also recommended QLs for Haegarda upon market launch. See Appendix D for the QLs.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 30-day implementation period. Based on the P&T Committee's recommendation, the effective date is November 22, 2017.

C. Antiretroviral Agents: Human Immunodeficiency Virus (HIV)

The antiretroviral agents for HIV include 27 unique chemical entities that are combined into over 42 medications. The class was further categorized based on mechanism of action of the individual active ingredients into the integrase strand transfer inhibitors (INSTIs), non-nucleoside reverse transcriptase inhibitor (NNRTIs), nucleoside/nucleotide reverse transcriptase inhibitor (NRTIs), and combination products.

Only a few of the older HIV agents are available in generic formulations. Therefore, the clinical effectiveness review focused on the place in therapy of the new branded entrants to the market.

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

- The newer antiretroviral regimens are associated with fewer serious and intolerable adverse effects than regimens used in the past. First-line (recommended) antiretroviral agents are generally safe and well tolerated in comparison to the other products.
- In treatment-naïve patients, the optimal therapy for HIV should include at least three different drugs, from two or more different drug classes, ideally administered once daily. Current guidelines recommend a regimen containing two NRTIs plus one protease inhibitor or one INSTI.
- First line single-tablet regimens include Triumeq, Stribild, and Genvoya.
- Emtricitabine/tenofovir disoproxil fumarate (Truvada) is the only product FDA approved for HIV pre-exposure prophylaxis (PrEP) based on the iPrEX and PartnersPrEP studies enrolling a population of men who have sex with men, high-risk individuals, or serodiscordant couples
- A systematic review from 11 placebo-controlled trials enrolling 9,000 patients comparing Truvada versus placebo reported that treatment resulted in a 51% reduction in the risk of HIV infection (risk ratio = 0.49, 95% CI: 0.28–0.85, P = 0.001). In terms of safety, Truvada is comparable to placebo.

- Effectiveness of Truvada for PreEP is dependent on adherence. PrEP therapy with Truvada is more effective in patients with high rates of medication adherence, and is essentially not effective in patients who have low adherence rates.
- The HIV antiretroviral agents have a low degree of therapeutic interchangeability; treatment choice must be tailored to the individual patient by considering drug characteristics and risk of resistance.

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 of the top three most cost-effective treatment regimens, Triumeq was the most cost effective, followed by Genvoya, and Stribild.
- BIA results showed that designating all the HIV antiretroviral agents as formulary on the UF had a lower budget impact on MHS costs than the current baseline.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following, listed alphabetically by trade name, with first-line or recommended products bolded:

    - **UF**:
        - Aptivus (tipranavir)
        - Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
        - Combivir (lamivudine/zidovudine)
        - **Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)**
        - Crixivan (indinavir)
        - **Descovy (emtricitabine/tenofovir alafenamide)**
        - Edurant (rilpivirine)
        - Emtriva (emtricitabine)
        - Epivir (lamivudine)
        - Epzicom (abacavir/lamivudine)
        - Evotaz (atazanavir/cobicistat)
        - Fuzeon (enfuviritide)
        - **Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide)**
        - Intelence (etravirine)
        - Invirase (saquinavir)
        - Isentress (raltegravir)
        - **Isentress HD (raltegravir extended-release)**
        - Lexiva (fosamprenavir)
        - Kaletra (lopinavir/ritonavir)
        - **Norvir (ritonavir)**
        - **Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)**
        - Prezcobix (darunavir/cobicistat)
        - **Prezista (darunavir)**
        - Rescriptor (delavirdine)

- Retrovir (zidovudine)
- Reyataz (atazanavir)
- **Selzentry (maraviroc injection and oral solution)**
- **Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)**
- Sustiva (efavirenz)
- **Tivicay (dolutegravir)**
- **Triumeq (abacavir/dolutegravir/lamivudine)**
- Trizivir (abacavir/lamivudine/zidovudine)
- **Truvada (emtricitabine/tenofovir disoproxil fumarate)**
- Tybost (cobicistat)
- Videx EC (didanosine delayed-release)
- Videx Pediatric (didanosine)
- Viracept (nelfinavir)
- Viramune (nevirapine)
- Viramune XR (nevirapine ER)
- Viread (tenofovir disoproxil fumarate)
- Zerit (stavudine)
- Ziagen (abacavir)

- **NF**: None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) that designating a BCF HIV antiretroviral agent is clinically inappropriate. Reasons against selecting a BCF product include limiting treatment choices in a disease where resistance is a concern, rapidly changing treatment guidelines, patient comorbidities, individual drug-drug interaction profiles, transmitted resistance, and the likelihood of improved antiretroviral regimens becoming available in the U.S. market.

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

V. NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5)

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly-approved drugs reviewed at the August 2017 P&T Committee meeting, a brief summary of their clinical attributes, their formulary recommendations, and see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) the following:

- **UF**:
    - brigatinib (Alunbrig) – Oral Oncology Agents for Lung Cancer
    - methotrexate (Xatmep) oral solution – Antirheumatic Drugs
    - midostaurin (Rydapt) – Oral Oncology Agents for Acute Myeloid Leukemia (AML)
    - niraparib (Zejula) – Oral Oncology Agents for Ovarian Cancer
    - prasterone (Intrarosa) vaginal insert – Vaginal Lubricants
    - ribociclib/letrozole (Kisqali Femara Co-Pack) – Oral Oncologic Agents for Breast Cancer

- **NF:**
    - abaloparatide (Tymlos) injection – Osteoporosis Agents
    - brodalumab (Siliq) injection – Targeted Immunomodulatory Biologics (TIBs)
    - dronabinol (Syndros) oral solution – Antiemetic and Antivertigo Agents
    - fluticasone/salmeterol (AirDuo RespiClick) oral inhaler – Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
    - mixed amphetamine salts ER (Mydayis) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
    - morphine sulfate ER (Morphabond XR) – Narcotic Analgesics
    - safinamide (Xadago) – Parkinson's Disease Drugs
    - sarilumab (Kevzara) injection – TIBs
    - valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) MN criteria for abaloparatide (Tymlos), brodalumab (Siliq), dronabinol oral solution (Syndros), fluticasone/salmeterol (AirDuo RespiClick), mixed amphetamine salts ER (Mydayis), morphine sulfate ER (Morphabond XR), safinamide (Xadago), sarilumab (Kevzara), and valbenazine (Ingrezza). See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) the following:

- Applying the same manual PA criteria for sarilumab (Kevzara) and brodalumab (Siliq) in new and current users, as is currently in place for the

other non step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for brodalumab, a trial of secukinumab (Cosentyx) is required if the patient cannot be treated with Humira. See Appendix C for the full criteria.

- Applying PA criteria to new users of midostaurin (Rydapt), ribociclib/letrozole (Kisqali Femara Co-Pack), prasterone vaginal insert (Intrarosa), safinamide (Xadago), and valbenazine (Ingrezza).

- Applying PA criteria to new and current users of dronabinol oral solution (Syndros), fluticasone/salmeterol (AirDuo RespiClick), methotrexate (Xatmep) oral solution, and mixed amphetamine salts ER (Mydayis). See Appendix C for the full criteria.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) an effective date upon the first Wednesday after the signing of the minutes in all POS, on October 25, 2017.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **New Manual PA Criteria**

a) **TIBs:—Guselkumab (Tremfya)**

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. Guselkumab (Tremfya) is the fifth TIB approved for treating moderate to severe plaque psoriasis; it will be reviewed for formulary status as a newly-approved drug at an upcoming meeting.

(1) ***COMMITTEE ACTION: GUSELKUMAB (TREMFYA) AUTOMATED AND MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria for Tremfya, in new and current users, to require a trial of adalimumab (Humira) first, consistent with the existing step therapy criteria for the TIBs Drug Class. See Appendix C for the full criteria.

b) **GI-2 Agents for Opioid-Induced Constipation (OIC)—Naloxegol (Movantik) and Methylnaltrexone (Relistor) Manual PA Criteria**

The GI-2 drugs were previously reviewed for UF status in November 2015, and the chloride channel activator lubiprostone (Amitiza) was selected for UF status. Naloxegol (Movantik) and methylnaltrexone (Relistor) are peripherally-acting mu opioid receptor antagonists (PAMORAs) approved for OIC. OIC treatment

guidelines list lifestyle modifications and laxatives as first line treatment, with PAMORAs and chloride channel activators recommended as second-line agents.

(1) ***COMMITTEE ACTION: NALOXEGOL (MOVANTIK) AND METHYLNALTREXONE (RELISTOR) MANUAL PA CRITERIA*** The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Movantik and Relistor in all new and current users, requiring a trial of Amitiza first. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria and Step Therapy**—Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications. Updated manual PA will apply to new users.

   a) **Acne Agents—Topical Acne and Rosacea Agents: Dapsone Gel 5% and 7.5% (Aczone)**—Aczone was reviewed in August 2016 with step therapy and manual PA criteria recommended. Current clinical practice guidelines for acne specify women over the age of 18 as the group who gain the most benefit from Aczone. However, the Aczone package insert states the drug is approved for patients 13 years of age and older. The manual PA criteria were updated to reflect the labeled indication. Note that no changes are recommended for the existing step therapy criteria.

   b) **TIBs: Tocilizumab (Actemra)**—PA criteria were updated for tocilizumab (Actemra) to allow for the new indication for giant cell arteritis.

   c) **Ophthalmic Immunomodulatory Agents: Lifitegrast (Xiidra)**—Xiidra was reviewed as a new drug in November 2016 with manual PA criteria recommended. Criteria were updated to have an expiration date of one year, similar to what is in place for cyclosporine (Restasis).

   d) **Corticosteroids – Immune Modulators: Crisaborole (Eucrisa)**—Eucrisa was reviewed for formulary status in May 2017. The manual PA criteria were updated to allow for prescribing by allergists or immunologists, in addition to dermatologists.

   e) **Proton Pump Inhibitors (PPIs): Esomeprazole Delayed Release Packets for Suspension (Nexium Packets)**—Esomeprazole (Nexium) was designated NF and non step-preferred at an interim meeting in March 2017; a trial of at least three formulary step-preferred products is required prior to use of Nexium. Nexium delayed release packets for suspension are approved for patients as young as one month of age, and are also approved for use in patients with percutaneous endoscopic gastrostomy (PEG) tubes. The Nexium PA criteria were revised to allow use of the delayed release packets for suspension in patients younger than five years and in patients with PEG tubes.

f) **Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors Step Therapy and Manual PA Criteria**—Existing PA criteria for the SGLT2 inhibitors require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses. The P&T Committee recommended simplifying the step therapy and manual PA requirements for the SGLT2 inhibitors. All new users of SGLT2 inhibitors are required to try only metformin unless contraindications exist. Empagliflozin remains the preferred agent within the SGLT2 inhibitor class.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND STEP THERAPY***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for Aczone, Actemra, Xiidra, Eucrisa, Nexium delayed release packets for suspension, and the step therapy and manual PA changes for the SGLT2 inhibitors.

B. Quantity Limits (QLs)

1. **General QLs—**QLs were reviewed for eight drugs: the TIBs brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), and ustekinumab vials (Stelara); brigatinib (Alunbrig) for lung cancer, ribociclib-letrozole (Kisqali-Femara) for breast cancer, midostaurin (Rydapt) for leukemia, and fluticasone/salmeterol (AirDuo RespiClick) for asthma.

a) ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) QLs for Siliq, Kevzara, Tremfya, Stelara, Alunbrig, Kisqali-Femara, Rydapt, AirDuo RespiClick. See Appendix D for the QLs.

2. **Defaults QLs for the TIBs and Oncology Drugs**—QLs already exist for the TIBs and oncologic drugs classes. Several new products are in the pipeline, making maintenance of individual QLs time intensive. Default QLs are recommended due to concerns of adherence and discontinuation or dosage reduction in these costly agents.

a) ***COMMITTEE ACTION: TIBS AND ONCOLOGIC AGENTS DEFAULT QLs—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) default QLs for the TIBs and oncologic agents of up to a 30-day supply in the Retail Network and of up to a 60-day supply in the MTFs/Mail Order. Any new TIB approved by the FDA that is intended for self-injection and any new oral oncology drug approved by the FDA will be subject to the default QLs.

C. PA and QLs Implementation Periods

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

- 13 for, 0 opposed, 1 abstained, 1 absent—The new step therapy and manual PA for Tremfya 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 January 17, 2018.
- 14 for, 0 opposed, 1 abstained, 0 absent—The new manual PAs for Movantik and Relistor 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 January 17, 2018.
- 14 for, 0 opposed, 1 abstained, 0 absent—Updates to the current PAs for dapsone 5% and 7.5% gel (Aczone), tocilizumab (Actemra), lifitegrast (Xiidra), crisaborole (Eucrisa), esomeprazole delayed release packets for suspension (Nexium Packets) and the step therapy and manual PA for the SGLT2 inhibitors become effective upon signing of the minutes in all POS.
- 13 for, 0 opposed, 1 abstained, 1 absent—The QLs for Siliq, Kevzara, Tremfya, Stelara vials, Alunbrig, Kisqali-Femara, Rydapt, AirDuo RespiClick become effective upon signing of the minutes.
- 13 for, 0 opposed, 1 abstained, 1 absent—The default QLs for new TIBs and oncologic agents become effective upon signing of the minutes.

VII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for two product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

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

- Pulmonary-1 Agents: Pulmonary Miscellaneous drugs for Idiopathic Pulmonary Fibrosis—pirfenidone 801mg tablets (Esbriet) as UF, step-preferred, with the same PA, and 30-day supply QLs as Esbriet 267 mg.

- Endocrine Agents Miscellaneous: Iron Chelators—deferasirox sprinkles (Jadenu Sprinkles) as UF, similar to Jadenu tablets.

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

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was 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 (15 for, 0 opposed, 0 abstained, 0 absent) the following product be designated NF on the UF:

- Canton Labs: naproxen sodium (Naprosyn) 500 tablet

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following pre-authorization criteria for Naprosyn:

1. Obtaining the product by home delivery would be detrimental to the patient; and,
2. For branded 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 (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Naprosyn; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is January 17, 2018.

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

See Appendix F for the mail order status of medications designated NF during the August 2017 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the August 2017 meeting, including the newly-approved drugs affected by the EMMPI, will be effective upon the first Wednesday after the signing of the minutes, on October 25, 2017.

A. Newly-Approved Drugs per 32 CFR 199.21(g)(5)

1. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF STATUS***

The P&T Committee recommended (13 for, 0 opposed, 1 abstained 1 absent):

a) **Do Not Add:** Prasterone (Intrarosa) is associated with low persistence rates; addition of oral oncology agents such as midostaurin (Rydapt),

niraparib (Zejula), ribociclib/letrozole (Kisqali-Femara), methotrexate (Xatmep) oral solution, and brigatinib (Alunbrig) to the EMMPI program should be considered at a future date, pending more experience with availability of these agents at mail order.

2. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR NF STATUS***

   The P&T Committee recommended (13 for, 0 opposed, 1 abstained 1 absent):

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: sarilumab (Kevzara), abaloparatide (Tymlos), safinamide (Xadago), and fluticasone/salmeterol (AirDuo RespiClick).

   b) **Do Not Add:** The previously established exception from the mail order requirement for C-II controlled substances applies to morphine sulfate ER tablets (Morphabond XR), mixed amphetamine salts ER (Mydayis), and dronabinol oral solution (Syndros). The following agents may not be feasible to provide through mail order and should be excepted pending further information: brodalumab (Siliq) and valbenazine (Ingrezza).

3. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR PRASTERONE (INTRAROSA)***—The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) excluding prasterone (Intrarosa) from the Auto-Refill program administered by Express Scripts, Inc, at TRICARE Mail Order Pharmacy, to be implemented upon signing of the minutes.

X. PRENATAL VITAMINS AND OTHER PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK

The P&T Committee discussed a list containing 694 National Drug Codes (NDCs) that the First DataBank drug database will transition from designation as prescription drugs to non–prescription items in January 2018. The affected agents are primarily prenatal vitamins containing folic acid but also include various urinary pH modifiers and prescription fluoride or zinc products. The action resulted from an FDA guidance regarding medical foods in September 2016.

The P&T Committee recommended temporarily continuing coverage for the affected drugs under the TRICARE pharmacy benefit, to allow adequate time for a full evaluation and to dovetail with current efforts to standardize non-prescription items supplied by MTFs (both across MTFs and across MHS points of service).

The issue of prenatal vitamins was specifically considered by the Committee. Prenatal vitamins are a low-cost intervention known to improve outcomes by preventing neural tube defects and providing adequate iron stores to prevent anemia and decrease nausea and vomiting during pregnancy. U.S. Preventive Services Task Force (USPSTF) guidelines recommend that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg of folic acid (Grade A recommendation). Therefore, continued coverage of prenatal

vitamins is highly desirable in order to ensure uninterrupted access to essential care. The P&T Committee further noted that provision of prenatal vitamins as part of the TRICARE pharmacy benefit is more important for the MHS than civilian health plans, given worldwide assignment of female service members and beneficiaries to countries with variable availability of food products fortified with folic acid.

The P&T Committee also recommended standardizing the availability of prenatal vitamins across the MHS points of service (retail, mail order, and MTFs). The highest volume, most cost effective options that would provide a variety of formulations to meet the clinical needs of beneficiaries were identified, with the selected products comprising 91% of the dispensed prescriptions.

A. ***COMMITTEE ACTION: PRENATAL VITAMINS AND OTHER PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following, effective upon signing of the minutes:

1. **Classes other than the Prenatal Vitamins**: Temporarily continuing coverage for products on the list of 694 NDCs losing prescription status in classes other than prenatal vitamins, to allow time for full evaluation and review for standardization.

2. **Prenatal Vitamins:** Adding the following 8 products (by brand name) to the over-the-counter (OTC) program and the MTF OTC test list: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi + DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA to standardize availability across the MHS. (Note: Some of these brand names may be used by multiple manufacturers; the intent is to select the lowest cost, highest value products that provide the same formulations.)

3. Evaluating statutory and/or regulatory authorities to address continued coverage of selected vitamins and other products when considered to be clinically and cost effective.

XI. NDAA 2017, SECTION 743: DRUG ACQUISITION COST PARITY IN THE TRICARE PHARMACY BENEFITS PROGRAM

The Committee reviewed Section 743 of NDAA 2017, results of DHA discussions with chain drug store and pharmaceutical manufacturer representatives, and historical data on cost parity in bidding. Additionally, the Committee invited manufacturers to offer cost parity bids for the August 2017 P&T Committee meeting.

Currently, manufacturers may voluntarily offer cost parity. Overall, historical trends and discussions with representatives suggest manufacturers will not pursue parity pricing. Similarly, despite encouragement to consider cost parity for the current meeting, cost parity

pricing was not offered for any bids. Copayments are currently highest at the retail network. Only non-Medicare patient prescriptions are eligible for the pilot. Administrative and contracting complexity will increase with the pilot.

A. ***COMMITTEE ACTION*—**The P&T Committee recommended against (15 for, 0 opposed, 0 abstained, 0 absent) pursuing the price parity pilot.

XII. ITEMS FOR INFORMATION

A. PROTON PUMP INHIBITORS

The Committee was briefed on utilization of PPIs, following the recommendation from the March 2017 Interim Meeting to designate esomeprazole as NF and non step-preferred. Comparable to 2007 brand switch from Aciphex to Nexium, the transition has been rapid at both the MTFs and purchased care. The utilization of cost effective agents has been broad with the assistance of appropriate prior authorization and medical necessity procedures. As expected, a small percentage of patient remain on the previously step-preferred brand product.

XIII. ADJOURNMENT

The meeting adjourned at 1440 hours on August 10, 2017. The next meeting will be in November 2017.

Appendix A—Attendance: August 2017 DoD 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 Formulary Recommendations for Newly-Approved Drugs per 32 CFR 199.21(g)(5)

Appendix F—Mail Order Status of Medications Designated Nonformulary During the August 2017 DoD P&T Committee Meeting

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

Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☐ concurs with all recommendations.

☒ concurs with the recommendations, with the following modifications:

Prenatal vitamins and other products losing OTC status in First DataBank: Note that following the August 2017 P&T Committee meeting, the POD was notified of First DataBank's plans to delay the January 1, 2018 implementation. As a result, implementation of the above recommendations to add 8 products to the OTC program are delayed pending further clarification. They will be continued to be covered as prescription products.

☐ concurs with the recommendations, except for the following:

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

10 OCT 17
Date

Appendix A—Attendance: August 2017 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
LTC Michele Hudak, MSC for CAPT Edward Norton, MSC	Deputy, DHA Integrated Utilization Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
Lt Col John Oberlin, MC	Air Force, Physician
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
CDR Heather Hellwig, MSC for CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Mr. Joe Canzolino	Department of Veterans Affairs
Voting Members Absent	
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Nonvoting Members Present	
Mr. Randy Stone	Office of General Counsel, DHA
MAJ Norman Tuala via telephone	Defense Logistics Agency Troop Support
Dean Valibhai, PharmD, MBA via telephone	DHA Purchased Care Branch
Guests	
Dr. Barclay Butler (SES)	Defense Health Agency, J4 Component Acquisition Executive
LCDR Joseph Galka	Defense Logistics Agency Troop Support
Soo Kun Kim	Defense Logistics Agency Troop Support
Mr. Dwight Bonham	DHA Contract Operations Division
Mr. Keith Boulware	DHA Contract Operations Division
Ms. Teresa Lee	DHA Contract Operations Division
LTC Joseph Yancey	Defense Health Agency, J3 Operations
CAPT Ryan Schupbach	Indian Health Service
CDR Marisol Martinez	Centers for Disease Control and Prevention

Appendix A—Attendance (continued)

Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, 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
David Folmar, PharmD, BCPS	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
LCDR Christina Andrade	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
CPT Zachary Leftwich, MSC	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS, via telephone	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
CDR Eric Parsons, MSC	DHA Purchased Care Branch
David Meade, PharmD via telephone	DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via telephone	DHA Integrated Utilization Branch
Maj Robert Kennedy, BSC	San Antonio Military Medical Center
Maj Gregory Palmrose, BSC	University of Texas PhD Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• insulin glargine 100 U/mL (Basaglar) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus)
• insulin degludec (Tresiba) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus)
• insulin detemir (Levemir Pen) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control • No formulary alternative: The patient is pregnant and is not able to use insulin glargine (Lantus). **Formulary Alternatives:** insulin glargine (Lantus) **Note that Medical Necessity only applies to detemir pen; detemir vials remain formulary**
• abaloparatide (Tymlos) **Osteoporosis Agents**	• Use of formulary agents has resulted in therapeutic failure **Formulary Alternatives:** teriparatide (Forteo), bisphosphonates
• brodalumab (Siliq) **Targeted Immunomodulatory Biologics (TIBs)**	• 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) have resulted in therapeutic failure **Formulary Alternatives:** adalimumab (Humira), secukinumab (Cosentyx), ustekinumab (Stelara), and apremilast (Otezla)
• sarilumab (Kevzara) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira) is contraindicated • Patient has experienced significant or likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) and methotrexate have resulted in therapeutic failure • No alternative formulary agent: The patient has symptomatic congestive heart failure. **Formulary Alternative:** adalimumab (Humira)

Drug / Drug Class	Medical Necessity Criteria
• dronabinol oral solution (Syndros) **Antiemetic & Antivertigo Agents**	• No alternative formulary agent: patient has failed formulary antiemetics or has weight loss due to AIDS meds, and has difficulty swallowing dronabinol capsules **Formulary Alternatives:** dronabinol capsules (Marinol, generics), ondansetron (Zofran, generics), aprepitant (Emend), benzodiazepines, metoclopramide, promethazine, prochlorperazine, or corticosteroids, dexamethasone, or megestrol
• fluticasone/salmeterol (AirDuo RespiClick) **Pulmonary-1s: Inhaled Corticosteroids / Long-Acting Beta Agonists (ICS/LABAs)**	• No alternative formulary agent. The patient requires salmeterol as the LABA component and requires the lower dose found in AirDuo compared to Advair OR • The patient requires fluticasone/salmeterol and cannot manipulate the Diskus or hydrofluoroalkane metered-dose inhaler (HFA MDI) device **Formulary Alternatives:** fluticasone/salmeterol (Advair Diskus, Advair HFA)
• mixed amphetamine salts ER (Mydayis) **Attention Deficit Hyperactivity Disorder (ADHD) Drugs**	• Use of generic Adderall XR and Concerta have resulted in therapeutic failure **Formulary Alternatives:** mixed amphetamine salts ER (Adderall XR, generics), extended-release methylphenidate (Concerta, generics)
• morphine sulfate ER (Morphabond XR) **Narcotic Analgesics**	• Patient has experienced therapeutic failure from at least two formulary long-acting narcotic analgesics. **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)
• safinamide (Xadago) **Parkinson's Disease Drugs**	• Patient has experienced significant adverse effects from a formulary MAO-B inhibitor (selegiline or rasagiline) that are not expected to occur with safinamide • Use of formulary agent resulted in therapeutic failure **Formulary Alternatives:** selegiline, rasagiline
• valbenazine (Ingrezza) **Neuromuscular Miscellaneous Agents**	• Use of formulary agent has resulted in therapeutic failure **Formulary Alternatives:** tetrabenazine (Xenazine), deutetrabenazine (Austedo)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• insulin degludec (Tresiba) **Basal Insulins**	**Changes from August 2017 meeting are in bold.** Manual PA criteria apply to all new users of Tresiba. Manual PA criteria—Tresiba is approved if all criteria are met: 1. **Patient is age ≥ 1** AND 2. Patient must have tried and failed or is intolerant to insulin glargine (Lantus) • PA does not expire • Non-FDA approved uses are not approved.
• insulin detemir pens and vials (Levemir) **Basal Insulins**	Manual PA criteria apply to all new users of Levemir pens and vials. Manual PA criteria—Levemir pen or vial is approved if all criteria are met: 1. Patient must have tried and failed insulin glargine (Lantus) Or 2. Patient is pregnant and cannot use insulin glargine (Lantus) • PA does not expire • Non-FDA approved uses are not approved.
• insulin glargine 100 U/mL (Basaglar) **Basal Insulins**	Manual PA criteria apply to all new users of Basaglar. Manual PA criteria—Basaglar is approved if the following criteria is met: 1. Patient must have tried and failed insulin glargine (Lantus). • PA does not expire • Non-FDA approved uses are not approved.
• insulin glargine 300 U/mL (Toujeo) **Basal Insulins**	**Note – No changes from the previous PA from November 2015 were recommended at the August 2017 meeting.** Manual PA criteria apply to all new users of Toujeo. Manual PA criteria—Toujeo is approved if: • The patient is at least 18 years of age AND • The patient has diabetes and is using a minimum of 100 units of insulin glargine (Lantus) per day AND • The patient requires a dosage increase with Lantus and has experienced a clinically significant, severe hypoglycemia episode, despite splitting the Lantus dose AND • The patient has been counseled regarding the risk of dosing errors. • Note that the following are not acceptable reasons for Toujeo: o Non-adherence to previous insulin treatment o Patient or prescriber preference for the use of Toujeo o Patient or prescriber preference for a smaller injection volume Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• plasma-derived human C1 esterase inhibitor IV (Cinryze) • plasma-derived human C1 esterase inhibitor SQ (Haegarda) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	Manual PA criteria apply to all new users of Cinryze and Haegarda. <u>Manual PA criteria</u>—Cinryze or Haegarda is approved if: • The patient is ≥13 years old (Cinryze) or ≥12 years old (Haegarda) **AND** • The patient must be diagnosed with hereditary angioedema (HAE) Type I, II, or III (HAE with normal C1-esterase inhibitor) **AND** • The drug is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist **AND** • The patient must experience ≥2 HAE attacks per month **AND** • The patient has tried and failed an attenuated androgen (danazol) **OR** o Patient has experienced or is expected to experience serious adverse effects from the use of an androgen (e.g., virilization of women, stroke, or myocardial infarction, venous thromboembolism) **OR** o Patient is female of childbearing age • Cinryze or Haegarda is not approved for any indication other than HAE. • PA does not expire.
• brodalumab (Siliq) **Targeted Immunomodulatory Biologics (TIBs)**	Step Therapy and Manual PA Criteria apply to all new and current users of brodalumab (Siliq). <u>Automated PA criteria</u>: 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 <u>Manual PA criteria</u>: If automated criteria are not met, coverage is approved for Siliq if: • Contraindications exist to Humira and Cosentyx • Inadequate response to Humira and Cosentyx • Adverse reactions to Humira and Cosentyx not expected with Siliq. AND Coverage approved for patients > 18 years with: • Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy AND • The patient does NOT have suicidal ideation and behavior Coverage NOT provided for concomitant use with other TIBs, including but not limited to abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), tocilizumab (Actemra), rituximab (Rituxan), ustekinumab (Stelara), apremilast (Otezla), secukinumab (Cosentyx), ixekizumab (Taltz) or infliximab (Remicade) Off-label uses are NOT approved. Prior Authorization expires in 6 months <u>Renewal PA Criteria</u>: After 6 months, PA must be resubmitted. Continued use of Siliq will be allowed if the patient has responded to therapy and has not exhibited suicidal ideation and behavior.

Drug / Drug Class	Prior Authorization Criteria
• sarilumab (Kevzara) **Targeted Immunomodulatory Biologics (TIBs)**	Step therapy and Manual PA Criteria apply to all new and current users of sarilumab (Kevza 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 Kevzara 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: • Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs) 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), ustekinumab (Stelara), apremilast (Otezla), rituximab (Rituxan), secukinumab (Cosentyx), or ixekizumab (Taltz). Off-label uses are not approved, including uveitis, polyarticular and systemic juvenile idiopathic arthritis (JIA) or ankylosing spondylitis PA does not expire.
• guselkumab (Tremfya) **Targeted Immunomodulatory Biologics (TIBs)**	Step therapy and Manual PA Criteria apply to all new and current users of guselkumab (Tremfya). 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 Tremfya if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-tumor necrosis factor [TNF] or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic congestive heart failure (CHF) • Adverse reactions to Humira not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy 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), ustekinumab (Stelara), apremilast (Otezla), rituximab (Rituxan), secukinumab (Cosentyx), or ixekizumab (Taltz).

Drug / Drug Class	Prior Authorization Criteria
• midostaurin (Rydapt) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Rydapt. Manual PA criteria—Rydapt is approved if: • Patient is ≥ 18 AND • Rydapt is being prescribed by or in consultation with a hematologist/oncologist AND • Patient uses Rydapt in combination with standard chemotherapy protocols AND • Patient has a diagnosis of Acute Myelogenous Leukemia (AML) and FLT3 mutation as determined by FDA-approved test OR • Patient has a diagnosis of advanced systemic mastocytosis (aggressive systemic mastocytosis; systemic mastocytosis associated with hematologic neoplasm) or mast cell leukemia Off-label uses are not approved. PA expires in 1 year. Renewal Manual PA criteria: Rydapt is approved indefinitely for continuation of therapy if patient has documented clinical and/or symptom improvement.
• ribociclib-letrozole (Kisqali Femara Co-Pack) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Kisqali-Femara. Manual PA criteria—Kisqali-Femara is approved if: • Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND • Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer Off-label uses are not approved. PA does not expire.
• dronabinol (Syndros) **Antiemetic & Antivertigo Agents**	Manual PA criteria apply to all new and current users of Syndros. Manual PA criteria—Syndros is approved if all criteria are met: • Patient is ≥18 years old AND • Patient cannot take dronabinol capsule due to swallowing difficulties AND • Patient has chemotherapy-induced nausea and vomiting that has not responded to therapy with other antiemetics, including 5HT3 antagonists (ondansetron, granisetron), substance P/neurokinin (NK1) receptor antagonists (aprepitant), benzodiazepine, metoclopramide, phenothiazines (promethazine or prochlorperazine), or dexamethasone OR • Patient has weight loss due to AIDS and has not responded to steroids or megestrol Off-label uses are NOT approved, including use as an opioid-sparing agent for patient receiving opioids PA does not expire.
• fluticasone/salmeterol (AirDuo RespiClick) **Pulmonary ICS/LABAs**	PA criteria apply to all new and current users of AirDuo RespiClick who are 12 years of age or older. Note that AirDuo will not be part of the current automated step therapy for the ICS/LABA oral inhalers; separate manual PA will be required. Manual PA criteria—AirDuo RespiClick is approved if: • Patient has a diagnosis of asthma AND • Patient is older than 12 years of age AND • Patient requires salmeterol as the LABA component and requires the lower dose found in AirDuo versus Advair Diskus or HFA OR • Patient requires fluticasone/salmeterol and cannot manipulate the Advair Diskus or Advair HFA metered dose inhaler Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• methotrexate (Xatmep) oral solution **Antirheumatic Drugs**	PA criteria apply to all new and current users of Xatmep. Automated PA criteria • Xatmep will be approved for patients 12 years of age and younger Manual PA criteria—Manual PA criteria apply if the patient is older than 12 years of age. Xatmep is approved if: • The patient must have a diagnosis of acute lymphoblastic leukemia (ALL) or active polyarticular juvenile idiopathic arthritis (pJIA); AND • The patient has a history of difficulty swallowing tablets or has a medical condition that is characterized by difficulty swallowing or inability to swallow Off-label uses are not approved. PA does not expire.
• mixed amphetamine salts ER (Mydayis) **ADHD Drugs**	Manual PA criteria apply to all new and current users of Mydayis. Manual PA criteria—Mydayis is approved if all criteria are met: • Patient is 13 years of age or older AND • Patient has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND • Patient has tried and failed generic Adderall XR AND • Patient has tried and failed generic Concerta Off-label uses are NOT approved. PA does not expire.
• prasterone (Intrarosa) **Vaginal Lubricants**	Manual PA criteria apply to all new users of Intrarosa. Manual PA criteria—Intrarosa coverage approved for 1 year if all criteria are met: 1. Patient is a post-menopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy. 2. Patient has tried and failed a low dose vaginal estrogen preparation (e.g., Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem). 3. Patient does not have any of the following: i. Undiagnosed abnormal genital bleeding ii. Pregnant or breastfeeding iii. History of breast cancer or currently have breast cancer 4. Use of Intrarosa will be for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be reevaluated periodically as clinically appropriate to determine if treatment is still necessary. Off-label uses are not approved. PA expires in 1 year. PA Renewal criteria: PA is approved indefinitely if the patient has had improvement in the severity of dyspareunia symptoms.
• safinamide (Xadago) **Parkinson's Disease Drugs**	Manual PA criteria apply to all new users of Xadago. Manual PA Criteria: Coverage approved if all criteria are met: 1. Patient is ≥ 18 years old AND 2. Patient has a diagnosis of Parkinson's disease AND 3. Patient has tried and failed rasagiline or selegiline AND 4. Xadago is used as an adjunct to levodopa/carbidopa or a dopamine agonist. Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• valbenazine (Ingrezza) **Neuromuscular Miscellaneous Agents**	Manual PA criteria apply to all new users of Ingrezza. <u>Manual PA Criteria</u>: Coverage approved if all criteria are met: 1. Age > 18 years 2. Prescribed by or in consultation with a neurologist or psychiatrist 3. Patient has moderate to severe tardive dyskinesia along with schizophrenia, schizoaffective disorder, or a mood disorder 4. Patient does not have congenital long QT syndrome or arrhythmias associated with QT prolongation 5. Patient has had an adequate trial and has failed or has a contraindication to tetrabenazine or deutetrabenazine 6. Provider has considered use of clonazepam and ginkgo biloba 7. Patient is not taking any of the following: • MAOI inhibitor • Another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine) • CYP3A4 inducers Off-label uses are NOT approved. PA does not expire.
• methylnaltrexone (Relistor) • naloxegol (Movantik) **Gastrointestinal-2 Agents for Opioid-Induced Constipation**	Manual PA criteria apply to all new and current users of Movantik and Relistor. <u>Manual PA criteria</u>: Coverage will be approved if: • The patient is ≥ 18 years with a diagnosis of opioid-induced constipation (OIC); AND • The patient is concurrently taking an opioid agonist and is not receiving other opioid antagonists; AND • The patient has failed or is unable to tolerate two or more of the following: o At least one stimulant laxative (e.g., sennosides or bisacodyl) o At least one osmotic laxative (e.g., MiraLAX, lactulose, or magnesium citrate); AND • The patient has failed therapy with lubiprostone (Amitiza); AND • The patient does not have a known or suspected GI obstruction or is not at increased risk of recurrent obstruction); AND • The patient is not currently taking a drug metabolized by CYP3A4 (for Movantik) Non-FDA approved uses are not approved. Prior authorization does not expire.
• dapsone 5% gel (Aczone) • dapsone 7.5% gel (Aczone) **Topical Acne and Rosacea Agents**	**Changes from August 2017 meeting are in bold and strikethrough. See the August 2016 meeting minutes for the complete automated PA criteria implemented on February 8, 2017.** <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**~~ **<u>></u>13 years** with a diagnosis of inflammatory acne, AND o The patient has tried and failed at least 3 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
• tocilizumab (Actemra) **Targeted Immunomodulatory Biologics – Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Changes from August 2017 meeting are in bold. See August 2014 meeting minutes for the complete automated PA criteria implemented on February 18, 2014.** Manual PA criteria: If automated criteria are not met, coverage is approved for Actemra 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 • Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to the SQ formulation of Actemra AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs) • Subcutaneous Actemra is not approved for use in systemic or pJIA • **Adult patients with giant cell arteritis** Coverage is NOT provided for concomitant use other TIBs.
• lifitegrast ophthalmic solution (Xiidra) **Ophthalmic Anti-Inflammatory / Immunomodulatory Agents**	**Changes from August 2017 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of lifitegrast ophthalmic solution. Manual PA criteria: Coverage will be approved if: 1. The patient is 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~~ PA expires in one year.** **Renewal PA Criteria: After one year, PA must be resubmitted. Coverage approved indefinitely if:** • **Patient must have documented improvement in signs of dry eye disease (DED) as measured by at least one of the following:** o **Decrease in corneal fluorescein staining score OR** o **Increase in number of mm per 5 minutes using Schirmer's tear test in comparison to original scores AND** • **Patient has documented improvement in ocular discomfort AND** • **Patient is not using Xiidra and Restasis as combination therapy.**
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	**Changes from August 2017 meeting are in bold.** Manual PA criteria apply to all new and current users of Eucrisa. Manual PA Criteria: coverage will be approved if: • Patient has mild to moderate atopic dermatitis AND • Prescribed by a dermatologist, **allergist or immunologist** AND • Patient has a contraindication to, intolerability to, or failed treatment with at least one high potency / class 1 topical corticosteroid. Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• esomeprazole delayed release packets for suspension (Nexium) **Proton Pump Inhibitors (PPIs)**	**Changes from August 2017 meeting are in bold. See the February 2017 Interim Meeting minutes for complete automated PA criteria implemented on June 28, 2017.** PA criteria apply to all new and current users of esomeprazole (Nexium). Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if: • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole tablets (Aciphex, generics), and the patient had an inadequate response. • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics), and the patient was unable to tolerate them due to adverse effects. • Treatment with omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency). OR • **For esomeprazole delayed release packets for suspension only:** o **The patient is younger than 5 years of age. OR** o **The patient requires a percutaneous endoscopic gastrostomy (PEG) tube.**
• canagliflozin (Invokana) • canagliflozin/ metformin (Invokamet) • dapagliflozin (Farxiga) • dapagliflozin/ metformin ER (Xigduo XR) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	**Changes from August 2017 meeting are in strikethrough.** All new users of an SGLT2 inhibitor are required to try metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin ~~or a sulfonylurea (SU) and a DPP-4 inhibitor~~ first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first. Automated PA criteria • The patient has filled a prescription for metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. OR • The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. AND Manual PA criteria—If automated PA criteria are not met, Jardiance or Glyxambi is approved (e.g., a trial of metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ ~~are~~ is NOT required) if: • The patient has had an inadequate response to metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~; or • The patient has experienced a significant adverse effect from metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~; or • The patient has a contraindication to metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~. AND The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• plasma-derived human C1 esterase inhibitor SQ (Haegarda) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	▪ MTF/Mail: 60 vials/90 days Retail: 20 vials/30 days
• plasma-derived human C1 esterase inhibitor IV (Cinryze) • plasma-derived human C1 esterase inhibitor IV (Berinert) • recombinant C1 esterase inhibitor IV (Ruconest) • Icatibant SQ (Firazyr) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	▪ Note no changes from the QLs from August 2016 ▪ 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
• brodalumab (Siliq) • guselkumab (Tremfya) • sarilumab (Kevzara) • ustekinumab (Stelara) vial formulation **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail Network: 28-day supply ▪ Mail/MTF: 56-day supply
• ribociclib-letrozole (Kisqali-Femara) **Oral Oncologic Drugs**	▪ Retail Network: 28-day supply ▪ MTF/Mail: 56-day supply
• midostaurin (Rydapt) **Oral Oncologic Drugs**	▪ Retail Network: 28-day supply MTF/Mail: 56-day supply
• brigatinib (Alunbrig) **Oral Oncologic Drugs**	▪ Retail Network: 30-day supply Mail/MTF: 60-day supply
• fluticasone/salmeterol (AirDuo RespiClick) **Pulmonary-1 Agents: Long-Acting Beta Agonists/Inhaled Corticosteroids Combinations**	▪ Retail Network: 1 inhaler in 30 days MTF/Mail: 3 inhalers in 90 days
• fluticasone/azelastine (Dymista) **Nasal Allergy Drugs**	▪ Retail: 1 inhaler in 30 days ▪ MTF/Mail: 3 inhalers in 90 days

Appendix E—Formulary Recommendations for Newly-Approved Drugs Per 32 CFR 199.21(g)(5)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
abaloparatide (Tymlos) injection	Osteoporosis agents	▪ teriparatide (Forteo)	Postmenopausal osteoporosis in women with a high risk for fracture	• 2nd available parathyroid hormone (PTH) analog indicated for the treatment of postmenopausal osteoporosis; not approved for use in men or for prevention of osteoporosis • Evaluated in one placebo controlled trial (18 mo) with teriparatide as an active comparative and an extension study (additional 6 mo); no head-to-head studies – Abaloparatide had a lower rate of new vertebral fractures at 18 mo (0.6%) compared to placebo (4.2%) – Bone density (BMD) improved at all sites • Indirect comparison showed rates of new vertebral fractures were lower than teriparatide and similar to rates of non- vertebral fractures – Absolute rate of new vertebral fractures of abaloparatide (3.6%) vs teriparatide (9.3%) – Absolute rate of non-vertebral fractures of abaloparatide (2%) compared to teriparatide (1.46%) • Similarities to teriparatide include common ADRs, once daily SQ administration, and BBW regarding osteosarcoma • No compelling advantage over existing formulary agents	• NF • Add to mail
brigatinib (Alunbrig)	Oral Oncologic Agents for Lung Cancer	▪ crizotinib (Xalkori) ▪ alectinib (Alecensa)	Advanced anaplastic lymphoma kinase positive (ALK+) non-small cell lung cancer (NSCLC) failing crizotinib	• ALK+ accounts for 2-7% of NSCLC • 3rd agent approved after progression with crizotinib, targeting advance disease • Effective in those who had brain metastases where this tumor often presents • Accelerated approval based on tumor size reduction, requires additional studies to verify • Phase II trial that led to approval based on objective response rates will also assess overall survival, progression free survival; and pending Phase III study comparing as 1st line therapy	• UF • Exempt from mail
brodalumab (Siliq) injection	Targeted Immuno-modulatory Biologics (TIBs)	▪ adalimumab (Humira) ▪ ustekinumab (Stelara) ▪ secukinumab (Cosentyx) ▪ etanercept (Enbrel) ▪ ixekizumab (Taltz)	Adults w/ moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy AND have failed other systemic therapies	• 3rd IL-17A receptor antagonist (like Cosentyx & Taltz) • Dosed 210 mg SQ on Weeks 0, 1, & 2, followed by 210 mg SQ every 2 weeks • Treatment beyond 16 wks in patients who have not achieved an adequate response (after 12-16 wks of treatment) is not likely to result in greater success • In two head-to-head trials, Siliq (IL-17A) was superior to Stelara (IL12/23) • All IL-17 antagonists increase risk of infections, latent tuberculosis reactivation, and should be avoided with live vaccines • BBW: Siliq is the only TIB with a black box warning for risk of suicidal ideations and behavior, requiring REMS program enrollment • Step therapy exists for the class; Humira preferred	• NF and Non Step-Preferred • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
dronabinol (Syndros) oral solution	Antiemetic & Antivertigo Agents	▪ dronabinol caps generic ▪ Marinol caps brand ▪ ondansetron ▪ aprepitant	• Adults only • Anorexia in AIDS pts • Chemo-induced nausea & vomiting	• New oral solution of the cannabinoid receptor antagonist dronabinol (Marinol), which is available as generic capsules • No clinical studies available; FDA approval was based on bioavailability testing to Marinol capsules • DEA Schedule: Syndros is C-II vs C-III for Marinol • Contains dehydrated alcohol; risk of disulfiram or metronidazole drug interactions; avoid use in pregnancy and preterm neonates. • Potential risk of dosing errors with supplied oral syringe which is not used for administration • Provides an alternative delivery system for patients who have failed conventional antiemetic therapy and who have difficulty swallowing dronabinol capsules • Overall has no advantages compared to UF antiemetics and dronabinol capsules	• NF • Exempt from mail
fluticasone/ salmeterol (AirDuo RespiClick) oral inhaler	Inhaled Corti-costeroids/ Long-Acting Beta Agonists (ICS/LABAs)	▪ fluticasone/ salmeterol (Advair Diskus & HFA) ▪ fluticasone/ vilanterol (Breo)	Treatment of asthma for patients age 12 and older	• Another option for treating asthma in patients older than 12 years • Same active ingredients as Advair but with different doses of fluticasone and salmeterol • No evidence of benefit over current therapy • Step Therapy applies in this class • Advair HFA and Diskus are the preferred agents	• NF and Non Step-Preferred • Add to mail list
methotrexate (Xatmep) oral solution	Antirheumatics	methotrexate	Acute lymphoblastic leukemia (ALL) as a component of combo chemo maintenance regimen in pediatric pts Active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of / inadequate response to first-line therapy including NSAIDs	• Initial US approval for methotrexate in 1953 • Convenient ready to use oral solution for pediatric indications, and for pts who are intolerant to currently available MTX options • Currently not FDA approved, ready to use oral formulation of MTX for use by pediatric patients, or those with difficulty swallowing or needle phobia	• UF • Exempt from mail
midostaurin (Rydapt)	Oral Oncologic Agents for Acute Myeloid Leukemia (AML)	No available pharmacy benefit comparator	AML in combo with chemotherapy; aggressive systemic mastocytosis, systemic mastocytosis w/associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)	• 1st oral tyrosine kinase approved in AML (FLT3+ with approved test) • Additionally approved for advanced systemic mastocytosis (SM) • Demonstrated increased overall survival benefit, reducing mortality • In advanced SM clinical response in 60% of pts reported • Current treatment options for AML are chemotherapies, medical benefit • No similar oral option	• UF • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
mixed amphetamine salts ER (Mydayis)	Attention Deficit Hyperactivity Disorder (ADHD) drugs	▪ Adderall XR, generics ▪ Adzenys XR ▪ Dyanavel ▪ Concerta, generics ▪ Aptensio XR ▪ Quillivant XR	Treatment of ADHD in patients 13 years and older	• Approved for patients ≥ 13 years of age • Effects can last up to 16 hrs; insomnia is the most common AE • BBW: CNS stimulants, including amphetamine extended-release oral formulations, have a high potential for abuse and dependence. • Multiple direct competitors available • Active ingredient in Mydayis is the same as Adderall XR • No compelling clinical advantages over existing formulary agents	• NF • Exempt from mail
morphine sulfate ER (Morphabond XR)	Narcotic Analgesics	▪ morphine ER (MS Contin) ▪ morphine ER (Arymo ER)	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment	• 3rd morphine abuse deterrent formulation (ADF) long-acting narcotic analgesic • 8th abuse deterrent opioid • Another option for treating chronic pain • ADFs have not been shown as better than non-ADFs in deterring inappropriate opioid use	• NF • Exempt from mail
niraparib (Zejula)	Oral Oncologic Agents for Ovarian Cancer	▪ olaparib (Lynparza) ▪ rucaparib (Rubraca)	Maintenance tx of adult pts with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy	• 3rd available PARP (Poly ADP-Ribose Polymerase) inhibitor for ovarian cancer • For maintenance therapy, in those who are platinum sensitive • Does not require multiple lines of therapy outside of platinum sensitive courses • Does not require co-diagnostic in the FDA label, unlike prior agents • Concerns regarding effect of this agent on subsequent chemotherapies that are inevitably required in this disease that has high rate of recurrence	• UF • Exempt from mail
prasterone (Intrarosa) vaginal insert	Vaginal Lubricants	▪ ospemifene (Osphena) ▪ conjugated estrogen cream (Premarin)	Treatment of moderate to severe dyspareunia due to menopause	• Prasterone is an inactive endogenous steroid precursor (dehydroepiandrosterone or DHEA); vaginal insert • ACOG Guidelines and Am Journal of Obstetrics and Gynecology – Vaginal symptoms are best treated with systemic or topical hormonal therapy, but topical methods are preferable due to fewer AEs – Give hormonal therapy in the lowest dose and for the shortest period possible to decrease risk of serious AEs • Prasterone dosed at 0.50% (6.5 mg) vaginally at bedtime for 12 weeks showed statistical significance in decreasing dyspareunia compared to placebo • Short-term AEs only for vaginal discharge were statistically significant compared to placebo • Long-term AEs in association with vaginal DHEA is uncertain and lacks safety data • Prasterone is the first topical (locally applied) inactive hormone approved for dyspareunia	• UF • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
ribociclib letrozole (Kisqali Femara Co-Pack)	Oral Oncologic Agents for Breast Cancer	▪ palbociclib (Ibrance) + aromatase inhibitor	Breast Cancer	• Kisqali reviewed in May 2017 as individual agent and made UF • This formulation adds letrozole, which has been available for 20 years • No changes to either agent, provides convenience packaging and allows for one pharmacy transaction • Agents are typically co-prescribed	• UF • Exempt from mail
safinamide (Xadago)	Parkinson's Disease Drugs	▪ rasagiline ▪ selegiline	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's Disease experiencing "off" episodes	• 2nd line adjunctive MAO-B treatment behind rasagiline • Must be used in conjunction with levodopa/carbidopa	• NF • Add to mail
sarilumab (Kevzara) injection	Targeted Immuno-modulatory Biologics (TIBs)	▪ adalimumab (Humira) ▪ tocilizumab (Actemra)	Adults with mild to moderate RA with inadequate response or intolerance to at least one DMARD	• 2nd IL-6 receptor antagonist for RA; same as Actemra • Can be used alone in cases involving intolerance to MTX or when treatment with MTX is inappropriate • Dose: 200 mg SQ every 2 weeks; 150 mg SQ every 2 weeks if decreased white count or platelets; or increased LFTs • One head-to-head trial vs Humira showed Kevzara had superior reduction of disease activity and improved RA signs and symptoms; but Humira was under-dosed • Under FDA review for uveitis, ankylosing spondylitis and juvenile idiopathic arthritis • No evidence Kevzara would have different efficacy or safety profile than Actemra • Step Therapy exists for the class; Humira is preferred	• NF and Non step-preferred • Add to mail list
valbenazine (Ingrezza)	Neuro-muscular Miscellaneous Agents	▪ clonazepam ▪ amantadine ▪ tetrabenazine (Xenazine)	Tardive dyskinesia	• 3rd FDA approved VMAT2 inhibitor and the first indicated for tardive dyskinesia (TD) • Administered orally once daily • Efficacy based on one 6-week placebo-controlled trial using the AIMS score to determine improvement in TD symptoms • Valbenazine reduced the AIMS score by 3.2 points from baseline compared to placebo (0.1) • No difference between valbenazine and placebo in clinician global impression change for TD symptoms • Study limitations: short trial duration and no head-to-head studies • Generally well tolerated; somnolence & QT prolongation were the major ADRs • Numerous drug interactions exist including interactions with MAOIs, CYP3A4 inducers and inhibitors, CYP2D6 inhibitors, and digoxin • Offers another treatment option for patients with TD	• NF • Exempt from mail

Appendix F—Mail Order Status of Medications Designated Nonformulary During the August 2017 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
August 2017	**Basal Insulin Analogs** Maintain the following UF and NF drugs on the EMMPI list: ▪ insulin degludec (Tresiba) ▪ insulin detemir pen and vial (Levemir) ▪ insulin glargine pen and vial (Lantus) ▪ insulin glargine 300 U/mL (Toujeo) ▪ insulin glargine 100 U/mL (Basaglar) **Newly-Approved Drugs per 32 CFR 199.21(g)(5)** ▪ sarilumab (Kevzara) ▪ abaloparatide (Tymlos) ▪ safinamide (Xadago) ▪ fluticasone/salmeterol (AirDuo RespiClick)	**Newly-Approved Drugs per 32 CFR 199.21(g)(5)** C-II controlled substances exception applies ▪ morphine sulfate ER tablets (Morphabond XR) ▪ mixed amphetamine salts ER (Mydayis) ▪ dronabinol oral solution (Syndros) Addition of oral oncology agents to the EMMPI program should be considered at a future date ▪ midostaurin (Rydapt) ▪ niraparib (Zejula) ▪ ribociclib/letrozole (Kisqali-Femara) ▪ methotrexate (Xatmep) oral solution ▪ brigatinib (Alunbrig) Other ▪ prasterone (Intrarosa) due to low persistence rates ▪ brodalumab (Siliq) pending further information ▪ valbenazine (Ingrezza) pending further information

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
Aug 2017	**Basal Insulin Analogs**	UF Class Review Previously reviewed Feb 2010	**BCF Step-Preferred** ▪ glargine pen and vial (Lantus)	**UF Non Step-Preferred** ▪ detemir vial (Levemir) ▪ glargine 300 U/mL (Toujeo)	**NF Non Step-Preferred** ▪ degludec (Tresiba) ▪ detemir pen (Levemir) ▪ glargine 100 U/mL (Basaglar)	Pending signing of the minutes / 30 days The effective date is Nov 22, 2017	▪ Manual PA criteria apply to all new users ▪ Manual PAs for Toujeo, Tresiba, Basaglar, and Levemir pen	▪ Must try Lantus first in all new users of Toujeo, Tresiba, Basaglar, and Levemir See Appendix C
Aug 2017	**Corticosteroids-Immune Modulators Drug Class - Hereditary Angioedema (HAE) Subclass**	UF Class review Class not previously reviewed	▪BCF: No HAE product selected ▪Corticosteroid - Immune Modulator Subclass BCF product includes prednisone	▪ plasma-derived human C1 esterase inhibitor IV (Cinryze) ▪ plasma-derived human C1 esterase inhibitor IV (Berinert) ▪ recombinant C1 esterase inhibitor IV (Ruconest) icatibant SQ (Firazyr)	None	Pending signing of the minutes / 30 days The effective date is Nov 22, 2017	Manual PA criteria apply to Cinryze and Haegarda	▪ New patients must try attenuated androgen (Danazol) prior to use of Cinryze or Haegarda. See Appendix C Haegarda approved in July 2017, but not yet reviewed
Aug 2017	**Antiretroviral Agents for HIV**	UF Class Review	▪None	▪ All HIV drugs marketed in the U.S. as of Aug 2017 were recommended for UF status, as listed on pages 8 to 9 of this document.	None	Pending signing of the minutes	-	-

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

Appendix H—Table of Abbreviations

A1c	hemoglobin A1c
ACE	angiotensin converting enzyme
ADHD	attention deficit hyperactivity disorder
ALK+	anaplastic lymphoma kinase positive gene
AML	acute myeloid leukemia
BCF	Basic Core Formulary
BIA	budget impact analysis
CFR	Code of Federal Regulations
CHF	congestive heart failure
CMA	cost minimization analysis
DHA	Defense Health Agency
DMARDs	disease modifying anti-rheumatic drugs
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
GI	gastrointestinal
GLP1RA	glucagon-like peptide-1 receptor agonist
ICS/LABA	inhaled corticosteroid/long-acting beta agonist
IV	intravenous
HAE	hereditary angioedema
HFA/MDI	hydrofluoroalkane metered-dose inhaler
HIV	human immunodeficiency virus
INSTIs	integrase strand transfer inhibitors
IR	immediate release
JIA	juvenile idiopathic arthritis
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NDC	National Drug Code
NNRTIs	nucleoside reverse transcriptase inhibitor
NRTIs	nucleoside/nucleotide reverse transcriptase inhibitor
NPH	
NF	nonformulary
NSCLC	non-small cell lung cancer
OTC	over-the-counter
OIC	opioid-induced constipation
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAMORAs	peripherally-acting mu opioid receptor antagonists
PARP	poly-ADP ribose polymerase-1 enzyme
PEG	percutaneous endoscopic gastrostomy

pJIA	polyarticular juvenile idiopathic arthritis
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPI	proton pump inhibitor
PrEP	pre-exposure prophylaxis
PTH	parathyroid hormone
QLs	quantity limits
SGLT2	sodium glucose co-transporter 2
SQ	subcutaneous
TD	tardive dyskinesia
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
UF	Uniform Formulary
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
XR	extended release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

Addendum August 9, 2017

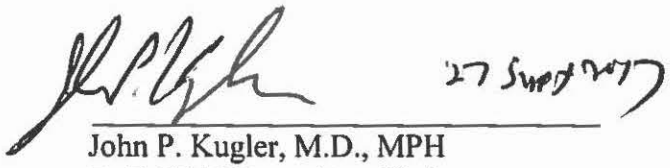
I. NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) 2017 PILOT PROGRAM: INCORPORATION OF VALUE-BASED HEALTH CARE IN PURCHASED CARE COMPONENT OF TRICARE AND MEDICATION ADHERENCE

A pilot program outlined in the NDAA 2017 requires identification of high-value medications where copayments or cost shares would be reduced for targeted populations of covered beneficiaries. The DoD Pharmacy and Therapeutics (P&T) Committee identified rosuvastatin (Crestor generics) and insulin glargine pens (Lantus) as candidates for inclusion in the pilot, which is intended to assess the effects of copayment reduction or elimination on medication adherence rates. Implementation was recommended for January 1, 2018, to align with currently recommended regulatory language.

A. ***COMMITTEE ACTION: MEDICATION ADHERENCE PILOT RECOMMENDATION***—The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) the following:

- Rosuvastatin (Crestor generics): Eliminating the cost share for rosuvastatin at the Mail Order and Retail points of service; the resulting cost share will be $0.
- Insulin glargine pens (Lantus): Lowering the normal brand formulary cost share of $20 at the Mail Order and $24 at the Retail Network to the Tier 1 (generic) formulary cost share that is currently $0 and $10, respectively.

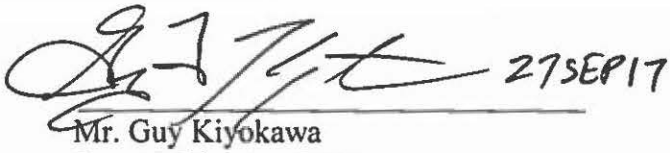
SUBMITTED BY



27 Sep 2017

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

DECISION ON RECOMMENDATIONS



27SEP17

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

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

Second Addendum October 11, 2017

I. NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) 2017 PILOT PROGRAM: INCORPORATION OF VALUE-BASED HEALTH CARE IN PURCHASED CARE COMPONENT OF TRICARE AND MEDICATION ADHERENCE

BACKGROUND: A pilot program outlined in the NDAA 2017, Section 701(h) requires identification of high-value medications to assess the effects of their copayment reduction or elimination on medication adherence rates for targeted populations of covered beneficiaries. The Medication Adherence Pilot is applicable to prescriptions dispensed at the TRICARE Retail Pharmacy Network and Mail Order Pharmacy (MOP).

DISCUSSION: "High-value medications" are defined as prescription medications for management of chronic conditions that improve health outcomes and create health value for covered beneficiaries. Medications covered under the TRICARE pharmacy benefit that treat chronic diseases were potentially eligible for inclusion in the Pilot. Chronic conditions of particular importance to the Military Health System (MHS) include those with a significant disease burden in the MHS population, those that have high healthcare utilization, chronic diseases where medications are available to prevent hospitalizations, and those with high healthcare costs associated with the chronic disease. Diabetes mellitus and hyperlipidemia were identified as two chronic diseases meeting these criteria.

The DoD P&T Committee evaluated additional factors when determining the optimal target medications for inclusion in the Pilot, including current numbers of affected beneficiaries, drug copays, the cost risk to DoD if copays were not collected, and current medication costs at the TRICARE Retail Pharmacy Network and MOP. Insulin and statin therapy are gold standards for treating diabetes mellitus and hyperlipidemia, respectively, and an analysis of MHS prescription data reported an appreciable number of beneficiaries filling prescriptions for insulin glargine pens (Lantus) and rosuvastatin.

The reduction or elimination of copayments for the selected high-value medications will limit the government's ability to subsidize the cost of these medications. Selection of the agents was assessed based on their ability to impact chronic diseases over time, clinical effectiveness, relative cost effectiveness to available alternatives, and overall effect of the loss of copayments.

When taking into consideration the aforementioned factors, the P&T Committee, identified rosuvastatin (Crestor generics) and insulin glargine pens (Lantus) as candidates for inclusion in the Pilot. Implementation was recommended for January 1, 2018, to align with currently recommended regulatory language.

The criteria and processes used by the DoD P&T Committee to select insulin glargine pens (Lantus) and rosuvastatin as the two drugs for inclusion in the Medication Adherence pilot will be set forth in changes to the TRICARE Operations Manual, Chapter 18, Demonstration and Pilot Projects, in order to implement the Congressionally-directed Medication Adherence Pilot.

Note that in lieu of public notice provided through the Federal Register, individual notice will be given by the contractor to each beneficiary prescribed insulin glargine pens (Lantus) or rosuvastatin for a chronic condition when such medication has been identified as available at reduced copay under the Pilot and advising the beneficiary of his/her eligibility under the Pilot.

A. ***COMMITTEE ACTION: MEDICATION ADHERENCE PILOT RECOMMENDATION—***The P&T Committee recommended (14 for, 0 against, 1 abstained, 0 absent) the following:

- Rosuvastatin (Crestor generics): Eliminating the cost share for rosuvastatin at the Mail Order and Retail points of service; the resulting cost share will be $0.
- Insulin glargine pens (Lantus): Lowering the normal brand formulary cost share of $20 at the Mail Order and $24 at the Retail Network to the Tier 1 (generic) formulary cost share that is currently $0 and $10, respectively.

SUBMITTED BY

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

DECISION ON RECOMMENDATIONS

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

19 Oct 2017

Note that the Addendum to the August 2017 DoD P&T Committee meeting minutes was officially signed on September 27, 2017, based on subsequent effective authority of the Interim Final Rule of October 1, 2017.

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 10 and 11, 2017, 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 2017 Minutes—**RADM Colin Chinn, MC, USN, Acting Deputy Director, DHA, approved the minutes from the March 7, 2017, DoD P&T Committee interim meeting for the proton pump inhibitors on March 31, 2017, and approved the minutes from the February 2017 DoD P&T Committee meeting on May 4, 2017.

2. **Clarification to the February 2017 Minutes**

    a) **Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) Implementation Date—**The implementation date for all EMMPI recommendations from the February 2017 meeting, including the newly-approved drugs affected by the EMMPI, will occur upon signing of the minutes.

    b) **Nexium Branded Products—**Nexium branded and generic products are non-formulary and therefore generally not available in Military Treatment Facilities (MTFs) or in the Retail Network point of service (POS). They are available in the mail order program and at the MTFs through the non-formulary special approval process for eligible beneficiaries.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5) (previously known as "innovator drugs"), and full drug class reviews included, but were not limited to, the requirements stated in 32 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. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass—Idiopathic Pulmonary Fibrosis (IPF) Drugs

Background—The IPF drugs have not been previously reviewed for UF status. Manual prior authorization (PA) requirements have been in place since February 2016 for both nintedanib (Ofev) and pirfenidone (Esbriet).

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

- IPF is difficult to diagnose and has limited therapeutic options. Nintedanib (Ofev) and pirfenidone (Esbriet) are the first therapeutic advances for the disease, and have different mechanisms of action. How nintedanib and pirfenidone slow the decline of lung function in IPF is not fully understood.
- There are no studies directly comparing nintedanib and pirfenidone. These two drugs may delay disease progression; however, the most appropriate subset of IPF patients who will respond to therapy and who will tolerate the adverse effects is difficult to predict.
- While neither agent is curative, FDA approval was based on studies showing nintedanib and pirfenidone may reduce the rate of inexorable decline in lung function that is the hallmark of IPF.
- Available meta-analyses suggest that nintedanib and pirfenidone favorably affect endpoints of lung function including forced vital capacity over 52 weeks. Overall, the available evidence suggests these two drugs have similar efficacy when compared to placebo.
- The most commonly reported adverse events for nintedanib and pirfenidone include gastrointestinal (GI) effects. Pirfenidone uniquely can cause rash/photosensitivity, while nintedanib is rated as pregnancy Category D. Pirfenidone should not be used in patients with renal dysfunction, and is associated with a different drug interaction profile than nintedanib.
- Both products are associated with significant discontinuation rates, and may require dosage reductions or temporary stoppage due to adverse effects.

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

- CMA results showed that pirfenidone (Esbriet) was the most cost-effective IPF agent, followed by nintedanib (Ofev).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating pirfenidone (Esbriet) as formulary and step-preferred, with nintedanib (Ofev) as formulary

and non step-preferred, demonstrated the largest estimated cost avoidance for the Military Health System (MHS).

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

    - **UF and Step-Preferred:** pirfenidone (Esbriet)
    - **UF and Non Step-Preferred:** nintedanib (Ofev)
    - **NF:** no products

    Note that as part of this recommendation, all new users of an IPF agent are required to try Esbriet first. Additionally, no IPF products were recommended for BCF addition. For the Pulmonary-1 Drug Class, there are several BCF drugs, including fluticasone (Flovent), salmeterol (Serevent), and fluticasone/salmeterol (Advair).

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updating the current manual PA criteria to require a trial of pirfenidone (Esbriet) in new users, prior to use of nintedanib (Ofev). The step therapy requirement for a trial of Esbriet in new users is included in the manual PA criteria. No changes were recommended to the current manual PA for Esbriet. Coverage for the IPF agents requires a confirmed IPF diagnosis, management by a pulmonologist, and non-smoking status. PA will expire after one year of therapy, with renewal criteria requiring a significant slowing of the annual rate of decline of forced vital capacity (FVC). See Appendix C for full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***QLs currently apply to Esbriet and Ofev. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the current quantity limit of a 30-day supply for both IPF agents, at all three points of service, consistent with current manufacturer packaging.

4. ***COMMITTEE ACTION: EMMPI REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding the IPF drugs to the EMMPI list upon signing of the minutes. See Appendix F.

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation. Based on the P&T Committee's recommendation, the effective date is August 30th, 2017.

B. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers

Background—The Ophthalmic-1 Dual Acting Antihistamine and Mast Cell Stabilizer (AH/MCS) Drug Class was previously reviewed for UF status in August 2010. Ketotifen (Zaditor, generic) is available over-the-counter (OTC) and was not included in the review.

Three products containing the active ingredient olopatadine are available. Olopatadine 0.1% (Patanol) is administered twice daily, is available as a generic formulation, and is the current BCF selection for the class. Olopatadine 0.2% (Pataday) has been marketed since 2004 and is administered once daily; generic formulations are expected later this year. Olopatadine 0.7% (Pazeo) entered the market in 2015 and is administered once daily; it was designated NF at the February 2016 meeting.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 1 opposed, 0 abstained, 0 absent) the following for the ophthalmic AH/MCS:

- The ophthalmic AH/MCS are the standard of care for treating the signs and symptoms of allergic conjunctivitis. Allergic conjunctivitis is a highly seasonal condition, and MHS utilization for the class reflects this variability.
- Clinical practice guidelines from the American Academy of Ophthalmology and the American Optometric Association recommend the AH/MCS as first-line therapy for acute and chronic allergic conjunctivitis. The guidelines do not prefer one product over another.
- A 2015 Cochrane review and 2016 meta-analysis concluded there is insufficient evidence to discern whether one AH/MCS is the more effective than another. Olopatadine may be more effective than OTC ketotifen, but less effective than alcaftadine; however, these differences among products may not be clinically relevant.
- In terms of efficacy and safety, head-to-head studies show olopatadine 0.1% (Patanol) is comparable to olopatadine 0.2% (Pataday). Olopatadine 0.7% (Pazeo) reduced ocular itching to a greater extent than olopatadine 0.2%; however, although these results were statistically significant 24 hours following administration (when the next daily dose is due), the result did not meet the threshold for clinical significance.
- With regard to safety and tolerability, the overall adverse event rate is low. All the products can cause burning, stinging, headaches, dry eye, blurred vision, and hyperemia. Bepotastine (Bepreve) may cause taste perversion in up to 25% of patients.
- There is no new data to change the conclusion from the previous review that the AH/MCS are highly therapeutically interchangeable.

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

- CMA results showed that generic azelastine (Optivar) was the most cost-effective AH/MCS, followed by generic epinastine (Elestat), brand olopatadine 0.7% (Pazeo), generic olopatadine 0.1% (Patanol), brand olopatadine 0.1% (Patanol),

brand emedastine (Emadine), brand bepotastine (Bepreve), brand alcaftadine (Lastacaft), and brand olopatadine 0.2% (Pataday).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating generic olopatadine 0.1% (Patanol), generic azelastine (Optivar), generic epinastine (Elestat), and brand olopatadine 0.7% (Pazeo) as UF, and brand emedastine (Emadine), brand bepotastine (Bepreve), brand alcaftadine (Lastacaft), and brand olopatadine 0.2% (Pataday) as NF, 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, 0 absent) the following, based on clinical and cost effectiveness:

   - **UF:**
     - olopatadine 0.1% (generic Patanol)
     - olopatadine 0.7% (Pazeo)
     - azelastine 0.05% (generic Optivar)
     - epinastine 0.05% (generic Elestat)

   - **NF:**
     - olopatadine 0.2% (Pataday)
     - alcaftadine 0.25% (Lastacaft)
     - bepotastine 1.5% (Bepreve)
     - emedastine 0.05% (Emadine)

   Note that the drugs recommended for NF status are exempt from the "NF goes to Mail" requirement, due to the acute use exception. See Appendix F.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining olopatadine 0.1% (generic Patanol) on the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the dual acting AH/MCS. All new and current users of a NF product, olopatadine 0.2% (Pataday), Lastacaft, Bepreve, and Emadine require a trial of two formulary products within the past 90 days, unless the patient has experienced intolerable adverse events from the formulary products, or is pregnant. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for olopatadine 0.2% (Pataday), Lastacaft, Bepreve, and Emadine. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 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 letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is November 1, 2017.

V. NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) ("INNOVATOR DRUGS")

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly-approved drugs reviewed at the May 2017 P&T Committee meeting, a brief summary of their clinical attributes, their formulary recommendations, and see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

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

- **UF**:
    - deflazacort (Emflaza) – Corticosteroids – Immune Modulators – for Duchenne Muscular Dystrophy (DMD)
    - deutetrabenazine (Austedo) – Neurological Agents Miscellaneous for Huntington's Disease
    - dupilumab (Dupixent) – Corticosteroids – Immune Modulators – Immune Modulators Subclass for Atopic Dermatitis
    - ribociclib (Kisqali) – Oral Oncologic Agents for Breast Cancer
    - telotristat (Xermelo) – GI-2 Miscellaneous Agents for carcinoid syndrome diarrhea

- **NF:**
    - crisaborole (Eucrisa) – Corticosteroids – Immune Modulators – Immune Modulators Subclass for Atopic Dermatitis
    - insulin degludec/liraglutide (Xultophy) – Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA)
    - morphine sulfate ER (Arymo ER) – Narcotic Analgesics and Combinations
    - oxymetazoline (Rhofade) – Acne Agents – Topical Acne and Rosacea Agents Subclass

- plecanatide (Trulance) – GI-2 Miscellaneous Agents for chronic idiopathic constipation

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for crisaborole (Eucrisa), plecanatide (Trulance), insulin degludec/liraglutide (Xultophy), morphine sulfate ER (Arymo ER), and oxymetazoline (Rhofade). See Appendix B for the full criteria.

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

- Applying the same manual PA criteria for insulin degludec/liraglutide (Xultophy) in new and current users, as is currently in place for insulin glargine/lixisenatide (Soliqua) and the other non step-preferred GLP1RAs. Patients must first try metformin or a sulfonylurea, and exenatide weekly injection (Bydureon) and albiglutide weekly injection (Tanzeum) prior to Xultophy. Additionally, for Xultophy, patients are required to be on basal insulin at a dosage of less than 50 units daily. See Appendix C for the full criteria.

- Applying the same step therapy and manual PA criteria for topical oxymetazoline (Rhofade) in new and current users as is currently in place for the non step-preferred topical rosacea products. Patients must first try one generic metronidazole step-preferred formulation and topical azelaic acid prior to Rhofade.

- Applying PA criteria to the following: new and current users of crisaborole (Eucrisa), dupilumab (Dupixent), deflazacort (Emflaza), plecanatide (Trulance), and telotristat (Xermelo); and in new users of deutetrabenazine (Austedo) and ribociclib (Kisqali). See Appendix C for the full criteria.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday after the signing of the minutes in all points of service (POS), including the new PAs for dupilumab (Dupixent), crisaborole (Eucrisa), deflazacort (Emflaza), plecanatide (Trulance), telotristat (Xermelo), liraglutide/insulin degludec (Xultophy), deutetrabenazine (Austedo), oxymetazoline (Rhofade), ribociclib (Kisqali).

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

a) **Non-Insulin Diabetes Drug: Biguanides—Metformin Extended Release (ER), Fortamet, and Glumetza Manual PA Criteria**

Fortamet and Glumetza are branded formulations of metformin ER (Glucophage XR), which were designated as NF at the November 2010 meeting, and maintained as NF in August 2016. Glumetza and Fortamet are available in 500 mg and 1000 mg tablets while generic metformin ER products are available in 500 mg and 750 mg tablets.

(1) ***COMMITTEE ACTION: FORTAMET AND GLUMETZA MANUAL PA CRITERIA***—Due to the significant cost differences between Fortamet and Glumetza and generic metformin ER, and the lack of clinically compelling benefits over generic metformin ER, the Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA in all new and current users of Glumetza and Fortamet. The patient will be required to try generic metformin ER first. Prior authorization will not expire. See Appendix C for the full criteria.

b) **Diuretics Carbonic Anhydrase Inhibitor: Dichlorphenamide (Keveyis) Manual PA Criteria**

Keveyis is an orphan drug approved for treating primary hyperkalemic or hypokalemic periodic paralysis, or related variants. The active ingredient dichlorphenamide was first marketed in 1958 under the brand name Daranide, but discontinued from the market. Keveyis was FDA-approved in August 2015, but just recently launched.

Acetazolamide (Diamox, generic) is commonly used off-label for this condition, but only one published retrospective trial is available. FDA approval for Keveyis was based on two clinical trials enrolling a total of 65 patients. The mechanism of action of Keveyis for treating periodic paralysis is unknown.

(1) ***COMMITTEE ACTION: DICHLORPHENAMIDE (KEVEYIS) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) new manual PA criteria for Keveyis, requiring a diagnosis of hypo- or hyperkalemic periodic paralysis as outlined in the product labeling, and a trial of acetazolamide. Prior authorization will expire after two months. If the patient has responded to therapy, then Keveyis will be approved indefinitely. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria**—Updates to the manual PA criteria for several drugs was recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications, or FDA safety alerts, or availability of low cost generics for NF drugs in classes with step therapy. Updated manual PA will apply to new users.

    a) **Gastrointestinal-2 Miscellaneous Agents: Eluxadoline (Viberzi)**—Viberzi was reviewed in February 2016 with manual PA criteria recommended. An update to the manual PA criteria was recommended, based on a recent FDA safety alert. Patients who have had a cholecystectomy will be excluded from using Viberzi.

    b) **Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Qudexy XR)** Qudexy XR was reviewed in May 2016 with manual PA criteria recommended. Criteria were updated to add the additional indication for migraine prophylaxis.

    c) **Non-Opioid Pain Syndromes: Pregabalin (Lyrica)**—Lyrica was reviewed in November 2011 with step therapy and manual PA criteria recommended. A trial of gabapentin is required prior to use of Lyrica, except in patients with seizure disorders. The manual PA criteria were updated to require a trial of duloxetine in addition to gabapentin for disorders not related to seizures or post-herpetic neuralgia.

    d) **Hepatitis C Virus Direct-Acting Antivirals: Ledipasvir/Sofosbuvir (Harvoni) and Sofosbuvir (Sovaldi)**—The direct-acting antivirals were most recently reviewed for formulary status in February 2017. The manual PA criteria were updated to reflect FDA approval in children 12 years of age and older.

    e) **Nasal Allergy Drugs: Fluticasone/Azelastine (Dymista)**—Dymista was reviewed in May 2014, with step therapy and manual PA criteria recommended. Currently, a trial of one step-preferred formulary nasal allergy drug (nasal formulations of generic fluticasone, flunisolide, azelastine, or ipratropium) is required prior to use of Dymista. Since the May 2014 class review, several nasal allergy drugs are now available in generic formulations, or OTC. Criteria were updated to include a trial of at least two formulary step-preferred drugs prior to use of Dymista.

    f) **Sedative Hypnotics: Newer Sedative Hypnotics—Eszopiclone (Lunesta) and Zolpidem ER (Ambien CR) Step Therapy**—Lunesta and Ambien CR were reviewed in May 2012 with the newer sedative hypnotics drug class, and both drugs are designated as UF and non step-preferred. Step therapy for the class requires a trial of a step-preferred drug (zolpidem IR or zaleplon) prior to use of non step-preferred agents. Cost-effective generic formulations of Lunesta and Ambien CR are now available.

    The step therapy criteria and manual criteria for the newer sedative hypnotics were updated to remove step therapy for eszopiclone and zolpidem ER.

Eszopiclone and zolpidem ER will be step-preferred agents in addition to zolpidem IR and zaleplon. Step therapy remains for non step-preferred agents including Rozerem, Intermezzo, Edluar, Silenor, and Zolpimist. Belsomra and Hetlioz have additional manual PA criteria. See Appendix C for the updated manual PA criteria for the class.

g) **Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq**)—The OAB drugs were most recently reviewed for formulary status in November 2012, with step therapy requiring a 12-week trial of one cost-effective generic formulation of tolterodine ER, oxybutynin ER, or trospium IR prior to use of the non step-preferred drugs. Mirabegron was reviewed as a new drug at the May 2014 meeting, and was designated as UF and non step-preferred. Since the previous P&T Committee review, several cost-effective generic formulations of other OAB drugs have entered the market.

Overactive bladder is characterized by a high placebo response rate, and benefits are seen with behavioral therapies. There do not appear to be clinically relevant differences in efficacy between mirabegron and the antimuscarinic OAB drugs, based on meta-analyses and clinical practice guidelines.

The manual PA criteria for mirabegron were updated to recommend a trial of two formulary step-preferred products first. The criteria will continue to allow patients who are at significant risk for central nervous system effects from antimuscarinic drugs to receive mirabegron. The criteria were also updated to reflect package insert cautions regarding use in patients with compromised renal function. Additionally, a trial of behavioral interventions (including pelvic floor muscle training in women and bladder training) is recommended, based on the clinical practice guidelines.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND STEP THERAPY***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Viberzi, Qudexy XR, Lyrica, Harvoni, Sovaldi, Dymista, and the step therapy changes to eszopiclone and zolpidem ER.

(2) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA***
The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) updates to the manual PA criteria for Myrbetriq, as outlined above. See Appendix C for the full criteria.

(3) ***COMMITTEE ACTION: MIRABEGRON (MYRBETRIQ) EMMPI REQUIREMENTS***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) adding mirabegron to the EMMPI list, upon signing of the minutes, consistent with the other drugs in the overactive bladder class that are in the program.

B. Quantity Limits (QLs)

1. QLs were reviewed for seven drugs: ribociclib (Kisqali) for breast cancer, niraparib (Zejula) for ovarian cancer, panobinostat (Farydak) for multiple myeloma, azelastine/ fluticasone (Dymista) for seasonal allergic rhinitis, and crisaborole (Eucrisa) and dupilumab (Dupixent) for atopic dermatitis.

    a) ***COMMITTEE ACTIONS: QLs—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for Kisqali, Zejula, Farydak, Dymista, Eucrisa, and Dupixent. 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:

    - 16 for, 0 opposed, 0 abstained, 0 absent—The new manual PAs for extended-release metformin (Fortamet, Glumetza, generics), and dichlorphenamide (Keveyis) 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 1, 2017.
    - 16 for, 0 opposed, 0 abstained, 0 absent—Updates to the current PAs for eluxadoline (Viberzi), topiramate ER (Qudexy XR), pregabalin (Lyrica), ledipasvir/sofosbuvir (Harvoni), sofosbuvir (Sovaldi), and fluticasone/azelastine (Dymista), and the step therapy changes for eszopiclone and zolpidem ER become effective upon signing of the minutes in all POS.
    - 12 for, 0 opposed, 0 abstained, 4 absent—Updates to the current PA for mirabegron (Myrbetriq) become effective upon signing of the minutes in all POS.
    - 16 for, 0 opposed, 0 abstained, 0 absent—The QLs for Kisqali, Zejula, Farydak, Dymista, Eucrisa, and Dupixent become effective upon signing of the minutes.

VII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for two product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug. Requirements for formulary status, medical necessity criteria, manual prior authorization and step therapy criteria, and quantity limits apply to line extension products.

A. *COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION*—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) clarifying the formulary status of the following two products to reflect the current formulary status, step therapy/PA criteria, and QLs for the parent compound. Implementation will occur upon signing of the minutes.

- Attention Deficit Hyperactivity Disorder Drugs—Lisdexamfetamine chewable tablet (Vyvanse chewable) as NF with the same MN criteria as Vyvanse.

- Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors—Metformin extended-release (XR)/empagliflozin (Synjardy XR) as formulary and step-preferred with the same automated PA criteria as Synjardy.
- These recommendations will become effective upon signing of the minutes.

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

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was 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 (11 for, 0 opposed, 0 abstained, 5 absent) the following product be designated NF on the UF:

- CSL Behring LLC: antihemophilic factor, recombinant single chain (Afstyla) 500 units, 1000 units, 2000 units, and 3000 units injection

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) the following pre-authorization criteria for Afstyla:

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.

Should the mail order requirement impact availability of a drug, the P&T Committee will allow an exception to the Section 703 rule. The following drug will not be available in the Mail Order:

- Afstyla (antihemophilic factor, recombinant single chain), 500 units, 1000 units, 2000 units, and 3000 units subcutaneous injection is only available in the Retail Network.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Afstyla; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is November 1, 2017.

IX. 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. See Appendix F for the mail order status of medications designated NF during the May 2017 P&T Committee Meeting.

Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")

A. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF STATUS***

The P&T Committee recommended (16 for, 0 opposed, 0 abstained 0 absent):

1. **Add:** Dupilumab (Dupixent) is suitable for mail and should be added to the EMMPI program.
2. **Do Not Add:** Deflazacort (Emflaza), telotristat (Xermelo), and deutetrabenazine (Austedo) are not feasible for mail order dispensing due to limited distribution requirements; addition of oral breast cancer agents such as ribociclib (Kisqali) to the EMMPI program should be considered at a future date.

B. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR NF STATUS***

The P&T Committee recommended (16 for, 0 opposed, 0 abstained 0 absent):

1. **Add:** Liraglutide/insulin degludec (Xultophy) and oxymetazoline (Rhofade) fall into classes that are already defined as automatic additions to the EMMPI program; the P&T Committee found no reason to exempt crisaborole (Eucrisa) or plecanatide (Trulance) from the mail order requirement.
2. **Do Not Add:** The previously established exception from the mail order requirement for C-II controlled substances applies to morphine sulfate ER tablets (Arymo ER).

X. RE-EVALUATION OF NF GENERICS

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 three previously reviewed UF drug classes: the second generation antihistamines, the antidepressants, and the testosterone replacement therapies.

Clinical Effectiveness Conclusion and Cost-Effectiveness Conclusion—The P&T Committee concluded that for all three drug classes, there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusions from when the classes were originally reviewed for UF placement. Specific comments, including the results of comparative cost reviews, are below:

- *Second Generation Antihistamines: Levocetirizine (Xyzal) and Desloratadine (Clarinex)*—Levocetirizine and desloratadine continue to offer no significant, therapeutically meaningful advantages over other similar agents on the UF. While unit costs for generic versions of levocetirizine and desloratadine have dropped considerably, they remain substantially more costly than OTC loratadine and OTC cetirizine, without offering any additional advantage. In addition, the impact of the recent approval of the OTC version of levocetirizine (Xyzal Allergy 24HR) is yet unknown.

- *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 capsules have been withdrawn, and are now available only as tablets; there appears to be at least one A-rated generic equivalent to Sarafem tablets. Both brand and generic Sarafem tablets, as well as brand and generic versions of Prozac Weekly, remain substantially more costly than generic fluoxetine capsules, which are available from multiple generic manufacturers at very low cost. Specific A-ratings for the generic fluoxetine capsules (i.e., to the discontinued Sarafem product vs. Prozac) are difficult to track operationally, but the vast majority of utilization across all POS is for the lowest cost generic fluoxetine capsules.

- *Testosterone Replacement Therapy (TRT):* This class was last reviewed in August of 2012, and the P&T Committee agreed there are no clinically relevant differences in efficacy or safety among available products, since they all contain testosterone. Fortesta (testosterone gel) was designated as UF and the sole step-preferred product. Androgel 1% and 1.62% gel were designated as NF and non step-preferred. As of May 2017, a number of the TRT products have become generically available, including Fortesta, Testim, Androgel 1% gel, and Androgel 1.62% gel. However, only generic Androgel 1% is now comparable to Fortesta in terms of weighted average cost across points of service and less costly than Fortesta at MTFs.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended the following, effective upon signing of the minutes:

1. The following products will remain NF, with both brand and generics subjected to mail order requirements:

    - (14 for, 1 opposed, 1 abstained, 0 absent)—*Second Generation Antihistamines:* levocetirizine (Xyzal, generics) and desloratadine (Clarinex, generics)
    - (16 for, 0 opposed, 0 abstained, 0 absent)—*Selective Serotonin Reuptake Inhibitors:* fluoxetine delayed release 90 mg (Prozac Weekly); Sarafem tablets and generic equivalents

2. The following will be returned to UF status and is no longer subject to the mail order requirement (since no brand agent currently exists):

    - (16 for, 0 opposed, 0 abstained, 0 absent)—*Selective Serotonin Reuptake Inhibitors:* all fluoxetine capsules currently designated as NF

3. The following agent will be returned to UF status and designated as step-preferred, with appropriate changes made to PA criteria to require an unsuccessful trial, contraindication, or intolerance to either Fortesta or generic Androgel 1% before receiving a non-preferred product. The brand product, but not the generic, remains on the EMMPI list.

    - (16 for, 0 opposed, 0 abstained, 0 absent)—*Testosterone Replacement Therapy:* Generic Androgel 1% gel

XI. UF SUB-WORKING GROUP UPDATE: ALIGNING OTC FORMULARIES

The P&T Committee was briefed on a plan by the UF Sub-Working Group, comprised of representatives from all the Services, regarding OTC drug dispensing at the MTFs. Currently, individual MTFs dispense a wide variety of OTC medications as determined by the local MTF. A transition to a more uniform list of OTC products available across MTFs, and ultimately across the pharmacy benefit is recommended. A phased approach to standardize OTC use across the MTFs is recommended. The Committee reviewed an initial OTC test list (based on historic usage across the system) to assess technical and other aspects of MTF coverage of OTC products under MHS Genesis. Phase one includes technical testing, phase two standardization of the MTFs and phase three standardization of all three points of service.

A. ***COMMITTEE ACTION*****—**The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the initial testing list of OTC products and the phased approach to standardization.

XII. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS

Management of the TRICARE pharmacy benefit requires a wide variety of actions, with various levels of involvement of the DoD P&T Committee, the Beneficiary Advisory Panel (BAP), and the Director, DHA. In May 2005 when the UF Rule was implemented, the P&T Committee developed a comprehensive list of the functions associated with formulary management and categorized each into one of three decision pathways, depending on the level of involvement required. Since May 2005, several new regulatory authorities have expanded the responsibilities of the P&T Committee, resulting in increasing complexity of the TRICARE pharmacy benefit, and the need for quick determination of issues.

The Committee reviewed an updated list of previously approved functions/actions since 2005 to manage the benefit. Operations are categorized according to the following processes: administrative functions (day-to-day maintenance not requiring DoD P&T Committee review); formulary recommendations requiring DoD P&T Committee review and approval by the Director, DHA; and formulary changes requiring DoD P&T Committee review and approval of the Committee's recommendations by the Director, DHA, after considering comments from the Beneficiary Advisory Panel (BAP). The updated list of functions is found in Appendix G.

XIII. ITEMS FOR INFORMATION

A. DEPLOYMENT DISPENSING

The Committee was briefed on the role of the DHA Pharmacy Operations Division in deployment dispensing. The Committee evaluated medications dispensed prior to deployment, as well as in-theater, and discussed the limitations of the data presented.

B. VETERANS AFFAIRS (VA) CONTINUITY OF CARE DRUG LIST

The P&T Committee was briefed on the updated DoD/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. Additions, deletions, and clarifications to the list were based on FY16 Active Duty prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The updated list will now go to the VA for review and will be posted on www.health.mil when finalized.

XIV. ADJOURNMENT

The meeting adjourned at 1230 hours on May 11, 2017. The next meeting will be in August 2017.

Appendix A—Attendance: May 2017 DoD 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 Formulary Recommendations for Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as Innovator Drugs)

Appendix F—Mail Order Status of Medications Designated Nonformulary During the May 2017 DoD P&T Committee Meeting

Appendix G—Pharmacy and Therapeutics Committee Processes and Recommendations/ Approval Authorities

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

Appendix I—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☐ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

RADM Colin Chinn, MC, USN
Acting Deputy Director, DHA
for R.C. Bono, VADM, MC, USN,
Director

7/27/17
Date

Appendix A—Attendance: May 2017 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Edward Norton, MSC	Acting Chief of DHA Pharmacy Operations Division
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
Col William Hannah, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Austin Parker, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
CAPT Shaun Carstairs, MC	Navy, Physician at Large
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
MAJ John Poulin, MC	Army, Physician at Large
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Lt Col Rodney Jorstad, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Doreen Lounsbery, COL (Ret.), MC, USA	TRICARE Regional Office-South, Medical Director
Voting Members Absent	
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Ms. Jennifer Zacher for Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
Ms. Leigh Bradley (SES)	General Counsel, DHA
LCDR Ebenezer Aniagyei via telephone	Defense Logistics Agency Troop Support
Dean Valibhai, PharmD, MBA, via telephone	DHA Purchased Care Branch
Guests	
COL Alfonso S. Alarcon, MD	Director, TRICARE Area Office Latin America & Canada
Mr. Jason Wray	Defense Logistics Agency Troop Support
Capt Kevin Bourne	Defense Logistics Agency Troop Support
Mr. Dwight Bonham	DHA Contract Operations Division
Mr. Bruce Mitterer	DHA Contract Operations Division
Mr. Evan Zaslow	DHA Contract Operations Division
Mr. James Berns	DHA Contract Operations Division

Appendix A—Attendance (continued)

Guests	
CAPT Matt Baker	Indian Health Service
Scott Holuby, PharmD, BCPS	Brooke Army Medical Center
Maj Shaoping Sumner	Air Force Pharmacy Resident
Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, DHA Formulary Management Branch
CAPT Walter Downs, 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
LCDR Christina Andrade	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
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS, via telephone	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
David Meade, PharmD via telephone	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via telephone	DHA Integrated Utilization Branch

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• alcaftadine (Lastacaft) • bepotastine (Bepreve) • emedastine (Emadine) • olopatadine 0.2% (Pataday) **Ophthalmic-1s: AH/MCS**	• Use of all formulary agents has resulted in therapeutic failure • No alternative formulary agent. Applies for Lastacaft and Emadine when the patient is pregnant and requires a Pregnancy Category B medication. **Formulary Alternatives:** azelastine, epinastine, olopatadine 0.1%, and olopatadine 0.7% (Pazeo)
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	• Use of formulary agents are contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agent has resulted in therapeutic failure **Formulary Alternatives:** high potency (Class 1) topical corticosteroids (various)
• liraglutide/insulin degludec (Xultophy) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Use of formulary agents (both GLP1RAs Bydureon and Tanzeum AND insulin glargine) has resulted in therapeutic failure **Formulary Alternatives:** exenatide once weekly (Bydureon), albiglutide (Tanzeum), and insulin glargine (Lantus)
• morphine sulfate ER (Arymo ER) **Narcotic Analgesics: Long-Acting High Potency Narcotic Analgesics**	• Patient has had therapeutic failure of at least two formulary long acting narcotic analgesics. **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)
• oxymetazoline (Rhofade) **Topical Acne and Rosacea Agents: Miscellaneous Topical Agents**	• Use of metronidazole and azelaic acid are contraindicated • Patient has tried and failed metronidazole and azelaic acid • Patient has experienced significant adverse effects from metronidazole and azelaic acid **Formulary Alternatives:** metronidazole (metronidazole (1% gel; 0.75% lotion, and 0.75% cream) and azelaic acid 15%
• plecanatide (Trulance) **GI-2 Miscellaneous Drugs**	• Use of linaclotide resulted in therapeutic failure **Formulary Alternative:** linaclotide (Linzess)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• nintedanib (Ofev) **Pulmonary 1-s: Pulmonary Miscellaneous Subclass**	**Changes from the May 2017 meeting are in BOLD** **All new users of nintedanib (Ofev) are required to try pirfenidone (Esbriet) first.** Manual PA criteria: **Pirfenidone (Esbriet) is the preferred IPF agent; coverage is approved for nintedanib (Ofev) if the following:** • **The patient has had a trial of pirfenidone (Esbriet) and either:** o **Failed therapy with Esbriet due to progression of IPF, e.g. improvement or effectiveness of therapy is defined by a less than 10% decline in percent predicted forced vital capacity (FVC) OR** o **Experienced intolerable adverse effects (e.g., rash, photosensitivity; GI AEs) OR** • **The patient has clinical factors where Esbriet is not appropriate** o **The patient is taking a drug which will interact with Esbriet that does not interact with Ofev [moderate to strong CYP inhibitors – CYP 450-1A2 (e.g., fluvoxamine)] OR** o **The patient has end stage renal disease (ESRD) on dialysis** AND Coverage approved for patients with the following: • The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND • The patient is being actively managed by a pulmonologist, AND • The patient is not currently receiving pirfenidone (Esbriet) with nintedanib (Ofev) concomitantly. Dual therapy is not allowed (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa). PA expires after 1 year. • PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Ofev will be approved if there has been a significant reduction in the annual rate of decline of FVC. • Renewal PA criteria is limited to one year.
• pirfenidone (Esbriet) **Pulmonary 1-s: Pulmonary Miscellaneous Subclass**	**Changes from the May 2017 meeting are in BOLD** Manual PA criteria will **continue to** apply to all new users of pirfenidone (Esbriet) Manual PA Criteria: Coverage approved for patients: • The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND • The patient is being actively managed by a pulmonologist, AND • The patient is not currently receiving pirfenidone (Esbriet) with nintedanib (Ofev) concomitantly. Dual therapy is not allowed (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa). PA expires after one year. • PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Esbriet will be approved if there has been a significant reduction in the annual rate of decline of FVC. • Renewal PA criteria is limited to one year.

Drug / Drug Class	Prior Authorization Criteria
• alcaftadine (Lastacaft) alcaftadine (Lastacaft) • bepotastine (Bepreve) • emedastine (Emadine) • olopatadine 0.1% (Pataday) **Ophthalmic 1-s: AH/MCS**	Manual PA criteria apply to all new and current users of Lastacaft, Bepreve, Emadine, and olopatadine 0.2% (Pataday). • The patient has ocular symptoms of allergic conjunctivitis AND o The patient has tried and failed two formulary alternatives (olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine) in the last 90 days, OR o Use of two formulary alternatives (olopatadine, azelastine, or epinastine) has resulted in intolerable adverse effects, OR o The patient is pregnant (for Lastacaft and Emadine only) PA does not expire.
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	Manual PA criteria apply to all new and current users of Eucrisa. Manual PA Criteria: coverage will be approved if: • Patient has mild to moderate atopic dermatitis AND • Prescribed by a dermatologist AND • Patient has a contraindication to, intolerability to, or failed treatment with at least one high potency / class 1 topical corticosteroid. Off-label uses are NOT approved. PA does not expire.
• dupilumab (Dupixent) **Corticosteroids – Immune Modulators – Immune Modulators subclass**	Manual PA criteria apply to all new and current users of Dupixent. Manual PA Criteria: coverage will be approved for initial therapy for 6 months if: • Patient has moderate to severe or uncontrolled atopic dermatitis AND • Patient must be 18 years of age or older AND • Prescribed by a dermatologist AND • Patient has a contraindication to, intolerability to, or failed treatment with at least **ONE** high potency / class 1 topical corticosteroid AND • Patient has a contraindication, intolerability to, or failed treatment with at least **ONE** systemic immunosuppressant. PA expires after 6 months. Renewal PA Criteria: coverage will be approved indefinitely for continuation of therapy if: 1. The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1) Off-label uses are NOT approved.
• deflazacort (Emflaza) **Corticosteroids – Immune Modulators**	Manual PA criteria apply to all new and current users of Emflaza. Manual PA Criteria: coverage will be approved indefinitely if all criteria are met: 1. Patient has a diagnosis of Duchenne Muscular Dystrophy AND 2. Prescribed by a neurologist AND 3. Patient is age 5 or older AND 4. Patient has tried prednisone for at least 6 months and has experienced at least one of the following adverse events: • Unmanageable weight gain OR • Patient has experienced severe behavioral adverse events s that requires a reduction in prednisone dose Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• plecanatide (Trulance) **GI-2 Miscellaneous Drugs**	Manual PA criteria apply to all new and current users of Trulance. Manual PA Criteria: Coverage approved if: 1. Patient is ≥ 18 years of age AND 2. Patient has clinically diagnosed chronic idiopathic constipation AND 3. Patient does not have gastrointestinal obstruction AND 4. Patient has failed or is intolerant to linaclotide (Linzess) AND 5. Dual therapy with another guanylate cyclase-C agonist is not allowed. Off-label uses are not approved. PA expires in one year. • PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Trulance will be approved if there has been improvement in constipation symptoms and NO dual therapy with another guanylate cyclase-C agonist. Renewal PA criteria is limited to one year.
• telotristat (Xermelo) **GI-2 Miscellaneous Drugs**	Manual PA criteria apply to all new and current users of Xermelo. Manual PA Criteria: Coverage approved for one year if all criteria are met: 1. Patient has diagnosis of carcinoid syndrome diarrhea. 2. Patient has had an inadequate treatment response to at least a 3-month trial of somatostatin analog therapy. 3. Telotristat must be used in combination with a somatostatin analog (i.e., octreotide or lanreotide). 4. Patient has ≥ 4 bowel movements daily. Off-label uses are NOT approved. PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Xermelo will be approved when a) used in combination with an somatostatin analog b) decrease from baseline in amount of average daily bowel movements, c) prescriber agrees to continue to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops, d) no severe constipation or abdominal pain develops. • Renewal PA criteria is limited to one year.
• liraglutide/insulin degludec (Xultophy) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new and current users of Xultophy are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin or a sulfonylurea first. Additionally, Bydureon and Tanzeum are the preferred agents in the GLP1RA Subclass. New and current users of Xultophy must try Bydureon and Tanzeum first. Manual PA Criteria: Coverage will be approved if the following criteria are met: • Xultophy is used as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus inadequately controlled on a basal insulin (< 50 units daily) • Patient has tried and failed therapy with metformin or sulfonylurea AND • The patient has had an inadequate response to Bydureon AND • The patient has had an inadequate response to Tanzeum. Prior Authorization does not expire. Off-label uses are not approved.

Drug / Drug Class	Prior Authorization Criteria
• deutetrabenazine (Austedo) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Austedo. Manual PA Criteria: Coverage approved for initial therapy for one year if all criteria are met: 1. Prescribed by or in consultation with a neurologist 2. Patient has a diagnosis of chorea associated with Huntington's Disease 3. Patient is not actively suicidal 4. Patient does not have depression, or is being adequately treated for depression 5. Patient does not have severe hepatic impairment 6. Patient is not taking any of the following: • MAOI inhibitor within the past 14 days • reserpine • tetrabenazine (Xenazine) or another VMAT-2 inhibitor 7. Patient has had an adequate trial of tetrabenazine for 12 weeks and had one of the following: • Experienced treatment failure • Experienced an adverse event that is not expected to occur with Austedo PA expires in one year. Manual PA Criteria (Renewal criteria: Coverage approved indefinitely for continuation of therapy if all criteria are met: 1. Patient has demonstrated improvement in chorea based on clinician assessment and is being monitored for depression and suicidal ideation Off-label uses are NOT approved (Tourette's, tardive dyskinesia, dystonia).
• oxymetazoline (Rhofade) **Topical Acne and Rosacea Agents: Miscellaneous Topical Agents**	All new and current users of Rhofade 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, Rhofade will be approved if: • Patient is at least 18 years of age and has the following diagnosis: o For **Rhofade**: patient has persistent facial erythema of rosacea **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 15%. PA expires in one year. Off-label uses are not approved.
• ribociclib (Kisqali) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Kisqali. Manual PA criteria: Kisqali is approved if: 1. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND 2. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND 3. The patient is a postmenopausal woman and Kisqali will be used as first-line endocrine therapy in combination with an aromatase inhibitor. Off-label uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• topiramate ER (Qudexy XR) **Anticonvulsant and Anti-Mania**	**Changes from May 2017 meeting are in BOLD and strikethrough** Manual PA criteria apply to all new users of 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). o **Migraine prophylaxis in adults (**Trokendi XR and **Qudexy 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.
• metformin extended-release (Fortamet and Glumetza) **Non-Insulin Diabetes Drugs: Biguanides**	Manual PA criteria apply to all new and current users of Fortamet and Glumetza. The provider must explain why the patient cannot take two generic 500mg ER tablets separately (for patients taking requiring 1000 mg metformin ER). PA will be approved if patient is on a dose-alternating schedule (e.g., 500 mg alternating with 1000 mg every other day). PA does not expire. Off-label uses are not approved.
• dichlorphenamide (Keveyis) **Diuretics: Carbonic Anhydrase Inhibitors**	Manual PA criteria apply to all new and current users of Keveyis. Manual PA criteria: Keveyis is approved for 2 months for initial therapy if: **Hypo/Hyperkalemic Periodic Paralysis (HypoPP/HyperPP) and Related Variants.** Initial Therapy. Approve for 2 months if the patient meets the following criteria (i, ii, iii, iv, and v): i. Patient has a confirmed diagnosis of primary hypokalemic or hyperkalemic periodic paralysis by meeting at least ONE of the following (a, b, or c): a) Patient with HypoPP has had a serum potassium concentration of less than 3.5 mEq/L during a paralytic attack; OR for patient with HyperPP, patient has had an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack; OR for patient with HyperPP, patient has had a serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L; OR b) Patient has a family history of the condition; OR c) Patient has a genetically confirmed skeletal muscle calcium or sodium channel mutation; AND ii. Patient has had improvements in paralysis attack symptoms with potassium intake; AND iii. Patient has tried and failed oral acetazolamide therapy (e.g., Diamox tablets, Diamox Sequels extended-release capsules, generics); AND iv. According to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient; AND v. Keveyis is prescribed by or in consultation with a neurologist or a physician who specializes in the care of patients with primary periodic paralysis (e.g., muscle

Drug / Drug Class	Prior Authorization Criteria
	disease specialist, or Physical Medicine and Rehabilitation [PMNR]). PA expires after two months. Renewal Manual PA criteria: Keveyis is approved indefinitely for continuation of therapy if: **Hypo/Hyperkalemic Periodic Paralysis (HypoPP/HyperPP) and Related Variants** • Patients Continuing Therapy. Approve indefinitely if the patient has responded to Keveyis (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician. Off-label uses are not approved.
• eluxadoline (Viberzi) **GI-2 Miscellaneous Drugs**	**Changes from May 2017 meeting are in BOLD** Manual PA criteria apply to all new users of eluxadoline (Viberzi). 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 a history of cholecystectomy. 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.
• pregabalin (Lyrica) **Antidepressants and Non-Opioid Pain Syndrome Agents**	**Changes from May 2017 meeting are in BOLD and will apply to new users of Lyrica.** Manual PA Criteria: coverage will be approved if: • Indication: Seizure disorder **and post-herpetic neuralgia** o The patient has a contraindication to gabapentin that is not expected to occur with pregabalin (Lyrica) o The patient experienced adverse events with gabapentin that are not expected to occur with Lyrica o The patient previously responded to Lyrica and changing to gabapentin would incur unacceptable risk OR • **Indication: Non-seizure related disorder (diabetic peripheral neuropathy and fibromyalgia)** o The patient has tried and failed gabapentin therapy (trial of Gralise or Horizant does not qualify) **AND** o **Patient has tried and failed duloxetine** OR o The patient has a contraindication to gabapentin or **duloxetine** that is not expected to occur with pregabalin OR

Drug / Drug Class	Prior Authorization Criteria
	o The patient experienced adverse events with gabapentin or **duloxetine** that are not expected to occur with pregabalin OR o The patient previously responded to pregabalin and changing to gabapentin or **duloxetine** would incur unacceptable risk PA does not expire.
• ledipasvir / sofosbuvir (Harvoni) **Hepatitis C Virus: Direct Acting Antivirals (HCV DAA)**	**Changes from May 2017 meeting are in BOLD** Coverage approved for patients **≥ 12 years** with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 4, 5, or 6 • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) HCV guidelines. PA expires after one year.
• sofosbuvir (Sovaldi) **Hepatitis C Virus: Direct Acting Antivirals (HCV DAA)**	**Changes from May 2017 meeting are in BOLD** <u>Manual PA criteria</u>: Ledipasvir / sofosbuvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir (Sovaldi) if : • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with the requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • The patient has experienced or is likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or GT3) AND Coverage approved for patients **≥ 12 years** with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 2, 3, or 4 • Used in combination with another HCV DAA (not used as monotherapy) • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) HCV guidelines. PA expires after one year.

Drug / Drug Class	Prior Authorization Criteria
• fluticasone/azelastine (Dymista) **Nasal Allergy Drugs**	**Changes from May 2017 meeting are in BOLD** Manual PA criteria apply to all new users of Dymista who are older than 4 years of age. Automated PA criteria: The patient has filled a prescription for azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Dymista is approved (e.g., trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is NOT required) if: • Patient has experienced any of the following issues with **at least two** of the following step-preferred nasal allergy drugs (fluticasone propionate, flunisolide, azelastine 137 mg, or ipratropium), which is not expected to occur with the non-preferred nasal allergy drugs: o inadequate response to the step-preferred drugs o intolerable adverse effects (persistent epistaxis, significant nasal irritation, pharyngitis) o contraindication
• eszopiclone (Lunesta) and zolpidem ER (Ambien CR) **Newer Sedative Hypnotics**	**Changes from May 2017 meeting are in BOLD** Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria: Coverage is approved if: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR, zaleplon, **zolpidem ER, or eszopiclone**. • Step-preferred agents include: zolpidem IR, zaleplon, zolpidem ER, and eszopiclone • Non step-preferred agents include: ramelteon (Rozerem), zolpidem SL (Edluar and Intermezzo), zolpidem spray (Zolpimist), doxepin (Silenor), suvorexant (Belsomra), and tasimelteon (Hetlioz) • Suvorexant (Belsomra) and tasimelteon (Hetlioz) have additional manual PA criteria PA applies to new users. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• mirabegron (Myrbetriq) **Overactive Bladder (OAB) Drugs**	**Changes from May 2017 meeting are in BOLD** Updated PA criteria apply to all new users of Myrbetriq <u>Automated PA criteria</u>: • The patient has filled a prescription for tolterodine ER (Detrol LA), oxybutynin ER, oxybutynin IR, or generic trospium IR (Sanctura) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. <u>Manual PA criteria</u>—If automated criteria are not met, Myrbetriq is approved if: 1. Patient has confirmed diagnosis of OAB with symptoms of urge incontinence, urgency, and urinary frequency **AND** 2. **Patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, AND** 3. Patient has had a 12-week trial with **2** formulary step-preferred products and had therapeutic failure **OR** 4. Patient has experienced central nervous system AEs with oral OAB medications **OR** is at increased risk for such central nervous system effects due to comorbid conditions or other medications, **AND** 5. **Patient does not have a CrCl < 15 mL/min OR** 6. **If CrCl 15-29 mL/min, dosage does not exceed 25 mg QD** PA does not expire.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• pirfenidone (Esbriet) **Pulmonary 1-s Pulmonary Miscellaneous Subclass**	▪ Retail Network, Mail Order, and MTF: 267 mg caps, #270 capsules (30-day supply)
• nintedanib (Ofev) **Pulmonary 1-s Pulmonary Miscellaneous Subclass**	▪ Retail Network, Mail Order, and MTF: 100 and 150 mg capsules, #60 caps (30-day supply)
• Ribociclib (Kisqali) **Oral Oncologic Drugs**	▪ Retail: 28 days supply ▪ MTF/Mail: 56 days supply
• Panobinostat (Farydak) **Oral Oncologic Drugs**	▪ Retail: 6 capsules in 28 days ▪ MTF/Mail: 12 capsules in 56 days
• Niraparib (Zejula) **Oral Oncologic Drugs**	▪ Retail: 90 capsules in 30 days ▪ MTF/Mail: 180 capsules in 60 days
• Fluticasone/azelastine (Dymista) **Nasal Allergy Drugs**	▪ Retail: #1 inhaler in 30 days ▪ MTF/Mail: #3 inhalers in 90 days
• Dupilumab (Dupixent) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	▪ Retail: 28 days supply ▪ MTF/Mail: 56 days supply
• Crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	▪ Retail: 120gm (2 tubes) in 28 days ▪ MTF/Mail: 240gm (4 tubes) in 56 days

Appendix E—Formulary Recommendations for Newly-Approved Drugs Per 32 CFR 199.21(g)(5) (formerly known as Innovator Drugs)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Crisaborole (Eucrisa)	Corticosteroids – Immune Modulators – Immune Modulators Subclass	• Topical Steroids • Tacrolimus 0.3% ointment • Elidel 1% cream	Atopic Dermatitis (AD) – mild to moderate	• Unique mechanism of action (MOA): topical boron containing molecule that selectively inhibits PDE-4 in target cells • 2 short-term pivotal trials: 28-day & no active comparator – Slightly more patients achieved a response than placebo following short-term Rx (32.2% vs. 22.0%) – Relative efficacy compared with more established therapies is unknown • Eucrisa is a therapeutic alternative among the available topical therapies for mild-moderate AD, notably topical corticosteroids and topical calcineurin inhibitors	• NF • Add to mail list
Deflazacort (Emflaza)	Corticosteroids – Immune Modulators	• Prednisone	Duchenne muscular dystrophy (DMD) in patients 5 years of age and older	• Corticosteroid prodrug indicated for Duchenne muscular dystrophy in patients age 5 years and older • First oral agent approved for DMD • Dosing at 0.9 mg/kg/day showed statistical significance compared to prednisone at 52 weeks in improvement of muscle strength and motor function • Due to only slight increases in muscle strength over prednisone, clinical significance is unclear • Better tolerated and resulted in less weight gain and psychiatric AEs compared to prednisone • Two-fold higher risk of cataract development over 52-week period • First oral agent with DMD indication, but uncertain place in therapy; provides another option to patients with DMD over prednisone	• UF • Exempt from mail
Deutetra-benazine (Austedo)	Neurological Agents Miscellaneous	• tetrabenazine (Xenazine) • neuroleptics	Chorea associated with Huntington's disease (HD)	• Vesicular monoamine transporter 2 (VMAT2) inhibitor results in decreased reuptake and availability of dopamine, which reduces chorea; some serotonin and norepinephrine depletion • 1st "deuterated" product approved by FDA • Deuterium (heavy hydrogen isotope) substituted for two molecules; proposed to have a longer t ½ and have less variable plasma levels than tetrabenazine • 2nd drug FDA-approved for HD chorea • Do not use concurrently with tetrabenazine (Xenazine) • Only improves the motor dysfunction part of the disease • Likely similar efficacy as tetrabenazine, with decreased dosing frequency and AEs.	• UF • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Dupilumab (Dupixent)	Corticosteroids – Immune Modulators – Immune Modulators Subclass	• Topical Steroids • Tacrolimus 0.3% oint • Elidel 1% cream • Prednisone • Cyclosporine • Azathioprine • Methotrexate	Atopic Dermatitis (AD) – moderate to severe	• Unique MOA: IL-4RA monoclonal antibody inhibiting IL-4 & IL-13 • 3 pivotal trials: 16 to 52 weeks & no active comparator – More patients achieved a response than placebo (38% vs. 10%) – Relative efficacy compared with more established therapies is unknown • First SC agent approved for AD • Indicated for carefully selected adult patients with mod-severe AD who are inadequately treated with other modalities or pharmacologic therapies	• UF • Add to mail list
Insulin degludec/ liraglutide (Xultophy)	GLP1RA	• Bydureon • Tanzeum • Victoza • Lantus • Tresiba • Soliqua	Adjunct to diet and exercise in adults with T2DM not controlled on basal insulin ≤ 50 units daily or liraglutide ≤ 1.8 mg daily	• Xultophy is one of two available basal insulin/GLP1RA combinations • Statistically and clinically significant in lowering A1c compared to the individual components • Addition of liraglutide to insulin may mitigate the expected weight gain • Limitations to use: fixed dose, difficult to titrate insulin • Should not be used in treatment naïve patients; patients must be on one of the individual components separately first, before using the combination agent • Xultophy offers the patient convenience of a fixed-dose combination; however, there are no additional compelling advantages over existing UF agents	• NF and non step-preferred • Add to mail list
Morphine sulfate (Arymo ER)	Narcotic Analgesics & Combinations	• Morphine/naltrexone (Embeda) • Morphine ER (MS Contin)	Pain severe enough to require daily, around-the-clock, long-term opioid therapy and where alternative tx options are inadequate	• 2nd FDA approved abuse deterrent long-acting morphine formulation, and the first morphine product using a physical/chemical barrier • Clinical Practice Guidelines do not recommend for or against abuse deterrent agents • Several UF alternatives are available for individuals who need a long-acting narcotic analgesic	• NF • Exempt from mail
Oxymetaz-oline (Rhofade)	Acne Agents: Topical Acne and Rosacea Agents Subclass	• metronidazole (MetroGel, MetroCream, MetroLotion) • azelaic acid (Finacea) • brimonidine (Mirvaso)	Topical treatment of persistent facial erythema associated with rosacea in adults	• Topical oxymetazoline formulation for rosacea • Minimal improvement of persistent erythema over vehicle-arm, with significant cost • Step therapy exists in the topical acne/rosacea class; all patients must try step-preferred agent(s): metronidazole gel, cream or lotion • No compelling advantage over existing UF agents	• NF and non step-preferred • Add to mail list

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Plecanatide (Trulance)	GI-2 Misc Agents	• Linaclotide (Linzess)	Chronic idiopathic constipation (CIC)	• 2nd available guanylate cyclase-C agonist indicated for chronic idiopathic constipation • Studied in 2 placebo controlled trials of 12 weeks duration • Response rate for plecanatide (21%) compared to placebo (10%) • Study limitations: significant placebo effect, lack of head-to-head trials, and unknown long-term safety • Similar efficacy and safety profile to linaclotide • May be taken without regard to food • Plecanatide has no compelling advantage over current formulary agents	• NF • Add to mail list
Ribociclib (Kisqali)	Oral Oncologic Agents	• Palbociclib (Ibrance)	Breast Cancer	• NCCN guidelines find Category 1 evidence to support use of ribociclib in combination with letrozole, similar to the available alternative, palbociclib (Ibrance) • While improvement in progression free survival (PFS) was shown in the pivotal study, extensive experience with palbociclib and lack of head-to-head data may limit utilization of ribociclib • Under investigation for additional breast cancer indications • 2nd CDK4/6 inhibitor option for HR+/HER2- endocrine-based therapy for advanced breast cancer, with similar safety profile	• UF • Exempt from mail
Telotristat (Xermelo)	GI-2 Misc Agents	• No similar agent	Carcinoid syndrome diarrhea	• Indicated for carcinoid syndrome diarrhea in adults • Approved for patients inadequately controlled on somatostatin analog (SSA) therapy alone • Novel MOA; inhibits tryptophan hydroxylase • Results from one phase III trial showed a decrease of 1.7 bowel movements (BM)/day over a 12-week period with telotristat compared to placebo (0.9 BM per day) • Response rate: 44% of pts with telotristat vs.20% of pts with placebo • Most common AEs: nausea, headache, & depression • Offers another option to patients with carcinoid syndrome diarrhea in users who are inadequately controlled on a somatostatin analog	• UF • Exempt from mail

Appendix F—Mail Order Status of Medications Designated Nonformulary During the May 2017 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
May 2017	**IPF Agents** ▪ pirfenidone (Esbriet) ▪ nintedanib (Ofev) **Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")** ▪ dupilumab (Dupixent) ▪ insulin degludec/liraglutide (Xultophy) ▪ oxymetazoline (Rhofade) ▪ crisaborole (Eucrisa) ▪ plecanatide (Trulance)	**Ophthalmic-1 Antihistamine/Mast Cell Stabilizers** Acute use exception applies ▪ alcaftadine (Lastacaft) ▪ bepotastine (Bepreve) ▪ emadastine (Emadine) ▪ olopatadine 0.2% (Pataday) **Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")** Limited distribution exception applies ▪ deflazacort (Emflaza) ▪ deutetrabenazine (Austedo) ▪ telotristat (Xermelo) CII controlled substances exception applies ▪ morphine sulfate ER tablets (Arymo ER) ▪ addition of oral breast cancer agents such as ribociclib (Kisqali) to the EMMPI program should be considered at a future date

Appendix G—Pharmacy and Therapeutics Processes and Recommendations/Approval Authorities

Process	Function
Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed-dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits (QLs). The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to QLs as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing adjudication edit limitations (Pharmacy Data Transaction Service [PDTS]), which are set well above the clinical maximum and are intended to prevent entry errors (e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler) or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. The PA criteria will be reviewed by the DoD P&T Committee at the next meeting. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non step preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to PA forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, QLs and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator drugs”), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015, with no formulary alternatives to adjudicate as Uniform Formulary (Tier 2 copayment), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly-approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes.

	▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be "grandfathered" when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative (EMMPI). ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Agreements Act (TAA) conflicts preclude purchase for use by the Mail Order Pharmacy, for products that will be discontinued from the market, or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative from the requirement for Mail Order Pharmacy dispensing in cases where Trade Agreements Act conflicts preclude purchase for use by the Mail Order Pharmacy, for products that will be discontinued from the market, or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing "brand over generic" authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. The branded product will adjudicate at the Tier 1 copayment at the Retail Pharmacy Network and Mail Order Pharmacy. The "brand over generic" authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating "line extension" products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug, and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug; for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents.

	▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., Handi-Haler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding forTPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA www.health.mil website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of PA criteria, and implementation plan (including effective date). ▪ Changes to existing PA criteria (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the UF, and designating products recommended for a copayment waiver. ▪ Removal of copayments or reducing copayments for an individual drug (e.g., branded product available at the Tier 1 copayment). ▪ Designating individual generic drugs as nonformulary (Tier 3 copayment).

Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)	▪ Establishment of QLs for a medication or class of medications, deletion of existing QLs, or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs. ▪ Addition or deletion of medications listed on the BCF or ECF. ▪ Addition or deletion of drugs or drug classes on the Expanded MFT/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes from the Mail Order Pharmacy auto-refill program. ▪ Exempting NF medications from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.

Appendix H—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 2017	**Pulmonary-1 Agents – Pulmonary Miscellaneous Subclass**	UF subclass review	▪ Basic Core Formulary: No IPF drug selected Pulmonary-1 drugs on the BCF include ▪ salmeterol oral inhaler (Serevent) ▪ fluticasone oral inhaler (Flovent) ▪ salmeterol / fluticasone oral inhaler (Advair)	**UF Step-Preferred** ▪ pirfenidone (Esbriet) **UF Non Step-Preferred** ▪ nintedanib (Ofev)	▪ None	Pending signing of the minutes / 30 days The effective date is August 30, 2017	▪ Manual PA required ▪ QLs apply; 30-day supply	▪ Must try Esbriet first in all new users before Ofev See Appendix C.
May 2017	**Ophthalmic-1 – Antihistamine and Dual Acting Antihistamine/ Mast Cell (AH/MCS) Stabilizers Subclass**	UF subclass; previously reviewed August 2010	▪ olopatadine 0.1% (Patanol generic)	▪ olopatadine 0.7% (Pazeo) ▪ azelastine 0.05% (Optivar generic) ▪ epinastine 0.05% (Elestat generic)	▪alcaftadine 0.25% (Lastacaft) ▪bepotastine 1.5% (Bepreve) ▪emedastine 0.05% (Emadine) ▪olopatadine 0.2% (Pataday)	Pending signing of the minutes / 90 days The effective date is November 1, 2017.	▪ Manual PA applies to the subclass	▪ Note: Patanol moves to NF status, and Pazeo moves to UF status ▪ See Appendix C

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

Appendix I—Table of Abbreviations

AEs	adverse events
AH/MCS	antihistamine/mast cell stabilizers
BCF	Basic Core Formulary
BIA	budget impact analysis
CFR	Code of Federal Regulations
CMA	cost minimization analysis
CrCl	creatinine clearance
DAA	direct acting antiviral agent
DHA	Defense Health Agency
DMD	Duchenne muscular dystrophy
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
ESRD	end stage renal disease
FVC	forced vital capacity
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GI	gastrointestinal
GLP1RA	glucagon-like peptide-1 receptor agonist
HCV	hepatitis C virus
HypoPP/HyperPP	hypo/hyperkalemic periodic paralysis
IPF	idiopathic pulmonary fibrosis drugs
IR	immediate release
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NCCN	National Comprehensive Cancer Network
NF	nonformulary
OAB	overactive bladder
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPI	proton pump inhibitor
QLs	quantity limits
SSA	somatostatin analog
SR	sustained release
SU	sulfonylurea
T2DM	type 2 diabetes mellitus
TRT	testosterone replacement therapies
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs
XR	extended release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 8 and 9, 2017, 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 2016 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2016 DoD P&T Committee meeting on February 2, 2017.

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

    a) **Section 703 Drug Implementation Date—**The implementation date for the Section 703 drugs Durlaza and Dyanavel XR will be May 10, 2017.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5) (previously known as "innovator drugs"), and full drug class reviews included, but were not limited to, the requirements stated in 32 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. Hepatitis C Virus (HCV) Drugs: Direct-Acting Antivirals (DAAs) Subclass

Background—The HCV DAAs Subclass was last reviewed for UF placement in May 2015. The standard of care for all HCV genotypes is oral therapy consisting of a cocktail of DAAs that are most commonly used in fixed-dose combinations and are based on their synergistic

mechanisms of action. Hepatitis C treatments are classified into sofosbuvir-based regimens and non-sofosbuvir (protease inhibitor) based regimens:

- **Sofosbuvir-Based Regimens**:
  - sofosbuvir (Sovaldi) plus daclatasvir (Daklinza)
  - sofosbuvir (Sovaldi) plus simeprevir (Olysio)
  - sofosbuvir/ledipasvir (Harvoni)
  - sofosbuvir/velpatasvir (Epclusa)

  Note that sofosbuvir is not used as monotherapy.

- **Non-Sofosbuvir (Protease Inhibitor) Based Regimens**:
  - paritaprevir/ritonavir/ombitasvir and dasabuvir (Viekira Pak)
  - paritaprevir/ritonavir/ombitasvir/dasabuvir extended release (Viekira XR)
  - paritaprevir/ritonavir/ombitasvir (Technivie)
  - grazoprevir/elbasvir (Zepatier)

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

- HCV Genotype 1 (GT1): There are currently six regimens recommended for treatment of genotype 1 chronic HCV: Epclusa, Harvoni, Sovaldi plus Daklinza, Sovaldi plus Olysio, Viekira (Viekira Pak and Viekira XR), and Zepatier. These drugs provide all-oral (interferon-free) therapies with sustained virologic response at 12 weeks (SVR12) ranging from 94% to 100%. Viekira Pak and Viekira XR require co-administration with ribavirin in some patients. GT1 is the most common HCV genotype in the United States.
- HCV Genotype 2 (GT2) and Genotype 3 (GT3)
  - Epclusa or Sovaldi plus Daklinza are regimens for patients with GT2 or GT3. Epclusa is the primary treatment regimen for both genotypes, as it represents an all-oral (interferon-free), and ribavirin-free therapy with SVR12 generally exceeding 95%. The only head-to-head trial of the HCV DAAs (ASTRAL-2) demonstrated superiority of Epclusa to Sovaldi plus ribavirin in patients with GT2. Genotype 3 cirrhotic patients are the most difficult to treat and require the addition of ribavirin to Epclusa.
  - For GT3, Sovaldi plus Daklinza represents an all-oral (interferon-free) therapy with SVR12 rates generally exceeding 89%. The SVR12 is significantly reduced in patients with cirrhosis, thus Sovaldi plus Daklinza is no longer the most effective regimen for this population.
- HCV Genotype 4 (GT4): Epclusa, Harvoni, Zepatier, and Technivie are regimens for patients with genotype 4 chronic HCV. Technivie is solely indicated for patients with

GT4. It is only used in patients without cirrhosis and is indicated in combination with ribavirin.

- Ribavirin may be used with some of the other HCV DAAs indicated in HCV GT1 or GT4 to shorten the course of therapy, or when certain baseline factors are present (e.g., treatment experienced patients or those with cirrhosis).
- There are no studies directly comparing Sovaldi plus Daklinza, Epclusa, Harvoni, Viekira, and Zepatier. Indirect comparisons of the individual clinical trials enrolling similar patient populations (i.e., treatment-naïve or treatment-experienced, with or without cirrhosis) show similar efficacy as assessed by SVR12.
- Due to the rapidly evolving field of hepatitis C, the use of these products outside of their FDA-labeled indications is common. The American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) Hepatitis C Guidelines (www.HCVguidelines.org) is a resource that experts reference for the most current information on HCV treatment.
- In the absence of head-to-head trials with all the DAAs, HCV treatment is based on individual patient characteristics, such as the HCV genotype and subtype, treatment history, stage of hepatic fibrosis, presence or absence of resistance-associated variants (RAVs), comorbidities, concomitant medications, and cost.

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

- CMA results showed that sofosbuvir/ledipasvir (Harvoni) was the most cost-effective HCV DAA regimen, followed by grazoprevir/elbasvir (Zepatier), sofosbuvir/velpatasvir (Epclusa), paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira Pak), paritaprevir/ritonavir/ombitasvir/dasabuvir XR (Viekira XR), sofosbuvir (Sovaldi), paritaprevir/ritonavir/ombitasvir (Technivie), daclatasvir (Daklinza), and simeprevir (Olysio).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating sofosbuvir/ledipasvir (Harvoni) as formulary and step-preferred, with all other DAA agents as formulary and non step-preferred, demonstrated the largest estimated cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

    - **UF and Step-Preferred:**
        - sofosbuvir/ledipasvir (Harvoni)

- **UF and Non Step-Preferred:**
  - daclatasvir (Daklinza)
  - grazoprevir/elbasvir (Zepatier)
  - paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira Pak)
  - paritaprevir/ritonavir/ombitasvir/dasabuvir ER (Viekira XR)
  - paritaprevir/ritonavir/ombitasvir (Technivie)
  - simeprevir (Olysio)
  - sofosbuvir (Sovaldi)
  - sofosbuvir/velpatasvir (Epclusa)

- **NF:** No products

Note that as part of this recommendation, all new users of an HCV DAA are required to try Harvoni first. Additionally, no HCV DAA products were recommended for Extended Core Formulary (ECF) addition. For the HCV Drug Class, ribavirin 200 mg capsules and peginterferon alfa-2a (Pegasys) were designated ECF in November 2012.

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new users of a HCV DAA prior to use of a non step-preferred product (Daklinza, Epclusa, Olysio, Sovaldi, Technivie, Viekira XR, Viekira Pak, Zepatier). The step therapy requirement for a trial of Harvoni in all new users is included in the manual PA criteria. A manual PA is also required for Harvoni. Coverage for the HCV DAAs is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.

   A trial of Harvoni is not required if:

   - Contraindications exist to Harvoni (advanced kidney disease with a creatinine clearance < 30 mL/min).
   - The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is not expected with the requested non step-preferred HCV DAA (e.g., concurrent use of high-dose proton pump inhibitor).
   - The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is not expected with the requested non step-preferred HCV DAA.
   - There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or HCV GT3).

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***QLs currently apply to all the HCV DAAs. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QL of a 28-day supply for all the HCV DAAs, consistent with current manufacturer packaging.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation. Based on the P&T Committee's recommendation, the effective date is June 7, 2017.

B. Antibiotics: Tetracycline Drugs Subclass

Background—The P&T Committee evaluated the tetracycline antibiotics for formulary placement. Doxycycline hyclate (Vibramycin, Vibra-Tabs) and minocycline immediate release (Minocin) are available in generic formulations. The newer entrants to the subclass all contain doxycycline or minocycline as the active ingredient, and are marketed with different salt forms, special packaging, release mechanisms (immediate release [IR] versus sustained release [SR] versus delayed release [DR]), or dosing strategies from the traditional generic products.

The clinical and cost-effectiveness evaluations focused on the use of doxycycline and minocycline for treatment of acne and rosacea. Use of the tetracycline antibiotics for treating infections was not addressed in the clinical review. The clinical effectiveness of tetracycline and demeclocycline were not reviewed; these products will remain on the UF due to unique clinical niches for treating rickettsial infections and syndrome of inappropriate antidiuretic hormone (SIADH) secretion, respectively. Additionally, use of doxycycline for deployment purposes is not affected by this formulary recommendation.

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

- Tetracycline, minocycline, and doxycycline are all effective in the treatment of moderate to severe acne and rosacea.
- Professional treatment guidelines for papulopustular rosacea recommend doxycycline 50 mg to 100 mg, minocycline 50 mg to 100 mg, or doxycycline 40 mg IR/DR (Oracea) as second-line therapy following topical medications, but there are concerns of conflict of interest with the guideline's authors.
- A 2015 Cochrane review evaluating doxycycline for treating rosacea found no significant difference in effectiveness between doxycycline 100 mg and 40 mg IR/DR (Oracea). There were significantly fewer adverse effects with the 40 mg lower dose; however, the results were based on low quality evidence and the clinical relevance of these results is questionable. There was high quality evidence to support efficacy of generic doxycycline 100 mg.
- Solodyn was originally developed as an extended-release (ER) minocycline formulation to reduce potential vestibular adverse effects associated with rapid absorption of generic minocycline IR formulations. However, pharmacokinetic studies showed the absorption profile for Solodyn does not differ significantly from that of minocycline IR.
- There are no head-to-head trials comparing the efficacy or safety of minocycline ER (Solodyn) with generic minocycline IR products for treating acne. A Cochrane review

from 2015 concluded there was no data to support minocycline ER formulations are safer than standard minocycline IR preparations.

- Overall, there is little evidence to support advantages of the newer doxycycline and minocycline products over the traditional generic formulations in terms of salt (monohydrate versus hyclate), dosage form (tablet versus capsule versus scored tablets), release mechanisms (IR versus ER versus DR), or dosing strategy (1 mg/kg dosing with minocycline ER versus traditional 50 mg or 100 mg dosing).

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

- CMA results showed that doxycycline monohydrate (generic), doxycycline hyclate (generic), and minocycline IR (generic) were the most cost-effective oral tetracyclines, followed by doxycycline 40 mg IR/DR (Oracea brand), doxycycline hyclate modified polymer coat (Doryx MPC), tetracycline (generic), doxycycline hyclate (Morgidox), demeclocycline (generic), doxycycline 40 mg IR/DR (Oracea generic), doxycycline hyclate (Targadox), doxycycline monohydrate (Monodoxyne NL), minocycline ER (Solodyn generic), minocycline ER (Solodyn brand), doxycycline hyclate (Acticlate), doxycycline hyclate (Doryx), doxycycline monohydrate (Monodox), and doxycycline monohydrate (Adoxa), in order from most cost effective to least cost effective.

- BIA was performed to evaluate the potential impact of designating selected agents as formulary (and step-preferred) or NF (and non step-preferred) on the UF. All modeled scenarios show savings against the current baseline. BIA results showed that designating doxycycline monohydrate (generic), doxycycline hyclate (generic), and minocycline (generic) as formulary and step-preferred, with the remaining products as NF and non step-preferred demonstrated the most cost-effective option for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:

    - UF and Step-Preferred:
        - doxycycline hyclate IR 50 mg, 75 mg, 100 mg, 150 mg, 200 mg tabs and caps (generic)
        - doxycycline monohydrate IR 50 mg, 75 mg, 100 mg, 150 mg, 200 mg tabs and caps (generic)
        - minocycline IR 50mg, 75 mg, 100 mg tabs and caps (generic)

    - NF and Non Step-Preferred:
        - doxycycline hyclate 75 mg unscored and 150 mg scored tabs, and 75 mg caps (Acticlate)
        - doxycycline hyclate 50 mg, 100 mg, 150 mg, and 200 mg DR tabs (Doryx and generic)

- doxycycline hyclate 60 mg and 120 mg DR modified polymer coat tabs (Doryx MPC)
- doxycycline hyclate 50 mg tabs (Targadox)
- doxycycline hyclate 50 mg, 100 mg caps (Morgidox)
- doxycycline monohydrate 40 mg IR/DR caps (Oracea and generics)
- doxycycline monohydrate 50 mg, 75 mg, 150 mg caps (Monodoxyne NL)
- doxycycline monohydrate 50 mg, 75 mg, 100 mg tabs, 150 mg caps (Adoxa)
- doxycycline monohydrate 75 mg, 100 mg caps (Monodox)
- minocycline ER 45 mg, 90 mg, 135 mg tabs (generics)
- minocycline ER 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg tabs (Solodyn)

- Note that as part of this recommendation, all new users of a non step-preferred product will be required to try a generic step-preferred doxycycline and/or minocycline product first.

- UF and not subject to the Step Therapy requirements:
  - doxycycline calcium/monohydrate 25 mg/5 mL, 50 mg/5 mL suspension (generic)
  - tetracycline hydrochloride 250 mg, 500 mg caps and 125 mg/5 mL suspension (generic)
  - demeclocycline hydrochloride 150 mg and 300 mg caps (generic)
  - Note that children under the age of 13 are exempt from step therapy.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following products for the BCF:

   - **Remain on the BCF:**
     - doxycycline hyclate IR 100 mg caps generic, as it is the most frequently dispensed doxycycline product at the MTFs

   - **Removed from the BCF:**
     - tetracycline 250 mg, 500 mg caps, due to infrequent use; it will remain on the UF

3. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) and MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) step therapy and manual PA criteria for the subclass. All new and current users of a NF, non step-preferred

doxycycline or minocycline product are required to first try one generic doxycycline IR (not including doxycycline 40 mg IR/DR) and one generic minocycline IR product for acne and rosacea, prior to use of the non step-preferred products.

The branded products of Doryx, Doryx MPC, and Acticlate will be allowed for treatment of susceptible infections, if the patient has failed or had clinically significant adverse events to generic doxycycline IR products.

Note that children under age 13 are exempt from the step therapy requirement, as are patients receiving tetracycline, doxycycline suspension, or demeclocycline. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN REQUIREMENTS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for the doxycycline and minocycline products recommended for NF status. See Appendix B for the criteria.

5. ***COMMITTEE ACTION: EMMPI REQUIREMENTS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) exempting the NF doxycycline products specifically labeled for treatment of susceptible infections from The Expanded MTF/MAIL Pharmacy Initiative (EMMPI) and NF to Mail Order Pharmacy requirements, due to the acute use exception. The Committee did not see a reason to exempt the doxycycline and minocycline products labeled for acne or rosacea. See Appendix F for the full list.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 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 letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 9 2017.

V. NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) ("INNOVATOR DRUGS")

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly-approved drugs reviewed at the February 2017 P&T Committee meeting, a brief summary of their clinical attributes, their formulary recommendations, and their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- **UF**:
  - Hepatitis B Agents: tenofovir alafenamide (Vemlidy)
  - Oral Oncologic Agents: rucaparib (Rubraca)
- **NF:**
  - Basal Insulins: insulin glargine (Basaglar KwikPen)
  - Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA): lixisenatide (Adlyxin)
  - GLP1RA: lixisenatide/insulin glargine (Soliqua)
  - Ophthalmic-1 Nonsteroidal Anti-inflammatory Drugs (NSAIDs): bromfenac 0.075% ophthalmic solution (BromSite)
  - Vitamin D Analogs: calcifediol (Rayaldee)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for bromfenac 0.075% solution (BromSite), calcifediol (Rayaldee), insulin glargine (Basaglar KwikPen), lixisenatide (Adlyxin), and lixisenatide/insulin glargine (Soliqua). See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: GLP1RAs LIXISENATIDE (ADLYXIN) AND LIXISENATIDE/INSULIN GLARGINE (SOLIQUA) STEP THERAPY AND MANUAL PA CRITERIA***—Step therapy currently applies to the GLP1RAs Subclass, requiring a trial of exenatide weekly injection (Bydureon) and albiglutide weekly injection (Tanzeum) first, before the other non step-preferred GLP1RAs (Byetta, Victoza, or Trulicity).

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) step therapy and manual PA criteria for Adlyxin and Soliqua in new and current users. Patients will be required to try metformin or a sulfonylurea, and Bydureon and Tanzeum, before Adlyxin or Soliqua. Additionally, for Soliqua, patients will be required to be on basal insulin at a dosage of less than 60 units daily. See Appendix C for the full criteria.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date upon signing of the minutes in all points of service (POS).

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Epinephrine Auto-Injectors: Manual PA Criteria**—The Auvi-Q, Adrenaclick, and EpiPen auto-injectors all contain epinephrine and are used in allergic emergencies,

including anaphylaxis. An authorized generic formulation of EpiPen from Mylan Pharmaceuticals is now available and manufactured by the same pharmaceutical company as the originator product. The manufacturer of the authorized generic to Adrenaclick cannot produce sufficient supply to keep up with demand. The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. Auvi-Q will be re-introduced in mid-February 2017, after market withdrawal in October 2015, due to reports the device failed to deliver a reliable dose of epinephrine.

A cost analysis and BIA favored dispensing the EpiPen brand auto-injector at the MTF and Mail Order points of service (POS), whereas in the Retail Pharmacy Network the EpiPen authorized generic is most cost effective. The Auvi-Q auto-injector is prohibitively more expensive than the other products.

a) ***COMMITTEE ACTION: EPINEPHRINE AUTO-INJECTORS MANUAL PA CRITERIA***—Due to the significant cost differences based on POS dispensing, the P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA in all new and current users of all formulations of EpiPen at the Retail Pharmacy Network; Adrenaclick at all POS; the Mylan authorized generic at the TRICARE Mail Order Pharmacy and MTFs; and in all new users of Auvi-Q at all POS (note that there are no current users of Auvi-Q). Patients will be required to try the EpiPen branded product at the TRICARE Mail Order Pharmacy and MTFs, or the authorized EpiPen generic formulation from Mylan Pharmaceuticals at the Retail Pharmacy Network, prior to use of any other epinephrine auto-injector product. The provider must document a patient-specific justification as to why the preferred agent is not acceptable. Prior authorization will not expire. See Appendix C for the full criteria.

2. **Oral Oncology Agents: Palbociclib (Ibrance) Updated Manual PA Criteria**
Ibrance was approved by the FDA in February 2015 for specific types of metastatic breast cancer. Manual PA criteria were recommended at the May 2016 meeting and implemented on November 2, 2016. An additional use as second-line therapy after endocrine-based treatment and in combination with fulvestrant was recently approved. The criteria were updated to add the new indication.

   a) ***COMMITTEE ACTION: PALBOCICLIB (IBRANCE) UPDATED MANUAL PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updating the manual PA criteria for new users. See Appendix C for the full criteria.

3. **Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Trokendi XR) Updated Manual PA Criteria**—Trokendi XR and Qudexy XR are branded ER formulations of topiramate dosed once daily. Generic topiramate IR formulations have been marketed since 1996. Manual PA criteria were recommended for Trokendi XR and Qudexy XR in August 2014 to limit use of the branded topiramate ER products to their FDA-approved indications for seizures and appropriate age ranges. A trial of topiramate IR

(generic Topamax IR) is required first. Trokendi XR is expected to receive FDA approval for use in migraine headache prophylaxis in March 2017.

a) ***COMMITTEE ACTION: TOPIRAMATE ER (TROKENDI XR) UPDATED PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updating the manual PA criteria for Trokendi XR to include use as prophylaxis in migraine headache after an inadequate response, or adverse event with topiramate IR. See Appendix C for the full criteria.

4. **Testosterone Replacement Therapies: Updated Manual PA Criteria**—The Testosterone Replacement Therapies (TRTs) were reviewed for formulary placement in August 2012, with testosterone transdermal 2% gel pump (Fortesta) designated as BCF and step-preferred. All other TRT products are non step-preferred.

   Updated step therapy and manual PA criteria are needed since publication of the Final Rule/technical amendment (81 FR 61068-61098), removing certain regulatory exclusions for the treatment of gender dysphoria for TRICARE beneficiaries. This rule change permits coverage of all nonsurgical medically necessary and appropriate care in the treatment of gender dysphoria. See the Final Rule for TRICARE Mental Health and Substance Use Disorder Treatment published on September 2, 2016 at https://www.gpo.gov/fdsys/pkg/FR-2016-09-02/pdf/2016-21125.pdf.

   a) ***COMMITTEE ACTION: TRT UPDATED MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 2 opposed, 1 abstained, 0 absent) updating the manual PA criteria for the topical and buccal TRT products to allow for use in patients undergoing female to male gender reassignment (endocrinologic masculinization), as outlined in the Final Rule and the TRICARE Policy Manual 6010.57-M. See Appendix C for the full criteria.

B. Quantity Limits (QLs)

1. QLs were reviewed for three drugs: rucaparib (Rubraca) for advanced ovarian cancer due to the potential for adverse reactions; methylnaltrexone tablets (Relistor) for opioid-induced constipation; and levalbuterol nebulization concentrated solution (Xopenex concentrate) for bronchospasm in patients with reversible obstructive airway disease. QLs already exist in these three distinct classes.

   a) ***COMMITTEE ACTIONS: QLs—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) QLs for Rubraca, Relistor tablets, and Xopenex nebulized concentrated solution. 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:

- 17 for, 0 opposed, 0 abstained, 0 absent—The new manual PA for the epinephrine auto-injectors (Auvi-Q, EpiPen [brand and generic] and Adrenaclick [generic]) become effective on the first Wednesday that occurs no later than 90 days after signing of the minutes in all POS, and that DHA send letters to patients currently receiving an epinephrine auto-injector in the Retail Network who are affected by this recommendation. Based on the P&T Committee's recommendation, the effective date is August 9, 2017.
- 17 for, 0 opposed, 0 abstained, 0 absent—The updated manual PAs for Ibrance, Trokendi XR and the testosterone replacement therapies 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 August 9, 2017.
- 17 for, 0 opposed, 0 abstained, 0 absent—The QLs for Rubraca, Relistor tablets, and Xopenex nebulized concentrated solution become effective upon signing of the minutes.

VII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for two product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug. Requirements for formulary status, medical necessity criteria, manual prior authorization and step therapy criteria, and quantity limits apply to line extension products.

- Targeted Immunomodulatory Biologics (TIBs)—secukinumab (Cosentyx) is available in a new auto-injector, the Sensoready Pen. Similar to the Cosentyx syringes, the Sensoready Pen is approved for treatment of ankylosing spondylitis, plaque psoriasis, and psoriatic arthritis.
- Alcohol Deterrents: Narcotic Antagonists—naloxone auto-injector (Evzio) is available in a new 2 mg/0.4 mL formulation, which will replace the currently marketed 0.4 mg/0.4 mL product.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) clarifying the formulary status of the following two products to reflect the current formulary status, step therapy/PA criteria, and QLs for the parent compound. Implementation will occur upon signing of the minutes.

- secukinumab (Cosentyx Sensoready Pen): UF and non step-preferred with the same manual PA criteria and QLs as Cosentyx prefilled syringes;
- naloxone auto-injector 2 mg/0.4 mL (Evzio): NF with the same MN criteria and QLs as Evzio 0.4 mg/0.4 mL.

VIII. FORMULARY STATUS UPDATE: ANTILIPIDEMIC-1s

A. Step Therapy: Rosuvastatin

The statins included in the Antilipidemic-1s Drug Class were most recently reviewed for formulary status in November 2013. Rosuvastatin (Crestor) was designated UF and non step-preferred, requiring a trial of a generic statin with equivalent low-density lipoprotein (LDL)-lowering intensity. Cost-effective generic formulations for rosuvastatin are now available and a Joint National Contract with the U.S. Department of Veterans Affairs (VA) will become effective on March 13, 2017.

1. ***COMMITTEE ACTION: ROSUVASTATIN FORMULARY STATUS UPDATE***
   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) designating rosuvastatin as UF and step-preferred. The Committee also recommended (17 for, 0 opposed, 0 abstained, 0 absent) adding rosuvastatin (generic) to the BCF, effective upon signing of the minutes. The corresponding PA forms for the non step-preferred statins will be updated to reflect the status of rosuvastatin as step-preferred, with implementation effective upon signing of the minutes.

IX. 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. See Appendix F for the mail order status of medications designated NF during the February 2017 P&T Committee Meeting.

A. Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")

1. ***COMMITTEE ACTION: NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF STATUS***

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained 0 absent) rucaparib (Rubraca) and tenofovir alafenamide (Vemlidy) were not suitable for addition to the EMMPI program based on the following factors: oncology drug or acute use, respectively. Addition of the hepatitis B virus drugs to the EMMPI list will be considered at a future date.

2. ***COMMITTEE ACTION:*** **NEWLY-APPROVED DRUGS PER 32 CFR 199.21(g)(5)** ***RECOMMENDED FOR NF STATUS***

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained 0 absent):

   a) The previously established exception from the mail order requirement applies to bromfenac 0.075% ophthalmic solution (BromSite) (acute use).

b) Insulin glargine (Basaglar KwikPen), lixisenatide (Adlyxin), and lixisenatide/insulin glargine (Soliqua) fall into classes that are already defined as automatic additions to the EMMPI program. The P&T Committee found no reason to exempt calcifediol (Rayaldee) from the mail order requirement.

X. ITEMS FOR INFORMATION

A. TRICARE Mail Order Pharmacy Auto-Refill Program Update

The Committee was briefed on the TRICARE Mail Order Auto-Refill program, and considered potential drug classes to remove from the program. Future reviews will include recommendations for updating medications eligible for the program.

B. New Drug Trends and Reviews of Previous P&T Committee Recommendations for NF Status and PA/Step Therapy

The P&T Committee reviewed utilization data and costs for new drugs that have entered the market after July 2015 that were evaluated for formulary status. Additionally, the Committee evaluated the effects of previous recommendations on utilization, including step therapy and prior authorization requirements, and the effects of NF status on utilization.

C. First Annual Review of Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")

The Committee was briefed on the utilization and cost trends for newly-approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. Sixty drugs were evaluated, with 29 remaining as NF, and 31 designated as UF. Updates on the metrics for the newly-approved drugs per 32 CFR 199.21(g)(5) will be presented periodically at upcoming P&T Committee meetings.

XI. ADJOURNMENT

The meeting adjourned at 1130 hours on February 9, 2017. The next meeting will be in May 2017.

Appendix A—Attendance: February 2017 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 Formulary Recommendations for Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as Innovator Drugs)

Appendix F—Mail Order Status of Medications Designated Nonformulary During the February 2017 DoD P&T Committee Meeting

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

Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☑ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1. **Palbociclib (Ibrance):** Implementation of the updated manual prior authorization for palbociclib (Ibrance) will occur upon signing.

2. **Testosterone Replacement Therapies:** Implementation of the updated manual prior authorization for the testosterone replacement therapies will occur upon signing.

3.

☐ concurs with the recommendations, except for the following:

RADM Colin Chinn, MC, USN
Acting Deputy Director, DHA
for R.C. Bono, VADM, MC, USN,
Director

4 May 2017
Date

Appendix A—Attendance: February 2017 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	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
CAPT Shaun Carstairs, MC	Navy, Physician at Large
MAJ Rosco Gore	Army, Internal Medicine Physician
MAJ John Poulin, MC	Army, Physician at Large
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Maj Dausen Harker, MC	Army, Family Practice Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Doreen Lounsbery COL (Ret.), MC, USA	TRICARE Regional Office-South, Medical Director
Voting Members Absent	
Ms. Jennifer Zacher for Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Guests	
COL Alfonso S. Alarcon, MD	Director, TRICARE Area Office Latin America & Canada
MAJ Norman Tuala	Defense Logistics Agency Troop Support
Mr. Jason Wray	Defense Logistics Agency Troop Support
Mr. Keith Boulware via telephone	DHA Contract Operations Division
LCDR Jessica Anderson	Indian Health Service
Capt Aubrie Wnek	Pharmacist, Goodfellow AFB

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
LCDR Christina Andrade	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Dean Valibhai, PharmD, MBA	DHA Purchased Care Branch
LT Teisha Robertson via telephone	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
David Meade, PharmD via telephone	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via telephone	DHA Integrated Utilization Branch
Maj Gregory Palmrose, BSC	University of Texas PhD student
Barbara Bustamante	Pharmacy Student, University of Incarnate Word
Gallissara Agavatpanitch	Pharmacy Student, University of Texas

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• doxycycline 40 mg IR/DR (Oracea and generics) **Antibiotics: Tetracyclines**	• Patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic doxycycline immediate-release products • No alternative formulary agent: the patient has ocular rosacea symptoms and has not responded to generic IR doxycycline (not including the generic 40 mg IR/DR) and has had an inadequate response to topical metronidazole products **Formulary Alternatives:** doxycycline hyclate or monohydrate 50 mg or 100 mg
• minocycline ER (Solodyn and generic) **Antibiotics: Tetracyclines**	• Patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic minocycline immediate release products. **Formulary Alternatives:** Minocycline IR 50 mg or 100 mg
• Acticlate, Doryx, Doryx MPC, Targodox, Morgidox, Monodoxyne NL, Adoxa, Monodox, minocycline ER generics **Antibiotics: Tetracyclines**	• Patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic doxycycline immediate release AND generic minocycline immediate release products • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** doxycycline IR 50 mg or 100 mg, minocycline IR 50 mg or 100 mg
• bromfenac 0.075% (BromSite) **Ophthalmic-1 Agents: NSAIDS**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents **Formulary Alternatives:** bromfenac 0.09% (Bromday), diclofenac 0.01% (Voltaren), flurbiprofen 0.03% (Ocufen), ketorolac 0.4% (Acular LS), ketorolac 0.45% (Acuvail), ketorolac 0.5% (Acular), nepafenac 0.01% (Nevanac)
• calcifediol (Rayaldee) **Vitamin D Analogs**	• Formulary agents have resulted in therapeutic failure. **Formulary Alternatives:** calcitriol (Rocaltrol), paricalcitol (Zemplar), doxercalciferol (Hectorol)
• insulin glargine (Basaglar KwikPen) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control. **Formulary Alternatives:** insulin glargine (Lantus) and insulin detemir vial (Levemir)

Drug / Drug Class	Medical Necessity Criteria
• lixisenatide (Adlyxin) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Patient has experienced significant adverse effects from the GLP1RA preferred products (Bydureon or Tanzeum) that are not expected to occur with Adlyxin, Victoza, Trulicity, and Byetta. **Formulary Alternatives:** exenatide once weekly (Bydureon) and albiglutide (Tanzeum)
• lixisenatide/insulin glargine (Soliqua) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Use of formulary agents (both GLP1RAs Bydureon and Tanzeum AND insulin glargine) has resulted in therapeutic failure **Formulary Alternatives:** exenatide once weekly (Bydureon), albiglutide (Tanzeum), and insulin glargine (Lantus)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• sofosbuvir / ledipasvir (Harvoni) **Hepatitis C - Direct Acting Antivirals (HCV DAA)**	Coverage approved for patients ≥ 18 years with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 4, 5 or 6 • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires after 365 days.
• sofosbuvir (Sovaldi) **Hepatitis C - Direct Acting Antivirals (HCV DAA)**	Manual PA criteria: • Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir (Sovaldi) if : • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with the requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • The patient has experienced or is likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or GT3) AND Coverage approved for patients ≥ 18 years with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 2, 3 or 4 • Used in combination with another HCV DAA (not used as monotherapy) • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires after 365 days.

Drug / Drug Class	Prior Authorization Criteria

• simeprevir (Olysio)
 	
Hepatitis C - Direct Acting Antivirals (HCV DAA)
	Manual PA criteria:
	• Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for simeprevir (Olysio) if:
	  • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
	  • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
	  • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA
	  • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)
	AND
	Coverage approved for patients > 18 years with:
	• A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
	• Laboratory evidence of chronic hepatitis C
	  o Document HCV RNA viral load
	• Has hepatitis C genotype 1
	• Used in combination with sofosbuvir (not used as monotherapy)
	• Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)
	Applies to new users only.
	Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.
	PA expires after 365 days.

• daclatasvir (Daklinza)
 	
Hepatitis C - Direct Acting Antivirals (HCV DAA)
	Manual PA criteria:
	• Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for daclatasvir (Daklinza) if:
	  • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min])
	  • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
	  • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA
	  • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)
	AND
	Coverage approved for patients ≥ 18 years with:
	• A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
	• Laboratory evidence of chronic hepatitis C
	  o Document HCV RNA viral load
	• Has hepatitis C genotype 3
	• Used in combination with sofosbuvir (not used as monotherapy)
	• Does not have advanced kidney disease (CrCl < 30 mL/min)
	Applies to new users only.
	Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.
	PA expires after 365 days.

Drug / Drug Class	Prior Authorization Criteria
• sofosbuvir / velpatasvir (Epclusa) **Hepatitis C - Direct Acting Antivirals (HCV DAA)**	Manual PA criteria: • Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir / velpatasvir (Epclusa) if: • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3) AND Coverage approved for patients ≥ 18 years with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 2, 3, 4, 5 or 6 • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires after 365 days.
• paritaprevir / ritonavir / ombitasvir (Technivie) **Hepatitis C - Direct Acting Antivirals (HCV DAA)**	Manual PA criteria: • Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for paritaprevir / ritonavir / ombitasvir (Technivie) if: • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • Has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3) AND Coverage approved for patients > 18 years with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 4 • Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C) • Does not have cirrhosis Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires after 365 days.

Drug / Drug Class	Prior Authorization Criteria

• paritaprevir / ritonavir / ombitasvir and dasabuvir Pak (Viekira Pak)
 	
• paritaprevir/ritonavir/ ombitasvir/dasabuvir XR (Viekira XR)
 	
Hepatitis C - Direct Acting Antivirals (HCV DAA)
	Manual PA criteria:
	• Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for paritaprevir / ritonavir / ombitasvir / dasabuvir Pak (Viekira Pak) or paritaprevir / ritonavir / ombitasvir / dasabuvir XR (Viekira XR) if:
	  • Contraindications exist to Harvoni (e.g., advanced kidney disease [CrCl < 30 mL/min])
	  • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
	  • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA
	  • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)
	AND
	Coverage approved for patients ≥ 18 years with:
	  • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
	  • Laboratory evidence of chronic hepatitis C
	  o Document HCV RNA viral load
	  • Has hepatitis C genotype 1
	  • Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)
	
	Applies to new users only.
	
	Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.
	
	PA expires after 365 days.

• grazoprevir / elbasvir (Zepatier)
 	
Hepatitis C - Direct Acting Antivirals (HCV DAA)
	Manual PA criteria:
	• Sofosbuvir / ledipasvir (Harvoni) is the preferred HCV DAA; coverage is approved for grazoprevir / elbasvir (Zepatier) if:
	  • Contraindications exist to Harvoni (e.g., advanced kidney disease [CrCl < 30 mL/min])
	  • The patient is likely to experience significant adverse reactions or drug- drug interaction to Harvoni that is NOT expected with requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI)
	  • The patient has experienced or likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA
	  • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 and GT3)
	AND
	Coverage approved for patients > 18 years with:
	  • The prescription is written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
	  • Laboratory evidence of chronic hepatitis C
	  o Document HCV RNA viral load
	  • Has hepatitis C genotype 1 or 4
	  • Testing for NS5A resistance in HCV GT 1a prior to treatment
	  • Does not have moderate to severe liver impairment or decompensated cirrhosis (Child-Pugh B or C)
	
	Applies to new users only.
	Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines.
	PA expires after 365 days.

Drug / Drug Class	Prior Authorization Criteria
• doxycycline hyclate 75 mg and 150 mg (Acticlate) • doxycycline hyclate 50, 100, 150, 200 mg DR (Doryx and generic) • doxycycline hyclate 60 mg and 120 mg DR modified polymer coat (Doryx MPC) • doxycycline hyclate 50 mg (Targadox) • doxycycline hyclate 50 mg, 100 mg (Morgidox) • doxycycline monohydrate 40 mg IR/DR (Oracea and generics) • doxycycline monohydrate 50 mg, 75 mg, 150 mg (Monodoxyne NL) • doxycycline monohydrate 50mg, 75 mg, 100 mg tabs & 150 mg (Adoxa) • doxycycline monohydrate 75 mg, 100 mg (Monodox) • minocycline ER 45 mg, 90 mg, 135 mg ER (generics) • minocycline DR 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn) **Oral Tetracycline Agents**	PA applies to both new and current users of non-preferred tetracycline oral agents. Automated PA Criteria: • Patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) **AND** one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 days Manual PA Criteria: If automated PA criteria are not met, the non step-preferred product is allowed if: **Acne Vulgaris or Rosacea** • For Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Monodoxyne NL: The patient has tried and had an inadequate response to or failed to tolerate the following: ▪ one generic immediate-release doxycycline product (hyclate or monohydrate salt) AND ▪ one generic immediate-release minocycline product • For Oracea and generic 40 mg IR/DR: The patient has rosacea with inflammatory lesions (papules and pustules) or ocular rosacea symptoms AND ▪ has tried generic immediate-release doxycycline (does not include doxycycline 40 mg IR/DR) and had an inadequate response or could not tolerate it due to gastrointestinal adverse events AND ▪ has not responded to topical rosacea treatments, including metronidazole 1% gel • For Solodyn or generic minocycline ER: The patient has acne with inflammatory lesions AND ▪ the patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events **Susceptible Infections** • For Doryx, Doryx MPC, and Acticlate: if used for susceptible infections, the patient has failed or had clinically significant adverse events to generic IR doxycycline • PA expires in 365 days.
• lixisenatide (Adlyxin) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new and current users of Adlyxin are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin or a sulfonylurea first. Additionally, Bydureon and Tanzeum are the preferred agents in the GLP1RA subclass. New and current users of Adlyxin must try Bydureon and Tanzeum first. Automated PA criteria: The patient has received a prescription for metformin or SU 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 PA criteria are not met, Adlyxin is approved (e.g., trial of metformin or SU is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis • The patient has experienced any of the following issues on a SU: o hypoglycemia requiring medical treatment

Drug / Drug Class	Prior Authorization Criteria
	• The patient has had inadequate response to metformin or a SU • The patient has a contraindication to metformin or a SU AND In addition to the above criteria regarding metformin and SU, the following PA criteria would apply specifically to new and current users of Adlyxin: • The patient has had an inadequate response to Bydureon and Tanzeum. Prior Authorization does not expire. Off-label uses are not approved.
• lixisenatide/insulin glargine (Soliqua) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new and current users of Soliqua are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin or a sulfonylurea first. Additionally, Bydureon and Tanzeum are the preferred agents in the GLP1RA subclass. New and current users of Soliqua must try Bydureon and Tanzeum first. Automated PA criteria: The patient has received a prescription for metformin or SU at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days, AND In addition to the above criteria regarding metformin and SU, the following PA criteria would apply specifically to new and current users of Soliqua: Manual PA Criteria: Coverage will be approved if the following: • Soliqua is used as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus inadequately controlled on a basal insulin (< 60 units daily) • The patient has had an inadequate response to Bydureon AND • The patient has had an inadequate response to Tanzeum Prior Authorization does not expire. Off-label uses are not approved.
• epinephrine auto-injectors (Auvi-Q, EpiPen, and Adrenaclick) **Respiratory Agents, Miscellaneous**	Patients will be required to try the EpiPen branded product at the MTF and TRICARE Mail Order Pharmacy, or the Mylan authorized generic EpiPen formulation at the Retail Network, prior to use of any other epinephrine auto-injector product. Manual PA criteria—Coverage will be approved if: • The provider documents a patient-specific reason why the patient cannot use the preferred product. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• palbociclib (Ibrance) **Oral Oncologic Agents**	**Changes from February 2017 meeting are in BOLD** 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, iii, or iv): 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 luteinizing 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 luteinizing 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. OR **iv. The patient is a pre-, peri-, or post-menopausal woman and has disease progression following endocrine therapy and is using palbociclib in combination with fulvestrant (Faslodex).** Other Non-FDA approved uses are not approved. Prior Authorization does not expire. .

Drug / Drug Class	Prior Authorization Criteria
• topiramate ER (Trokendi XR) **Anticonvulsants and Anti-Mania Agents**	**February 2017 updates are in BOLD** 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 ER 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). o **Migraine prophylaxis in adults (Trokendi XR)** • Coverage not approved for o Non-FDA approved indications, including weight loss and migraine headache (for Qudexy XR only) • 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 Prior Authorization does not expire.
• testosterone 2% gel pump (Fortesta) **Testosterone Replacement Therapies (Step-preferred product)**	**February 2017 updates are in BOLD** Manual PA criteria apply to all users of transdermal and buccal testosterone replacement products. • Coverage approved for male patients if: o Patient is male over the age of 17 years AND o Patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND o The patient is experiencing symptoms usually associated with hypogonadism • **Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:** o **Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND** o **Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the DSM; AND** o **Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND** o **Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria; AND** o **For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding.** Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• transdermal patch (Androderm) • transdermal gel tubes (Testim) • buccal tablets (Striant) • nasal gel (Natesto) • transdermal gel (Vogelxo) • transdermal gel and gel pump (Androgel 1%, 1.62%) • transdermal solution (Axiron) **Testosterone Replacement Therapies (Non step-preferred products)**	**February 2017 updates are in BOLD** Manual PA criteria apply to all users of transdermal and buccal testosterone replacement products. • Coverage approved for male patients if: o Patient is male over the age of 17 years AND o Patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND o The patient is experiencing symptoms usually associated with hypogonadism AND o The patient has tried Fortesta (testosterone 2% gel) for a minimum of 90 days AND failed to achieve total testosterone levels above 400 ng/dL (labs drawn 2 hours after Fortesta application) AND without improvement in symptoms. OR o The patient has a contraindication or relative contraindication to Fortesta that does not apply to the requested agent. OR o The patient has experienced a clinically significant skin reaction to Fortesta that is not expected to occur with the requested agent. OR o The patient requires a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members (for Androderm, Natesto, or Striant only). • **Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:** o **Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND** o **Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the DSM; AND** o **Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND** o **Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria; AND** o **For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding. AND** o **Does the patient have a contraindication or relative contraindication to Fortesta that does not apply to the requested agent? OR** o **Has the patient experienced a clinically significant skin reaction to Fortesta that is not expected to occur with the requested agent? OR** o **If the request is for Androderm, Natesto, or Striant, does the patient require a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members?** Prior authorization does not expire.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• rucaparib (Rubraca) **Oral Oncologic Agents**	▪ Retail: #60 tablets / 15 days ▪ Mail/MTF: #120 tablets / 30 days
• methylnaltrexone tablets (Relistor) **Gastrointestinal-Miscellaneous Agents – Drugs for Opioid-Induced Constipation**	Maximum days' supply: ▪ Retail: 30-day supply maximum ▪ MTF/Mail: 45-day supply maximum
• levalbuterol nebulization solution (Xopenex Concentrate) **Pulmonary-1 Agents – Short-Acting Beta Agonists**	▪ Retail: 60 mL / 30 days ▪ MTF/Mail: 180 mL / 90 days

Appendix E—Formulary Recommendations for Newly-Approved Drugs Per 32 CFR 199.21(g)(5) (formerly known as Innovator Drugs)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
bromfenac 0.075% ophthalmic solution (BromSite)	Ophthalmic-1 Agents: NSAIDS	• bromfenac 0.07% (Prolensa) • bromfenac 0.09% (Bromday generic)	Treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery	• 3rd available ophthalmic bromfenac product • Gel formulation does not translate into improved clinical efficacy • Bromfenac 0.075% has no clinically compelling advantages over existing UF agents	• NF • Exempt from mail order (acute use exception)
calcifediol (Rayaldee)	Vitamin D Analogs	• doxercalciferol (Hectorol) • calcitriol (Rocaltrol) • paricalcitol (Zemplar)	Treatment of secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxy vitamin D levels < 30 ng/mL	• The 4th oral vitamin D analog • All products are indicated for use in patients with secondary hyperparathyroidism and stage 3 or 4 chronic kidney disease (CKD) • Unlike the other oral vitamin D analogs, is not indicated for use in patients receiving dialysis • There are no head-to-head studies between calcifediol and other vitamin D analogs • Calcifediol has no clinically compelling advantages over existing UF agents	• NF • Add to mail order list (no exemptions)
insulin glargine (Basaglar KwikPen)	Basal Insulins	• degludec (Tresiba) • glargine (Lantus) • detemir (Levemir)	Glycemic control in adults with diabetes mellitus	• An insulin glargine product with the same amino acid sequence as Lantus approved via 505(b)2 pathway; not a biosimilar product • No difference between Basaglar and Lantus in glycemic control in two trials • The first competitor to Lantus to reach the market	• NF • Add to mail order list (no exemptions)
lixisenatide (Adlyxin)	GLP1RA	• exenatide (Byetta, Bydureon) • albiglutide (Tanzeum) • liraglutide (Victoza) • dulaglutide (Trulicity)	Improve glycemic control in T2DM	• The 6th available GLP1RA, and the 2nd once-daily GLP1RA • No clinically significant difference in glycemic control in head-to-head studies versus liraglutide or exenatide twice daily (Byetta) • No benefit or worsening of cardiovascular risk from the ELIXA outcomes trial • Offers no compelling advantages over existing UF agents; once weekly GLP1RAs are step-preferred	• NF and non step-preferred • Add to mail order list (no exemptions)

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
lixisenatide/ Insulin glargine (Soliqua)	GLP1RA	• exenatide (Bydureon) • albiglutide (Tanzeum) • lixisenatide (Adlyxin) • liraglutide/insulin degludec (Xultophy) – not launched yet • glargine (Lantus)	Adjunct to diet and exercise to improve glycemic control in adults with T2DM inadequately controlled on basal insulin (< 60 units daily) or lixisenatide	• First insulin/GLP1RA combination to reach market • Not approved for treatment-naïve patients • As per the package insert, the patient must be stabilized on both individual components first • Comparative trials versus glargine alone (2 studies) and lixisenatide alone (1 study). Results varied; however, two drugs provided greater glycemic control than one drug • Offers no compelling advantages other than providing a fixed-dose combination product	• NF and non step-preferred • Add to mail list (no exemptions)
tenofovir alafenamide (Vemlidy)	Hepatitis B Agents	• entecavir (Baraclude) • tenofovir disoproxil (Viread)	Treatment of chronic hepatitis B virus infection in adults with compensated liver disease	• Tenofovir alafenamide (Vemlidy) developed to reduce systemic exposure while maintaining efficacy over tenofovir disoproxil (Viread) • Vemlidy appears to provide a more favorable renal and bone safety profile in the treatment of chronic hepatitis B virus (HBV) in adults relative to Viread, with similar clinical efficacy • Preferred initial therapy for adults with immune active chronic HBV (HBeAg-positive or –negative)	• UF • Exempt from mail; consider adding HBV drugs in the future
rucaparib (Rubraca)	Oral Oncologic Agents	• olaparib (Lynparza)	Monotherapy in advanced ovarian cancer with BRCA gene mutation who have received at least 2 chemotherapies	• 2nd available PARP (Poly ADP-Ribose Polymerase) inhibitor for ovarian cancer • Intended for advanced ovarian cancer with BRCA gene mutation who have received at least 2 chemotherapies	• UF • Exempt from mail

Appendix F—Mail Order Status of Medications Designated Nonformulary During the February 2017 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
Feb 2017	**Antibiotics: Tetracyclines** Doxycycline and minocycline products with labeling for acne and rosacea are suitable for mail. ▪ ORACEA and generics (doxycycline monohydrate 40 mg DR/IR) ▪ SOLODYN and generics (minocycline ER) **Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")**: ▪ ADLYXIN (lixisenatide) ▪ BASAGLAR KWIKPEN (insulin glargine) ▪ RAYALDEE (calcifediol) ▪ SOLIQUA (lixisenatide/insulin glargine)	**HCV DAAs** Acute use exception applies **Antibiotics: Tetracyclines** Doxycycline products with labeling for susceptible infections are not appropriate for mail – acute use exception would apply. ▪ DORYX (doxycycline hyclate DR tabs) ▪ DORYX MPC (doxycycline hyclate DR modified polymer coats tabs) ▪ ACTICLATE (doxycycline hyclate scored and unscored tabs) **Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")** ▪ BROMSITE (bromfenac 0.075% ophthalmic solution)

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
Feb 2017	**Hepatitis C Virus (HCV) Agents – Direct Acting Antivirals (DAAs) Subclass**	UF subclass review Previously reviewed May 2015; Nov 2012	▪ Extended Core Formulary: No DAA selected ▪ peginterferon alfa-2a (Pegasys) ▪ ribavirin 200 mg capsules (generics); excludes RibaPak formulation	**UF Step-Preferred** ▪ ledipasvir/sofosbuvir (Harvoni) **UF Non Step-Preferred** ▪ daclatasvir (Daklinza) ▪ sofosbuvir / velpatasvir (Epclusa) ▪ simeprevir (Olysio) ▪ sofosbuvir (Sovaldi) ▪ paritaprevir / ritonavir/ ombitasvir (Technivie) ▪ paritaprevir / ritonavir/ ombitasvir / dasabuvir XR (Viekira XR) ▪ paritaprevir /ritonavir/ ombitasvir / dasabuvir Pak (Viekira Pak) ▪ grazoprevir / elbasvir (Zepatier)	▪ None	Pending signing of the minutes / 30 days The effective date is Jun 7, 2017	▪ Manual PA required ▪ QLs apply; 28-day supply	▪ Must try Harvoni first in all new users before the other HCV DAAs (See Appendix C)
Feb 2017	**Antibiotics: Tetracyclines Subclass**	UF subclass; not previously reviewed	▪ Doxycycline hyclate 100 mg caps (generic)	**UF –Step-Preferred:** ▪ doxycycline hyclate IR 50 mg, 75 mg, 150 mg, 200 mg tabs and caps (generic) ▪ doxycycline hyclate IR 100 mg tabs (generic) ▪ doxycycline monohydrate IR 50 mg, 75 mg, 100 mg, 150 mg, 200 mg tabs & caps (generic) ▪ minocycline IR 50 mg, 75 mg, 100 mg tabs and caps (generic)	**NF – Non Step-Preferred:** ▪ doxycycline hyclate (Acticlate) ▪ doxycycline hyclate DR (Doryx) ▪ doxycycline hyclate DR modified polymer coat (Doryx MPC) ▪ doxycycline hyclate (Targadox) ▪ doxycycline hyclate (Morgidox) ▪ doxycycline monohydrate 40 mg	Pending signing of the minutes / 90 days The effective date is August 9, 2017	▪ Step therapy applies to the subclass See Appendix C.	▪ Note: tetracycline 250 mg and 500 mg removed from the BCF. ▪ Children under the age of 13 are exempt from step therapy

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
				UF –Not Subject to Step ▪ doxycycline calcium/ monohydrate 25 mg/5 mL, 50 mg/5 mL suspension (generic) ▪ tetracycline 250 mg, 500 mg caps ▪ demeclocycline HCl 150 mg, 300 mg caps (generic)	IR/DR (Oracea and generics) ▪doxycycline monohydrate (Monodoxyne NL) ▪doxycycline monohydrate (Adoxa) ▪doxycycline monohydrate (Monodox) ▪minocycline ER 45 mg, 90 mg, 135 mg ER (generics) ▪minocycline ER 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn)			

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

Appendix H—Table of Abbreviations

AASLD/IDSA	American Association for the Study of Liver Diseases/Infectious Diseases Society of America
BCF	Basic Core Formulary
BIA	budget impact analysis
BRCA	breast cancer
CKD	chronic kidney disease
CMA	cost minimization analysis
CrCl	creatinine clearance
DAA	direct acting antiviral agent
DHA	Defense Health Agency
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER+	estrogen receptor positive
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GLP1RA	glucagon-like peptide-1 receptor agonist
GT	genotype
HBV	hepatitis B virus
HCV	hepatitis C virus
HER2	human epidermal growth factor receptor 2
IR	immediate release
LHRH	luteinizing hormone-releasing hormone
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NF	nonformulary
P&T	Pharmacy and Therapeutics
PA	prior authorization
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPI	proton pump inhibitor
QLs	quantity limits
RAVs	resistance-associated variants
SIADH	syndrome of inappropriate antidiuretic hormone secretion
SR	sustained release
SU	sulfonylurea
SVR12	sustained virologic response at 12 weeks
T2DM	type 2 diabetes mellitus
TIBs	targeted immunomodulatory biologics
TRT	testosterone replacement therapies
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs
XR	extended release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INTERIM MEETING

Addendum March 7, 2017

I. UNIFORM FORMULARY (UF) DRUG CLASS REVIEWS

A. Proton Pump Inhibitors (PPIs)

Background—Following the February 2017 DoD P&T Committee meeting, the Pharmacy Operations Division became aware of a contract cancellation that would significantly impact MHS expenditures for the PPI Drug Class. An interim meeting was held to determine the clinical and cost-effectiveness, and UF status of the PPIs. The PPIs were previously evaluated for UF status at the May 2007 meeting. Current automated prior authorization (PA) (step therapy) requiring a trial of omeprazole, esomeprazole (Nexium), pantoprazole, or rabeprazole applies to new users presenting with a prescription for a nonformulary PPI.

Relative 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. Recent updates to the safety of the PPIs were presented at the November 2016 P&T Committee meeting. There have been three drug safety communications from the U.S. Food and Drug Administration relating to long-term safety concerns with the PPIs as a class. The P&T Committee did not find new clinical evidence that would alter the conclusion from 2007 that the PPIs are highly therapeutically interchangeable. Risks of long-term use (>1 year) without a clear indication for use could outweigh the benefits of the PPIs. Deprescribing should be considered for appropriate patients.

Relative Cost-Effectiveness Analysis and Conclusion—The current costs for the PPIs were evaluated. Nexium brand is exponentially more expensive than therapeutically equivalent generic PPIs.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) esomeprazole (Nexium brand and generics) be designated nonformulary and non step-preferred. Nonformulary PPIs would be subject to the requirement that they generally be available only in the Mail Order Pharmacy, regardless of generic status. The formulary recommendation is as follows:

    - UF and Step-Preferred:
        - omeprazole (Prilosec generics)
        - pantoprazole (Protonix generics)
        - rabeprazole tablets (Aciphex generics)

- UF and Non Step-Preferred:
    - omeprazole 40 mg capsule (Prilosec)
    - rabeprazole sprinkles (Aciphex sprinkles)

- NF and Non Step-Preferred:
    - esomeprazole (Nexium brand and generics)
    - esomeprazole strontium
    - dexlansoprazole (Dexilant)
    - lansoprazole (Prevacid)
    - omeprazole/sodium bicarbonate (Zegerid)

- This recommendation includes step therapy (automated PA), which requires a trial of omeprazole, pantoprazole, and rabeprazole in new and current users presenting with a prescription for esomeprazole, and in new users presenting with a prescription for one of the other nonformulary PPIs.
- As part of this recommendation, the current Tier 1 copayment for Nexium will move to the Tier 3 nonformulary copayment at the Retail Network and Mail Order Pharmacy.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) removing esomeprazole from the BCF and adding pantoprazole to the BCF. Refer to the addendum signed by RADM C. Chinn for VADM R.C. Bono, Director, Defense Health Agency, on March 20, 2017.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) MN criteria for esomeprazole (Nexium), consistent with the other nonformulary PPIs. No changes to the current MN criteria for the other nonformulary PPIs were recommended. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: AUTOMATED (STEP THERAPY) AND MANUAL PA CRITERIA***—Existing automated PA (step therapy) requires a trial of omeprazole, Nexium, pantoprazole, and rabeprazole prior to use of a nonformulary PPI.

   The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) modifying the existing step therapy and manual PA criteria to require all new and current users of esomeprazole to try omeprazole, pantoprazole, and rabeprazole first. See Appendix C for the full criteria.

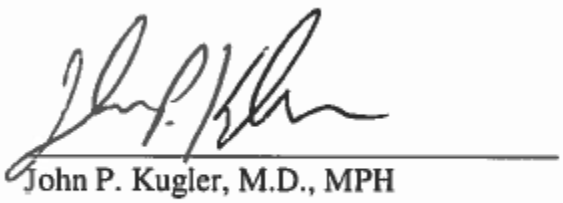
5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) 1) an effective date of the first Wednesday that occurs no later than 90 days after signing of the minutes in all points of service; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date will be no later than June 28, 2017.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

Appendix A—Table of Medical Necessity Criteria
Appendix B—Table of Prior Authorization Criteria
Appendix C—Table of Implementation Status of UF Recommendations/Decisions Summary

SUBMITTED BY



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

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

RADM Colin Chinn, MC, USN
Acting Deputy Director, DHA
for R.C. Bono, VADM, MC, USN,
Director, DHA

31 MAR 2017
Date

Appendix A—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• esomeprazole (Nexium) **Proton Pump Inhibitors (PPIs)**	• Use of ALL formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from ALL formulary agents • All formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole tablets (Aciphex, generics)

Appendix B—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• esomeprazole (Nexium) **Proton Pump Inhibitors (PPIs)**	PA criteria apply to all new and current users of esomeprazole (Nexium). Automated PA criteria: The patient has filled a prescription for omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole tablets (Aciphex, generics) at any Military Health Service (MHS) pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order), during the previous 180 days. AND Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if: • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole tablets (Aciphex, generics), and the patient had an inadequate response. • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics), and the patient was unable to tolerate them due to adverse effects. • Treatment with omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).

Appendix C—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 (NF) MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Mar 2017 Interim	**Proton Pump Inhibitors (PPIs)**	UF class review	**Step-Preferred:** ▪ omeprazole (Prilosec generics); excludes 40 mg branded product ▪ pantoprazole (Protonix, generics)	**UF and Step-Preferred:** ▪ rabeprazole tabs (Aciphex generics) **UF and Non Step-Preferred:** ▪ omeprazole 40 mg cap (Prilosec) ▪ rabeprazole sprinkles (Aciphex sprinkles)	**NF and Non Step-Preferred:** ▪ **esomeprazole (Nexium brand and generic)** ▪ esomeprazole strontium ▪ dexlansoprazole (Dexilant) ▪ lansoprazole (Prevacid) ▪ omeprazole/sodium bicarbonate Zegerid)	Pending signing of the minutes / BCF change at signing and NF no later than 90 days	See comments	▪Nexium removed from the BCF and made NF and non step-preferred ▪Pantoprazole generic added to the BCF ▪All new and current users of Nexium must try omeprazole, pantoprazole, and rabeprazole first (See Appendix C)

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS

INTERIM MEETING

Addendum March 20, 2017

BASIC CORE FORMULARY (BCF) CLARIFICATION

A. Proton Pump Inhibitors (PPIs)—Esomeprazole (Nexium)

Following the February 2017 DoD P&T Committee meeting, the Pharmacy Operations Division became aware of a contract cancellation that would significantly impact Military Health System expenditures for the PPI Drug Class. An interim meeting was held on March 7, 2017, to determine the clinical and cost-effectiveness, and Uniform Formulary (UF) status of the PPIs.

The PPIs were last reviewed for UF Placement in May 2007. At that time, omeprazole (Prilosec generic) and esomeprazole (Nexium) were designated as BCF and step-preferred, with the remainder of the PPIs designated as nonformulary and non step-preferred. Since that time, several cost-effective generic formulations have entered the market, and pantoprazole and rabeprazole have been designated with UF and step-preferred status. The branded esomeprazole (Nexium) product is exponentially more expensive than therapeutically equivalent generic PPIs. Generic formulations of esomeprazole are available, but are not Trade Agreements Act (TAA) compliant.

1. ***COMMITTEE ACTION: ESOMEPRAZOLE (NEXIUM) REMOVAL FROM THE BCF***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following for the PPIs, to be implemented upon signing:
    - Remove esomeprazole (Nexium) from the BCF,
    - Maintain omeprazole (Prilosec generics) on the BCF; note that this excludes 40 mg Prilosec capsules; and,
    - Add pantoprazole (Protonix generics) to the BCF.

SUBMITTED BY

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

DECISION ON RECOMMENDATIONS

RADM Colin Chinn, MC, USN
Acting Deputy Director, DHA
for R.C. Bono, VADM, MC, USN,
Director, DHA