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)

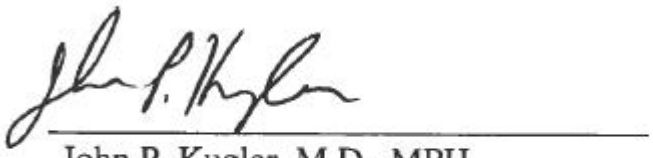
Appendix G—Mail Order Status of Medications Designated Nonformulary during the November 2017 DoD P&T Committee Meeting

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

Appendix I—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



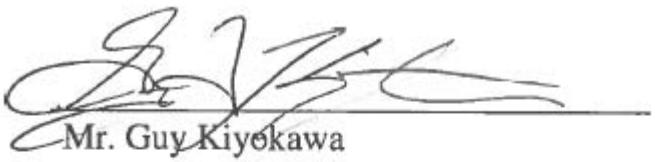
John P. Kugler, M.D., MPH
DoD P&T Committee Chair

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 Meeting	ADD to the Mail Order Requirement (NOT Exempted from Mail Order Requirement)	Exempted from Mail Order Requirement (Do NOT Add)
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