DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

August 2015

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 12 and 13, 2015, at the Defense Health Agency (DHA), Pharmacy Operations Division, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May Minutes**—Lt. Gen. Douglas J. Robb, DO, MPH, Director, DHA, approved the minutes from the May 2015 DoD P&T Committee meeting on July 20, 2015.

2. **Correction to the May 2015 Minutes**

   a) **Line Extension, Formulary Status Clarification—Testosterone Replacement Products: Testosterone Gel (Vogelxo)**

   At the May 2015 P&T Committee meeting, the formulary status of Vogelxo, an AB-rated generic to the proprietary product Testim, was presented as a line extension. Vogelxo was recommended to follow the same formulary placement and prior authorization criteria as its parent drug. The formulary status of Vogelxo was further clarified that it remain Uniform Formulary and non step-preferred, similar to the formulary status for Testim.

III. REQUIREMENTS

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

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. (See Section XII.)

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

A. Long-Acting Muscarinic Antagonist (LAMA): Umeclidinium (Incruse Ellipta)

Umeclidinium (Incruse Ellipta) is an oral inhaler approved for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). There are no studies evaluating reduction in COPD exacerbations as a primary endpoint. Similar to tiotropium (Spiriva), umeclidinium has a long duration of action. The FDA-approved dose of 62.5 mcg was based on trials showing umeclidinium produced statistically and clinically significant improvements in the forced expiratory volume in one second (FEV_1). The safety profile is similar to the other LAMAs.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that the main clinical benefits of umeclidinium are its one puff, once daily dosing, and the ease of use of the Ellipta device. Based on active controlled trials, the changes in FEV_1 with umeclidinium appear similar to that achieved with tiotropium.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) was performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that umeclidinium (Incruse Ellipta) was cost effective compared with other LAMA inhalers on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) umeclidinium (Incruse Ellipta) be designated formulary on the UF, based on clinical and cost effectiveness. Umeclidinium was not recommended for addition to the BCF.

2. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for umeclidinium (Incruse Ellipta), consistent with the FDA-approved package labeling. See Appendix D.

3. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE (TFL) BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***
The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding umeclidinium (Incruse Ellipta) to the maintenance drug list, due to the potential for additional cost avoidance and for consistency with other inhaled bronchodilators on the UF that are already included on the list.

4. ***COMMITTEE ACTION: UF AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the UF and Mail Order Pharmacy implementation become effective upon signing of the minutes.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Targeted Immunomodulatory Biologics (TIBs): Secukinumab (Cosentyx)

Secukinumab (Cosentyx) is a first-in-class human interleukin-17A (IL-17A) receptor antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

The TIBs were previously reviewed for UF placement in August 2014; adalimumab (Humira) was selected as the BCF and step-preferred drug. Step therapy, manual prior authorization (PA), and QLs apply to all the TIBs. In February 2015, the P&T Committee recommended manual PA criteria and QLs for secukinumab, consistent with the class.

- Five TIBs are approved for treating psoriasis: adalimumab (Humira), etanercept (Enbrel), ustekinumab (Stelara), apremilast (Otezla), and secukinumab (Cosentyx).
- In clinical trials, secukinumab demonstrated superior efficacy to placebo, etanercept, and ustekinumab in treating moderate to severe plaque psoriasis based on the Psoriasis Area and Severity Index 75 (PASI 75) score, which measures the severity and extent of psoriasis. There are no head-to-head trials comparing secukinumab and adalimumab.
- Secukinumab is well tolerated. The rates of adverse events (AEs) do not differ significantly for secukinumab and other TIBs.
- The FDA-approved 300 mg dose requires administration of two 150 mg injections, which is a potential inconvenience to the patient.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent), despite its unique mechanism of action, secukinumab (Cosentyx) offers no clinically compelling advantages over the existing TIBs on the UF approved for plaque psoriasis.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that secukinumab (Cosentyx) was cost effective compared with other TIBs on the UF approved for treating plaque psoriasis.

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

    - Secukinumab (Cosentyx) be designated formulary and non-preferred based on cost effectiveness and the previously accepted solicitation condition sets from the August 2014 P&T Committee TIBs Drug Class review. A trial of adalimumab (Humira) is required prior to use of Cosentyx.

- The current PA and QLs for Cosentyx, previously approved at the February 2015 P&T Committee meeting, be continued.

2. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding secukinumab (Cosentyx) to the maintenance medication drug list, as the other TIBs are included on the list.

3. ***COMMITTEE ACTION: UF AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the UF and Mail Order Pharmacy implementation become effective upon signing of the minutes.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Non-Insulin Diabetes Drugs: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

The SGLT2 inhibitors and their fixed-dose combinations with metformin and dipeptidyl dipeptidase-4 (DPP-4) inhibitors were reviewed for formulary placement. They are indicated as adjunctive therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).

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

- As a subclass, the SGLT2 inhibitors are effective in lowering hemoglobin A1c (A1c) by 0.4% to 1% when used as monotherapy and, when added on to other drugs, by 0.5% to 2% as part of dual therapy and by 0.3% to 1.3% as part of triple therapy.
- There are no head-to-head trials between any of the SGLT inhibitors, although there do not appear to be clinically relevant differences in their effects on lowering A1c when used as monotherapy or added on to other diabetes drugs.
- In addition to their effects on glycemic control, other actions of the SGLT2 inhibitors include a reduction in triglycerides and a modest increase in both low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol. The SGLT2 inhibitors also slightly decrease systolic blood pressure (by 4 mm Hg to 6 mm Hg) and body weight (reduction of 1.8 kg).

- The most common adverse drug reactions for all the SGLT2 inhibitors are female genital mycotic infections and urinary tract infections. The SGLT2 inhibitors are contraindicated in severe renal impairment, although empagliflozin and canagliflozin can be used in patients with estimated glomerular filtration rates as low as 45 mL/min. A recent FDA safety alert details the risk of ketoacidosis with the subclass. Patients with a history of bladder cancer should avoid use of dapagliflozin.
- Empagliflozin and dapagliflozin have a lower risk of drug-drug interactions than canagliflozin.
- The cardiovascular (CV) safety profile of SGLT2 inhibitors is currently unknown. At the time of the August 2015 DoD P&T Committee meeting, there were no published long-term CV outcomes trials.
- There is a high degree of therapeutic interchangeability between the SGLT2 inhibitors.
- The SGLT2 inhibitors have a limited role in treating T2DM due to a lack of clinically, compelling advantages over alternative therapies in lowering A1c, an unknown CV safety profile, and undesirable side effects, including genital mycotic and urinary tract infections.

Overall Relative Clinical Effectiveness Conclusion: Other than their potential for weight loss, the SGLT2 inhibitors offer no additional clinical advantages over the other non-insulin diabetes drugs on the UF.

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

- CMA results showed that empagliflozin (Jardiance) and empagliflozin/linagliptin (Glyxambi) were the most cost-effective SGLT2 inhibitors, followed by dapagliflozin (Farxiga), dapagliflozin/metformin (Xigduo XR), and lastly followed by canagliflozin (Invokana) and canagliflozin/metformin (Invokamet).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary (and step-preferred) or NF (and non step-preferred) on the UF. BIA results showed that designating empagliflozin (Jardiance) and empagliflozin/ linagliptin (Glyxambi) as formulary and step-preferred resulted in the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following:
    - UF and step-preferred:
        - Empagliflozin (Jardiance)
        - Empagliflozin/linagliptin (Glyxambi)
    - NF and non step-preferred:
        - Canagliflozin (Invokana)
        - Canagliflozin/metformin (Invokamet)

- Dapagliflozin (Farxiga)
- Dapagliflozin/metformin extended release (Xigduo XR)

- This recommendation includes step therapy (automated PA), which requires a trial of empagliflozin or empagliflozin/metformin prior to use of the NF, non step-preferred SGLT2 inhibitors in all new and current users. PA criteria currently apply to the SGLT2 inhibitors subclass.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee did not recommend (16 for, 0 opposed, 1 abstained, 0 absent) any of the SGLT2 inhibitors for addition to the BCF. Several other drugs from the non-insulin diabetes drug subclasses are designated with BCF status, including metformin IR, metformin ER, glyburide, glyburide micronized, glipizide, sitagliptin (Januvia), and sitagliptin/metformin (Janumet).

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/metformin ER (Xigduo XR). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) AND MANUAL PA CRITERIA***—Existing automated PA (step therapy) requires a trial of metformin, a sulfonylurea, or a DPP-4 inhibitor prior to use of a SGLT2 inhibitor.

   Additionally, empagliflozin-containing products (Jardiance or Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users must try a preferred empagliflozin product before trying canagliflozin- or dapagliflozin-containing products.

   The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) modifying the existing PA criteria to require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses prior to use of an SGLT2 inhibitor in new users. The P&T Committee also recommended step therapy criteria for Invokana, Invokamet, Farxiga, and Xigduo XR. See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding the SGLT2 inhibitors to the maintenance medication drug list due to the potential for additional cost avoidance. Other non-insulin diabetes drug subclasses are

included on the list, including the DPP-4 inhibitors, thiazolidinediones, glucagon-like peptide-1 receptor agonists, and sulfonylureas.

6. ***COMMITTEE ACTION: UF, PA, AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)

The GLP1RA subclass includes exenatide once weekly (Bydureon), exenatide twice daily (Byetta), liraglutide (Victoza), albiglutide (Tanzeum), and dulaglutide (Trulicity). The GLP1RAs that are not indicated for treating diabetes were excluded from this review (i.e., liraglutide is also available under the trade name Saxenda for weight loss).

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

- Metformin remains the first-line treatment in all patients with T2DM, unless contraindications exist.
- The GLP1RAs are all indicated for monotherapy as an adjunct to diet and exercise to improve glycemic control in adult patients with T2DM. They are not first-line therapies.
- The GLP1RAs are self-injectable medications that differ in the frequency of administration. Trulicity, Tanzeum, and Bydureon have the advantage of once weekly dosing; Victoza is dosed once daily; and, Byetta is dosed twice daily (BID).
- The GLP1RAs decrease A1c on average approximately 1% to 2% from baseline, when used as monotherapy or in combination with other oral agents.
- The results of seven head-to-head trials between the GLP1RAs do not show clinically significant differences in effects on glycemic control.
- Weight loss was observed in all seven head-to-head studies. When used as monotherapy or as an add-on agent, a 2 kg to 3 kg weight loss is expected with the GLP1RAs.

- GLP1RAs either do not adversely impact or provide small improvements in blood pressure. The subclass may also improve lipid parameters.
- The reported incidence of hypoglycemia with GLP1RAs is low, ranging from 3% to 9%. However, when a GLP1RA is used concurrently with a sulfonylurea, the incidence increases from 13% to 40%. Albiglutide has the lowest incidence of hypoglycemia when used with a sulfonylurea or as monotherapy.
- Nausea is the most common AE among all the GLP1RAs. Tanzeum has the lowest incidence of nausea (11.1%) compared to Bydureon (14.4%), Victoza (22.7%), Trulicity (12.1 % to 21.1%), or Byetta (29.9%).
- All the GLP1RAs are contraindicated for use in patients with pancreatitis. All the GLP1RAs except Byetta carry black box warnings for medullary thyroid cancer and multiple endocrine neoplasia syndrome type 2.
- There are no completed trials with any FDA-approved GLP1RA that assess long-term CV outcomes; CV safety studies are underway.
- Tanzeum and Trulicity have an advantage in offering a smaller needle size for patient convenience.
- Trulicity, Byetta, and Victoza have an advantage as they do not require mixing prior to administration.

Overall Relative Clinical Effectiveness Conclusion—The GLP1RAs have a high degree of therapeutic interchangeability, with no clinically relevant differences between the individual products.

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

- CMA results showed that exenatide twice daily (Byetta) was the most cost-effective GLP1RA, followed by albiglutide (Tanzeum), exenatide once weekly (Bydureon), dulaglutide (Trulicity), and liraglutide (Victoza).
- BIA was performed to evaluate the potential impact of designating selected agents as step-preferred, formulary, or NF on the UF. BIA results showed that designating exenatide once weekly (Bydureon) and albiglutide (Tanzeum) as formulary and step-preferred agents, with no grandfathering (i.e., step therapy would apply to all new and current users of a GLP1RA), demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (13 for, 2 opposed, 2 abstained, 0 absent) the following:
    - UF and step-preferred:
        - Exenatide once weekly (Bydureon)
        - Albiglutide (Tanzeum)
    - NF and non step-preferred:

- Exenatide twice daily (Byetta)
- Dulaglutide (Trulicity)
- Liraglutide (Victoza)

- This recommendation includes step therapy (automated PA), which requires a trial of exenatide once weekly (Bydureon) and albiglutide (Tanzeum) prior to use of the NF, non-preferred GLP1RA drugs, in all new and current users. PA criteria currently apply to the GLP1RAs subclass.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding exenatide once weekly (Bydureon) to the BCF.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for exenatide twice daily (Byetta), dulaglutide (Trulicity), and liraglutide (Victoza). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) AND MANUAL PA CRITERIA***—Existing automated PA (step therapy) criteria for the GLP1RAs requires a trial of metformin or a sulfonylurea first, based on positive long-term outcomes data with metformin and the sulfonylureas.

   Additionally, exenatide once weekly (Bydureon) and albiglutide are now recommended as the preferred GLP1RAs. New and current users must try Bydureon and Tanzeum prior to using Byetta, Trulicity, or Victoza.

   The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) maintaining the existing PA criteria, requiring a trial of metformin or sulfonylurea prior to use of a GLP1RA in all current and new users. The P&T Committee also recommended step therapy criteria for Byetta, Trulicity, and Victoza. See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding the GLP1RAs to the maintenance medication drug list due to the potential for additional cost avoidance.

6. ***COMMITTEE ACTION: UF, PA, AND MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all POS; and, 2) DHA send a letter to beneficiaries affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

☑ Approved ☐ Disapproved

Director, DHA, Decision:

Approved, but modified as follows:

C. Oral Oncology Drugs: Chronic Myelogenous Leukemia (CML)

The tyrosine kinase inhibitors (TKIs) used for treating CML were reviewed by the P&T Committee.

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

- Imatinib (Gleevec), nilotinib (Tasigna), and dasatinib (Sprycel) are approved in the United States for first-line therapy of chronic phase CML. Guidelines from the National Cancer Care Network and international guidelines also support the use of these three TKIs as first-line therapies
- Head-to-head trials between imatinib and the second generation TKIs found that dasatinib and nilotinib yield superior and more rapid hematologic, cytogenetic, and molecular responses in patients with chronic phase CML. However, to date, there are no statistically significant differences in overall survival between imatinib and the second generation TKIs.
- Imatinib advantages include pending generic availability, a well-known safety profile, and additional FDA indications other than CML. AEs include fatigue, myalgias, and fluid retention.
- Advantages of dasatinib and nilotinib compared to imatinib include fewer progressions to acute phase CML or blast phase CML. The second generation TKIs are preferred for use in moderate to high risk patients.
- Dasatinib (Sprycel) has been associated with pleural effusions and pulmonary arterial hypertension.
- Nilotinib (Tasigna) requires twice daily administration and a fasting window. It has a black box warning for QT interval prolongation, and has been associated with pancreatitis and hyperglycemia.

- Bosutinib (Bosulif) is currently limited to the second-line setting; it has not shown an advantage over imatinib when used as first-line therapy for chronic phase CML. It causes significant gastrointestinal toxicity, particularly diarrhea.
- Ponatinib (Iclusig) is the only TKI that is effective in patients with a specific mutation (T315I+). It has significant safety concerns, including vasoocclusive events, which led to its temporary removal from the market.

Overall Relative Clinical Effectiveness Conclusion: The P&T Committee concluded that the choice of CML drug depends on patient comorbidities, provider experience, continued response to initial treatment, prior treatment, and AE profiles.

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

- CMA results showed imatinib (Gleevec) was the most cost-effective TKI for CML.
- BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and formulary, non-preferred and formulary, and formulary without a step-therapy requirement. BIA results showed that all scenarios modeled were similar in projected cost avoidance to the Military Health System (MHS).

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

    - UF (no-step scenario):
        - Imatinib (Gleevec)
        - Dasatinib (Sprycel)
        - Nilotinib (Tasigna)
        - Bosutinib (Bosulif)
        - Ponatinib (Iclusig)
    - NF: None

2. ***COMMITTEE ACTION: SECTION 716 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TFL BENEFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding nilotinib (Tasigna) to the TFL Pharmacy Drug List. This is consistent with other CML agents included on the program that are not subject to a limited distribution process.

3. ***COMMITTEE ACTION: UF AND NILOTINIB (TASIGNA) AVAILABILITY THROUGH MAIL ORDER PHARMACY IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the UF and Mail Order Pharmacy implementation plans become effective upon signing of the minutes.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

D. Narcotic Analgesic Drugs: Long Acting High Potency Narcotic Analgesics

The Narcotic Analgesic Drug Class was previously reviewed in February 2007, and included both immediate release (IR) and extended release (ER) products. The long acting high potency opioids subclass includes the extended release/long acting (ER/LA) generic and branded formulations of morphine sulfate, morphine/naltrexone, fentanyl transdermal system, hydrocodone, hydromorphone, oxymorphone, oxycodone, and tapentadol. Sustained release morphine sulfate (MS Contin, generics) is currently the BCF agent.

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following for the long acting narcotic analgesics:

- The long acting opioids are recognized as the mainstay of chronic pain management, with well-documented evidence of their efficacy in the short-term.
- Current guidelines do not state a preference for the use of one long acting high potency narcotic analgesic over another in the treatment of moderate to severe pain.
- Tapentadol ER (Nucynta ER) is the only long acting narcotic analgesic with an FDA-approved indication for the treatment of neuropathic pain associated with diabetic peripheral neuropathy.
- There is no new evidence regarding the comparative effectiveness of the long acting high potency narcotics. Clinical trials differ significantly in terms of study designs, patient characteristics, types of pain treated, and titration schedules.
- Meaningful conclusions cannot be drawn from indirect comparisons of the drugs. Two systematic reviews concluded that there is insufficient evidence to suggest clinically relevant differences in efficacy and safety among the long acting narcotics.
- In general, the long acting opioids share similar safety profiles. Common AEs, include constipation, nausea, vomiting, and dizziness.
- While abuse-deterrent formulations offer a potential barrier to abuse via intravenous and intranasal routes, they have yet to demonstrate the ability to

prevent abuse altogether. Abusers can still overcome the technologies in these formulations via over consumption.

- Several DoD resources for providers are available to help ensure safe opioid prescribing and include the Sole Provider Program, the Prescription Monitoring Program, "Do no harm" mandatory training, Project ECHO (Extension for Community Healthcare Outcomes), and the VA/DoD Clinical Practice Guidelines "Management of Opioid Therapy for Chronic Pain" Toolkit.

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

- CMA results showed that generic sustained release morphine sulfate (MS Contin) was the most cost-effective ER/LA opioid.

- BIA was performed to evaluate the potential impact of scenarios designating selected ER/LA opioid agents as formulary or NF on the UF. BIA results showed that scenarios where all generic and branded formulations of the long acting high potency narcotic analgesics are designated formulary on the UF demonstrated cost avoidance for the MHS.

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

    - UF (no step scenario):
        - Fentanyl transdermal system (Duragesic, generics)
        - Hydrocodone ER (Hysingla ER)
        - Hydrocodone ER (Zohydro ER)
        - Hydromorphone ER (Exalgo, generics)
        - Morphine sulfate sustained release (MS Contin, generics)
        - Morphine ER (Avinza, Kadian, generics)
        - Morphine ER/naltrexone (Embeda)
        - Oxycodone controlled release (Oxycontin)
        - Oxymorphone ER (Opana ER, generics)
        - Tapentadol ER (Nucynta ER)

    - NF: None

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VI. BCF CLARIFICATION

A. Attention Deficit Hyperactivity Disorder (ADHD) Drugs—Methylphenidate LA (Ritalin LA)

The ADHD drugs were last reviewed in February 2012. At that time, Ritalin LA was added to the BCF, as it was the most cost-effective long acting methylphenidate formulation available at Military Treatment Facilities (MTFs). In July 2015, a new Ritalin LA dosage strength (60 mg) became available, which is significantly more costly than the other dosages. The Ritalin LA 60 mg dosage has the same FDA-approved indication as the other dosage strengths. There is currently low utilization of the other Ritalin LA dosages at the MTFs. The ADHD stimulants will be reviewed in November 2015.

1. ***COMMITTEE ACTION: BCF CLARIFICATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent), upon signing of the minutes, methylphenidate LA 60 mg (Ritalin LA) be excluded from the BCF; it will remain on the UF.

Director, DHA, Decision: ☐ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors: Alirocumab (Praluent) and Evolocumab (Repatha) PA Criteria**—The PCSK9 inhibitors are a new class of biologic drugs that lower LDL cholesterol. Alirocumab (Praluent) was approved on July 24, 2015, and is administered as biweekly subcutaneous injections. The second drug in the class and evolocumab (Repatha) is anticipated to obtain FDA approval on August 27, 2015.

   Praluent is indicated as an adjunct to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) who require additional LDL lowering. The product labeling states that the effect of Praluent on CV morbidity and mortality has not been determined. PA criteria were recommended for the PCSK9 inhibitors due to the lack of data on CV morbidity and mortality, unknown long-term safety profile, and anticipated high cost.

   a) ***COMMITTEE ACTION: PCSK9 INHIBITOR ALIROCUMAB (PRALUENT) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for alirocumab (Praluent) in

all new and current users. PA will be approved for patients with HeFH or patients with ASCVD with LDL levels greater than 100 mg/dL despite maximally tolerated statins doses (atorvastatin 40 mg to 80 mg and rosuvastatin 20 mg to 40 mg, or any statin at maximally tolerated doses in combination with ezetimibe). See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: ALIROCUMAB (PRALUENT) QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for alirocumab (Praluent) of two syringes or pens per 30 days in the Retail Network and six syringes or pens per 90 days in the MTFs and Mail Order Pharmacy. See Appendix D.

c) ***COMMITTEE ACTION: PCSK9 INHIBITOR EVOLOCUMAB (REPATHA) PA CRITERIA***—Due to the impending FDA approval of evolocumab, the P&T Committee also recommended (16 for, 0 opposed, 1 abstained, 0 absent), contingent upon FDA approval, manual PA criteria for evolocumab (Repatha) in all new and current users. PA will be approved for the FDA-approved indications and age range as noted in the product labeling. If the FDA-approved indications for Repatha are similar to Praluent, than the same PA criteria will apply to Repatha. See Appendix C for the full criteria.

INTERIM P&T COMMITTEE MEETING—Following the August 2015 P&T Committee meeting, Repatha obtained FDA approval on August 27, 2015. Therefore, the DoD P&T Committee held an interim meeting on September 3, 2015, to confirm the PA criteria for Repatha, and determine QLs and MN criteria. The product labeling for Repatha is similar to Praluent, with the exception that, in addition to patients with HeFH and clinical ASCVD, Repatha is also approved for treating patients with homozygous familial hyper-cholesterolemia (HoFH), including pediatric patients from ages 13 to 17 years.

d) ***COMMITTEE ACTION: PCSK9 INHIBITOR EVOLOCUMAB (REPATHA) MN CRITERIA***—FDA approval of Repatha occurred on August 27, 2015, following the implementation of the "120-Day Innovator Drug Rule," which requires newly approved innovator drugs to be placed on the third tier of the UF until review by the P&T Committee. (See Section XI, Innovator Drugs, below.) The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Repatha. See Appendix B for the full criteria.

e) ***COMMITTEE ACTION: EVOLUCOMAB (REPATHA) QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the following QLs for evolocumab (Repatha):

- Patients with HeFH and ASCVD will be able to obtain two of the 140 mg syringes per 30 days in the Retail Network; and, six of the 140 mg syringes per 90 days in the MTFs and Mail Order POS. See Appendix D.
- Patients with HoFH will be able to obtain three of the 140 mg syringes per 30 days in Retail Network; and, nine of the 140 mg syringes per 90 days in the MTFs and Mail Order POS. See Appendix D.

f) ***COMMITTEE ACTION: PCSK9 INHIBITOR (PRALUENT AND REPATHA) PA, QLs, AND MN IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the PA, QLs, and MN implementation plans become effective upon signing of the minutes in all POS.

2. **Inhaled Corticosteroids (ICS): Fluticasone Furoate (Arnuity Ellipta) and Mometasone (Asmanex HFA) PA Criteria**—The FDA approved Arnuity Ellipta and Asmanex HFA in August and April 2014, respectively. The ICS products were reviewed by the P&T Committee in May 2014 and automated PA (step therapy) and manual PA criteria were approved. Fluticasone propionate (Flovent Diskus and Flovent HFA) are the step-preferred ICS products; the remaining ICS products are non step-preferred.

   Arnuity Ellipta and Asmanex HFA are approved for treating asthma in patients 12 years of age and older; Flovent Diskus is approved in patients as young as four years of age. Arnuity Ellipta and Asmanex HFA were recommended to follow the same PA criteria as the other non step-preferred ICS products.

   a) ***COMMITTEE ACTION: ICS PRODUCTS FLUTICASONE FUROATE (ARNUITY ELLIPTA) AND MOMETASONE (ASMANEX HFA) STEP THERAPY AND PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) step therapy and manual PA criteria for all new users of Arnuity Ellipta and Asmanex HFA, consistent with the current PA for the other non step-preferred ICS products. See Appendix C for the full criteria.

3. **ICS and Long-Acting Beta2-Adrenergic Agonist (LABA) Combinations: Fluticasone furoate/vilanterol (Breo Ellipta) Manual PA Criteria**—Fluticasone furoate/vilanterol (Breo Ellipta) is indicated for the long-term treatment of COPD. In April 2015, the FDA-approved indication was further expanded to include the daily treatment of asthma in patients aged 18 years and older. The ICS/LABA products were reviewed by the P&T Committee in February 2014, where automated PA (step therapy) and manual PA criteria were approved for patients older than 12 years. Fluticasone propionate/salmeterol (Advair Diskus and Advair HFA) are the step-preferred ICS/LABA products; the remaining ICS/LABA products are non step-preferred.

a) ***COMMITTEE ACTION: ICS AND LABA COMBINATION PRODUCT FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) updating the manual PA criteria for Breo Ellipta to include the expanded FDA-approved indication for treating patients who are at least 18 years of age with asthma. See Appendix C for the full criteria.

4. **Insulin Drugs: Miscellaneous Insulin Delivery Devices (Valeritas V-Go) MN Criteria**—Manual PA criteria for the V-Go insulin delivery device were first recommended in August 2014. V-Go was designated with NF status at the November 2014 P&T Committee meeting. The P&T Committee recommended updating the current V-Go MN criteria to ensure that prior authorization has been determined. A PA form should be completed and approved before V-go is dispensed at any MHS point of service.

   a) ***COMMITTEE ACTION: V-GO INSULIN DELIVERY DEVICE MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) adding the requirement for completion of an approved PA form prior to MN determination. See Appendix B for the full criteria.

   b) ***COMMITTEE ACTION: V-GO INSULIN DELIVERY DEVICE PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) implementation upon signing of the minutes in all POS.

5. **Pulmonary Fibrosis Drugs: Nintedanib (Ofev) and Pirfenidone (Esbriet) PA Criteria**—Ofev and Esbriet are two oral drugs that were FDA-approved in October 2014 for treatment of idiopathic pulmonary fibrosis (IPF). Ofev and Esbriet improve symptoms in IPF, as measured by a reduction in the decline in forced vital capacity, but have not been shown to decrease mortality. Manual PA criteria were recommended to ensure appropriate use of the drug for IPF diagnoses. See Appendix C for the full criteria.

   a) ***COMMITTEE ACTION: PULMONARY FIBROSIS DRUGS NINTEDANIB (OFEV) AND PIRFENIDONE (ESBRIET) PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Ofev and Esbriet, consistent with the FDA-approved product labeling for use in IPF. Prior authorization will expire after one year. See Appendix C for the full criteria.

6. **Alzheimer's Disease Drugs: Memantine Extended Release (Namenda XR) and Memantine Extended Release/Donepezil (Namzaric) Manual PA Criteria**
   Namenda XR and Namzaric are both approved for treatment of patients with moderate to severe dementia of Alzheimer's disease. Namenda XR is an ER formulation of

memantine that is dosed once daily, in contrast to memantine IR, which is dosed twice daily. There are no studies addressing whether once daily therapy improves efficacy of memantine.

Namzaric contains a fixed-dose combination of memantine ER and donepezil (Aricept, generics). Memantine IR and donepezil are both available in low-cost generic formulations. FDA approval of Namzaric was based on bioequivalence studies and not clinical trial data. These two products will be reviewed as new drugs in November 2015. PA criteria were recommended to ensure appropriate use.

a) ***COMMITTEE ACTION: MEMANTINE (NAMENDA XR) AND MEMANTINE ER/DONEPEZIL (NAMZARIC) MANUAL PA CRITERIA*** The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Namenda XR and Namzaric in new users, consistent with the FDA-approved product labeling for Alzheimer's disease. See Appendix C for the full criteria.

7. **Sedative Hypnotics Drugs: Tasimelteon (Hetlioz) Renewal PA Criteria**—Hetlioz is approved for treatment of blind patients with non-24 hour sleep-wake disorder. The P&T Committee reviewed Hetlioz in February 2015 and designated it with NF status; PA and MN criteria were also established at that time. Currently, PA criteria expires after six months, as patients who do not respond after a six-month Hetlioz trial are unlikely to show therapeutic benefit. The P&T Committee recommended adding additional criteria to the existing PA to allow for the renewal of the PA after six months, based on patient response.

   a) ***COMMITTEE ACTION: TASIMELTEON (HETLIOZ) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) revising the manual PA criteria for Hetlioz to assess response after six months of therapy. See Appendix C for the full criteria.

8. **Cystic Fibrosis (CF) Drugs: Lumacaftor/Ivacaftor (Orkambi) Manual PA Criteria**—Orkambi is a fixed-dose combination product containing lumacaftor with ivacaftor (Kalydeco). Both drugs are potentiators of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Orkambi was FDA-approved in July 2015 for treatment of CF in patients at least 12 years of age who are homozygous for the F508del mutation in the CFTR gene. Currently, PA criteria apply to the ivacaftor component of Orkambi.

a) ***COMMITTEE ACTION: CF DRUG LUMACAFTOR/ IVACAFTOR (ORKAMBI) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Orkambi, consistent with the FDA-approved product labeling. See Appendix C for the full criteria.

9. **Topical Pain Products: Diclofenac Gel (Solaraze 3% Gel) Manual PA Criteria**
Solaraze is FDA-approved for the topical treatment of actinic keratosis.

a) ***COMMITTEE ACTION: DICLOFENAC GEL (SOLARAZE 3% GEL) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Solaraze 3% Gel in all new users, consistent with the FDA-approved product labeling for use in actinic keratosis. See Appendix C for the full criteria.

10. **PA and MN Criteria Implementation Periods**

a) ***COMMITTEE ACTION: PA CRITERIA AND MN CRITERIA IMPLEMENTATION PLAN***—For all of the PA and MN criteria discussed above (with the exception of the PCSK9 inhibitors and the V-Go insulin delivery device), the P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

B. QLs—QLs were reviewed for four drugs—one from the COPD class, one drug for basal cell carcinoma, and two drugs used in compounded prescriptions. QLs already apply to other products in the COPD and oncology drug classes.

1. ***COMMITTEE ACTIONS: QLs***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) QLs for tiotropium/olodaterol (Stiolto Respimat), vismodegib (Erivedge), lidocaine 5% ointment, and lidocaine/prilocaine cream (Emla cream, generic). See Appendix D.

☒ Approved ☐ Disapproved

Director, DHA, Decision

Approved, but modified as follows:

VIII. COMPOUND PRESCRIPTIONS

A. PA Criteria—The P&T Committee was presented with an update on the status of compounded medications. MHS expenditures for compounded medications are significant, but decreasing. Compounded medications continue to have a high potential for inappropriate use.

The decrease in number of compounded prescriptions filled and cost of compounded prescriptions is due in part to the enforcement of Express Scripts Commercial Reject List that was signed into practice by Dr. Jonathon Woodson, Assistant Secretary of Defense for Health Affairs, in May 2015. Modifications to the existing compounded prescription PA criteria were proposed in an effort to decrease inappropriate use and ensure safety for beneficiaries.

1. ***COMMITTEE ACTION: COMPOUND PRESCRIPTIONS MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) that the current PA criteria should expire after one year. PA approval will last for 12 months, or for the duration of therapy, if less than 12 months

2. ***COMMITTEE ACTION: COMPOUND PRESCRIPTIONS MANUAL PA CRITERIA IMPLEMENTATION PLAN***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all POS; and DHA send a letter to all beneficiaries with a PA currently in place with the following

    a) Notification to beneficiaries of the one-year time limit on future PAs; and,

    b) Upon implementation, the one-year time limit will go into effect on existing approved PAs.

Based on the P&T Committee's recommendation, the effective date is January 6, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

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

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was not in compliance with the FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity at the MTFs. These

NF drugs will remain available in the Mail Order POS without preauthorization.

A. ***COMMITTEE ACTION: DRUG DESIGNATED NF***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) the following product be designated NF on the UF:

- Neos Therapeutics: Hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) the following preauthorization criteria for hydrocodone/chlorpheniramine (CTM) ER, 12-hour suspension 10-8 mg/5 mL by Neos Therapeutics:

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

These preauthorization criteria do not apply to any other POS other than retail network pharmacies.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in the Retail Network; and 2) DHA send a letter to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is February 3, 2016.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

X. OVER-THE-COUNTER (OTC) DRUGS

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

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

A. OTC Drugs—Relative Cost-Effectiveness and Patient Access

The P&T Committee evaluated the relative cost-effectiveness and patient access considerations for the following OTC drugs currently covered as part of the OTC Demonstration Project: omeprazole 20 mg (Prilosec, Prilosec OTC, generics), loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics), and levonorgestrel 1.5 mg (Plan B, generics).

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 2 absent):

    a) Remove coverage of branded omeprazole (Prilosec OTC), as it is not cost effective, relative to comparable generic and prescription proton pump inhibitors.

    b) Generic formulations of omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics), and levonorgestrel (Plan B, generics) will remain designated as UF.

2. ***COMMITTEE ACTION: COPAYMENT WAIVER***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent)

    a) Continuing the current copayment waiver for levonorgestrel 1.5mg (Plan B, generics). Copayments for levonorgestrel 1.5 mg (Plan B) will remain $0.

    b) Removing the current copayment waiver for generic omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), and cetirizine with and without pseudoephedrine (Zyrtec, Zyrtec D, generics). Copayments will now be required for these medications.

3. ***COMMITTEE ACTION: PRESCRIPTION WAIVER***—The P&T Committee recommended (13 for, 0 opposed, 2 abstained, 2 absent):

    a) Continuing the current waiver of the requirement for a prescription for levonorgestrel 1.5mg (Plan B, generics). Levonorgestrel will continue be covered without a prescription.

b) Removing the current waiver of the requirement for a prescription for generic omeprazole, loratadine with and without pseudoephedrine (Claritin, Claritin D, generics), and cetirizine with or without pseudoephedrine (Zyrtec, Zyrtec D, generics). Prescriptions will now be required for these medications.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XI. INNOVATOR DRUGS

New authority enacted in section 702 of the FY15 NDAA establishes authority for the P&T Committee's review process of newly approved innovator drugs. The Final Rule published in the Federal Register on July 27, 2015, clarified this process for formulary placement of newly approved innovator drugs brought to the market under a New Drug Application (NDA) approved by the FDA (available at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy). The P&T Committee is provided up to 120 days to recommend tier placement on the UF. During this period, new drugs will be assigned a classification pending status; they will be available under terms comparable to NF drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs.

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

General MN criteria were recommended by the P&T Committee for these newly approved innovator drugs.

1. ***COMMITTEE ACTIONS: GENERAL MN CRITERIA FOR NEWLY APPROVED INNOVATOR DRUGS***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) general MN criteria for newly approved innovator drugs. In certain circumstances, specific MN criteria for these drugs may also established. The general criteria are as follows:

    - Use of the formulary agents is contraindicated.
    - The patient has experienced significant adverse effects from the formulary agents that are unlikely to occur with the NF agent.
    - The formulary agents have resulted in therapeutic failure.
    - There is no alternative formulary agent. A formulary agent is defined as a drug from the same drug class or used for the same indication as the NF drug.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XII. AVAILABILITY OF DRUGS THROUGH NATIONAL MAIL ORDER PHARMACY PROGRAM

Until recently, the statute (10 USC 1074g) required availability of NF (Tier 3) drugs in at least one of three POS (MTFs, retail network, or the mail order program), while the regulation (32 CFR 199.21(e)(1)) stated that NF drugs would be generally unavailable at MTFs and generally available in the retail network and the mail order program. This prevented NF drugs from being included in the list of covered medications under the TFL Pilot Program.

Section 702 of the FY15 NDAA changed the requirement to specify that NF medications "shall be available through the national mail-order pharmacy program." This change was implemented via the Final Rule published in the Federal Register on July 27, 2015 (available at https://www.federalregister.gov/articles/2015/07/27/2015-18290/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-tricare-pharmacy). The Final Rule clarifies that "non-formulary pharmaceutical agents are generally not available in military treatment facilities or in the retail point of service. They are available in the mail order program."

At the February 2015 meeting, the P&T Committee reviewed the criteria for waiving the requirement to use mail order and necessary exclusions of medications from the program, based on clinical considerations or operational feasibility. In addition to the exclusions from the program discussed in February 2015, the P&T Committee agreed that it would not be feasible to limit NF (Tier 3) blood glucose test strips to mail order. Not only are more than 150 different blood glucose test strips designated as NF, many are used by patients in very low volumes and cannot be efficiently handled by the mail order program.

1. ***COMMITTEE ACTIONS: NECESSARY EXCLUSIONS FROM THE NF-TO-MAIL REQUIREMENT***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) that the following categories or classes of NF (Tier 3) medications be excluded from the requirement to use mail order as the sole point of dispensing: medications for acute therapy, Schedule II controlled substances, antipsychotics, oncology agents, limited distribution drugs, and self-monitoring blood glucose system test strips.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

XIII. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE NATIONAL MAIL ORDER PHARMACY PROGRAM

In addition to increasing copayments (from $5/$17/$43 to $8/$20/$46 for Tiers 1, 2, and 3, respectively), the FY15 NDAA substantially expands the population of patients who "must generally refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program" to include all eligible covered beneficiaries (all beneficiaries except for Active Duty). As specified by the FY15 NDAA, the new program will begin October 1, 2015; the current TFL Pilot Program terminates on September 20, 2015. Regulations implementing the new program were published as an interim final rule in the Federal Register on August 6, 2015 (available at https://www.federalregister.gov/articles/2015/08/06/2015-19196/civilian-health-and-medical-program-of-the-uniformed-services-champustricare-refills-of-maintenance).

The new program is similar in structure to the TFL Pilot Program, including procedures for allowing two initial fills at retail and for waiving the requirement for medications for acute care needs, prescriptions covered by other health insurance, or when necessary due to personal need or hardship, emergencies, and other special circumstances. Unlike the pilot program, there is no opt-out option.

A. Expanded Maintenance Medication Program Drug List

Drugs for the expanded Maintenance Medication Program must meet the following requirements:

- the medication is prescribed for a chronic, long-term condition that is taken on a regular, recurring basis;
- it is clinically appropriate to dispense the medication from the mail order pharmacy;
- it is cost effective to dispense the medication from the mail order pharmacy;
- the medication is available for an initial filling of a 30-day or less supply through retail pharmacies;
- the medication is generally available at MTF pharmacies for initial prescription fill and refills; and,
- the medication is available for refill through the mail order pharmacy.

1. ***COMMITTEE ACTION: EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) the initial list of covered maintenance medications for the Expanded Maintenance Medication Program. See Appendix E.

The P&T Committee noted that the requirements under the program apply only to branded versions of the medications on the list. Many of these medications are available in generic formulations. In this case, the vast majority of prescriptions should be dispensed as generic versions of the products, consistent with TRICARE's mandatory generic policy, and would not be subject to the requirements of the program.

This list will be periodically revised and accessible on the TRICARE Pharmacy Program website and by telephone from the TRICARE Pharmacy Program Service Center.

XIV. ADJOURNMENT

The meeting adjourned at 1345 hours on August 13, 2015. The next meeting will be in November 2015.

Appendix A—Attendance: August 2015 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—Expanded Maintenance Medication Program Drug List
Appendix F—Table of Implementation Status of UF Recommendations/Decisions Summary
Appendix G—Table of Abbreviations

SUBMITTED BY:

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

DECISION ON RECOMMENDATIONS

Director, DHA, decisions are as annotated above.

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

30 Oct 2015
Date

Appendix A—Attendance: August 2015 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Nita Sood, USPHS for George Jones, PharmD, M.S.	DHA/POD Chief of Staff/ Operations Management Branch
CDR Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
CDR Aaron Middlekauf, USCG	Coast Guard, Pharmacy Officer
COL Jack Lewi, MC	Army, Internal Medicine Physician
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
MAJ Dausen Harker, MC	Army, Family Practice Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Shaun Carstairs, MC	Navy, Physician at Large
MAJ John Poulin, MC	Army, Physician at Large
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. Bryan Wheeler	Acting General Counsel, DHA
Guests	
Mr. Bill Davies via DCS	Chief, DHA Integrated Utilization Branch
CAPT Matthew Baker	Indian Health Service
Mr. Matthew Halbe via DCS	DHA Contract Operations Division
LT Ebenezer Aniagyel	Customer Pharm Ops Center, Defense Logistics Agency

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
MAJ Aparna Raizada, MS	DHA Formulary Management Branch
LTC Misty Carlson, MC	DHA Integrated Utilization Branch
CDR Marisol Martinez, USPHS	DHA Formulary Management Branch
Maj David Folmar, BSC	DHA Integrated Utilization Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Deputy Chief, P&T Section, Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Teresa Anekwe, PharmD, BCPS	DHA Formulary Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
Dean Valibhai, PharmD, MBA	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
David Meade, PharmD, BCPS via phone	DHA Integrated Utilization Branch
Ms. Deborah Garcia	DHA Formulary Management Branch contractor
Mr. Kirk Stocker	DHA Formulary Management Branch contractor
Esmond Nwokeji, PhD	DHA Formulary Management Branch contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Canagliflozin (Invokana) • Canagliflozin/metformin (Invokamet) • Dapagliflozin (Farxiga) • Dapagliflozin/metformin XR (Xigduo XR) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	• Patient has experienced significant adverse effects from empagliflozin-containing products that are not expected to occur with canagliflozin- or dapagliflozin-containing products **Formulary Alternatives:** empagliflozin-containing product (Jardiance, Glyxambi)
• Liraglutide (Victoza) • Dulaglutide (Trulicity) • Exenatide BID (Byetta) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Patient has experienced significant adverse effects from the GLP1RA preferred products (Bydureon or Tanzeum) that are not expected to occur with Victoza, Trulicity, and Byetta. **Formulary Alternatives:** exenatide once weekly (Bydureon) and albiglutide (Tanzeum)
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	• Use of statins is contraindicated. The contraindication must be listed on the medical necessity form. • The patient has had an inadequate response to a statin, with an LDL > 100 mg/dL despite statin therapy at maximal tolerated doses. • The patient is intolerant of statins. • No alternative formulary agent. The patient has homozygous familial hypercholesterolemia and requires additional LDL-C lowering, despite maximal doses of statin or other therapies (e.g., ezetimibe, LDL apheresis). **Formulary Alternatives:** statins, ezetimibe
• Valeritas Insulin Delivery Device (V-Go) **Insulin–Miscellaneous Delivery Devices**	• A Prior Authorization form is completed and approved. AND • Formulary agents result or are likely to result in therapeutic failure. Lack of documentation of a PA form for V-Go will result in denial of the medical necessity criteria. • **Formulary alternatives:** Uniform Formulary insulin products (insulin glargine, insulin lispro, insulin aspart) pens and vials

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Canagliflozin (Invokana) • Canagliflozin/ metformin (Invokamet) • Dapagliflozin (Farxiga) • Dapagliflozin/ metformin ER (Xigduo XR) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	All new users of an SGLT2 inhibitor are required to try metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin or a sulfonylurea (SU) and a DPP-4 inhibitor first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first. Automated PA criteria • The patient has filled a prescription for metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Or • The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria—If automated PA criteria are not met, Jardiance or Glyxambi is approved (e.g., a trial of metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes are NOT required) if: • The patient has had an inadequate response to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has experienced a significant adverse effect from metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes; or • The patient has a contraindication to metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes. AND In addition to the above criteria regarding metformin and at least one drug from 2 additional different oral non-insulin diabetes drug classes, the following PA criteria would apply specifically to all new and current users of canagliflozin (Invokana), canagliflozin/metformin (Invokamet), dapagliflozin (Farxiga), and dapagliflozin/ metformin ER (Xigduo XR): • The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.
• Exenatide twice daily (Byetta) • Dulaglutide (Trulicity) • Liraglutide (Victoza) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new users of Bydureon, Tanzeum, Byetta, Trulicity, and Victoza are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA. Patients currently taking a GLP-1RA must have had a trial of metformin or a sulfonylurea first. Additionally, Bydureon and Tanzeum are the preferred agents in the GLP-1RA subclass. New and current users of Byetta, Victoza and Trulicity must try Bydureon and Tanzeum first. Automated PA criteria: The patient has received a prescription for metformin or SU at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days,

Drug / Drug Class	Prior Authorization Criteria
	AND Manual PA criteria: If automated PA criteria are not met, Bydureon, Tanzeum, Byetta, Trulicity, or Victoza is approved (e.g., trial of metformin or SU is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis • The patient has experienced any of the following issues on a SU: o hypoglycemia requiring medical treatment • The patient has had inadequate response to metformin or a SU • The patient has a contraindication to metformin or a SU AND In addition to the above criteria regarding metformin and SU, the following PA criteria would apply specifically to new and current users of Byetta, Trulicity, and Victoza: • The patient has had an inadequate response to Bydureon and Tanzeum.
• Alirocumab (Praluent) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	Manual PA criteria apply to all new and current users of alirocumab (Praluent). Manual PA criteria—Alirocumab is approved if: • A cardiologist, lipidologist, or endocrinologist prescribes the drug. • The patient is at least 18 years of age. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR o If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. o Contraindication to statin

Drug / Drug Class	Prior Authorization Criteria
	▪ The contraindication must be defined. • Praluent is not approved for any indication other than HeFH or clinical ASCVD. • Praluent is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 75 mg every 2 weeks, or o 150 mg every 2 weeks. • PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Praluent will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/KexinType 9 (PCSK9) Inhibitor**	Manual PA criteria apply to all new and current users of evolocumab (Repatha). Manual PA criteria—Evolocumab is approved if: • A cardiologist, lipidologist, or endocrinologist prescribes the drug. • The patient is at least 18 years of age for HeFH and clinical ASCVD. For HoFH, patients as young as 13 years of age can receive the drug. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. • The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximal tolerated doses, according to the criteria below: o The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR o The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR o If the patient is statin intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND o The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: o Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least two trials of statin rechallenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.

Drug / Drug Class	Prior Authorization Criteria
	– Contraindication to statin ▪ The contraindication must be defined. • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: o 140 mg every 2 weeks, or o 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. • PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Repatha will be approved for the following: o The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND o The patient has documented adherence.
• Fluticasone furoate (Arnuity Ellipta) • Mometasone (Asmanex HFA) **Inhaled Corticosteroids (ICS)**	PA criteria apply to all new users of Arnuity Ellipta and Asmanex HFA who are older than 12 years of age. Automated PA criteria: The patient has filled a prescription for Flovent Diskus or Flovent HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Arnuity Ellipta and Asmanex HFA are approved (e.g., trial of Flovent Diskus or Flovent HFA is NOT required) if: • Patient has experienced any of the following issues with Flovent Diskus or Flovent HFA, which is not expected to occur with the non-preferred ICS: o inadequate response to the step preferred drugs o contraindication o patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk
• Fluticasone furoate/vilanterol (Breo Ellipta) **Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs) Combinations**	Existing step therapy criteria apply to all new and current users of Breo Ellipta who are older than 12 years of age. **New PA criteria for Breo Ellipta will apply to patients who are at least 18 years of age for treating asthma.** Automated PA criteria: The patient has filled a prescription for Advair or Advair HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria 1. Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) if: • Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with the non-preferred ICS/LABA combination drug: o inadequate response to Advair Diskus or Advair HFA o intolerable adverse effects o contraindication

Drug / Drug Class	Prior Authorization Criteria
	○ patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk **2. Additionally, Breo Ellipta is approved (e.g., trial of Advair Diskus or Advair HFA is NOT required) in patients who are 18 years of age and older for treating asthma if:** • Patient has experienced any of the following issues with either Advair Diskus or Advair HFA, which is not expected to occur with Breo-Ellipta: ○ inadequate response to Advair Diskus or Advair HFA ○ intolerable adverse effects
• Nintedanib (Ofev) Pirfenidone (Esbriet) **Pulmonary Fibrosis**	Manual PA criteria will apply to all new and current users of nintedanib (Ofev) and pirfenidone (Esbriet). Manual PA criteria: Ofev or Esbriet is approved if: • The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND • The patient is being actively managed by a pulmonologist, AND • The patient is only receiving one therapy – either Ofev or Esbriet. The patient cannot receive both drugs concomitantly (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa). PA will expire after one year. Subsequent PA approval (Renewal PA) will require clinical documentation of efficacy, and will be limited to one year.
• Memantine ER (Namenda XR) **Alzheimer's Disease**	Manual PA criteria apply to all new users of Namenda XR. Manual PA criteria Namenda XR is approved: • The patient is being treated for moderate to severe Alzheimer's or mixed dementia (Alzheimer's disease plus vascular dementia), AND • Taking Namenda IR (memantine) twice daily causes undue burden to the patient or care provider, AND • The patient's functional status has not declined while receiving Namenda IR.
• Memantine ER/donepezil (Namzaric) **Alzheimer's Disease**	Manual PA criteria apply to all new users of Namzaric. Manual PA criteria Namzaric is approved if: • The patient is being treated for moderate to severe dementia of the Alzheimer's type, AND • The patient is stabilized on one of the following regimens: ○ memantine IR 10 mg twice daily or memantine ER 28 mg once daily and donepezil hydrochloride 10 mg, OR ○ memantine IR 5 mg twice daily or ER 14 mg once daily and donepezil hydrochloride 10 mg, AND • The patient is unable to take Namenda (memantine) and Aricept (donepezil) separately, OR • The patient has progressive swallowing difficulties.

Drug / Drug Class	Prior Authorization Criteria
• Tasimelteon (Hetlioz) **Newer Sedative Hypnotics (SED-1s)**	For patients who have completed the initial 6-months trial of Hetlioz, renewal PA criteria will be determined. Renewal Manual PA criteria: Tasimelteon (Hetlioz) will be approved indefinitely if: • The patient is totally blind and has a documented diagnosis of non-24 sleep wake disorder AND • The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) AND • The patient has been receiving Hetlioz for 6 months and has had a documented response to therapy. PA will not be approved if the patient has not had a documented response to therapy. If the patient has not responded after 6 months, they will be deemed a non-responder.
• Lumacaftor/Ivacaftor (Orkambi) **Cystic Fibrosis**	PA apply to all new and current users of Lumacaftor/ivacaftor (Orkambi). Manual PA criteria: Orkambi is approved if: • Orkambi is prescribed for the treatment of cystic fibrosis in an age-appropriate patient population according to the product label. AND • The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, detected by an FDA-approved test.
• Diclofenac Gel (Solaraze 3% Gel) **Topical Pain**	PA criteria apply to all new users of Solaraze 3% Gel. Manual PA criteria Diclofenac 3% topical gel (Solaraze Gel) is approved if: • The patient has a documented diagnosis of actinic keratosis.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• Umeclidinium (Incruse Ellipta) **Long-Acting Muscarinic Agonists**	▪ Retail Network: 1 inhaler per 30 days ▪ MTF and Mail Order Pharmacy: 3 inhalers per 90 days ▪ Note that "institutional packs" of 7-day supply inhalers are limited to 1 inhaler at all points of service
• Tiotropium/olodaterol (Stiolto Respimat) **LAMA/LABA**	▪ Retail Network : One 28-metered actuations inhaler per 14 days OR ONE 60-metered actuations inhaler per 30 days ▪ MTF and Mail Order Pharmacy: Two 60-metered actuations inhalers per 60 days
• Alirocumab (Praluent) **Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor**	▪ Retail Network: 2 syringes or pens per 30 days ▪ MTF and Mail Order Pharmacy: 6 syringes or pens per 90 days
• Evolocumab (Repatha) **Proprotein Convertase Subtilisin/KexinType 9 (PCSK9) Inhibitor**	▪ HeFH and ASCVD o Retail Pharmacy Network: 2 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 6 of the 140 mg syringes per 90 days. ▪ HoFH o Retail Pharmacy Network: 3 of the 140 mg syringes per 30 days o MTF and Mail Order Pharmacy: 9 of the 140 mg syringes per 90 days
• Vismodegib (Erivedge) **Oral Oncologic Drugs**	▪ Retail Network : 28 capsules per 28 days ▪ MTF and Mail Order Pharmacy: 56 capsules per 56 days
• Lidocaine 5% Ointment **Topical Anesthetic**	▪ Retail Network: No more than 300 grams in 30 days ▪ MTF and Mail Order Pharmacy: No more than 300 grams in 30 days
• Lidocaine-Prilocaine Cream (Emla cream, generic) **Topical Anesthetic**	▪ Retail Network: No more than 300 grams in 30 days ▪ MTF and Mail Order Pharmacy: No more than 300 grams in 30 days

Appendix E—Expanded Maintenance Medication Program Drug List

ALZHEIMERS AGENTS	
ARICEPT	NAMENDA
ARICEPT ODT	RAZADYNE
EXELON	RAZADYNE ER
ANTIARRHYTHMICS	
CORDARONE	NORPACE CR
MULTAQ	RYTHMOL
NORPACE	RYTHMOL SR
ANTIBIOTICS	
TOBI	
ANTICOAGULANTS	
ARIXTRA	PRADAXA
ELIQUIS	SAVAYSA
FRAGMIN	XARELTO
LOVENOX	
ANTIDEPRESSANTS AND NON-OPIOID PAIN SYNDROME AGENTS	
CELEXA	PAXIL
EFFEXOR XR	PEXEVA
LEXAPRO	PROZAC
LUVOX CR	WELLBUTRIN
MARPLAN	WELLBUTRIN SR
NARDIL	WELLBUTRIN XL
PARNATE	ZOLOFT
ANTIGOUT AGENTS	
ULORIC	ZYLOPRIM
ANTIHISTAMINE-2 BLOCKERS AND OTHER ANTIULCER AGENTS	
CARAFATE	PEPCID
CYTOTEC	ZANTAC
ANTIHYPERTENSIVE AGENTS	
CATAPRES	MINIPRESS
CATAPRES-TTS	TENEX
CLORPRES	
ANTILIPIDEMICS-1	
ALTOPREV	PRAVACHOL
CADUET	SIMCOR
CRESTOR	VYTORIN
LESCOL	ZETIA
LIPITOR	ZOCOR
NIASPAN	

ANTILIPIDEMICS-2

COLESTID	QUESTRAN
FENOGLIDE	QUESTRAN LIGHT
FIBRICOR	TRICOR
LIPOFEN	TRIGLIDE
LOFIBRA	TRILIPIX
LOVAZA	

ANTINEOPLASTIC AND PREMALIGNANT LESION AGENTS

TARGRETIN

ANTIPLATELET-HEMORRHELOGIC AGENTS

AGGRENOX	PERSANTINE
BRILINTA	PLAVIX
EFFIENT	PLETAL

ANTIRHEUMATICS

PLAQUENIL

BENIGN PROSTATIC HYPERPLASIA AGENTS

CARDURA	PROSCAR
FLOMAX	UROXATRAL

BETA BLOCKERS AND HYDROCHLOROTHIAZIDE COMBINATIONS

BETAPACE	INNOPRAN XL
BETAPACE AF	LOPRESSOR HCT
COREG	SECTRAL
COREG CR	TENORETIC
CORGARD	TENORMIN
CORZIDE	TRANDATE
DUTOPROL	ZIAC
INDERAL LA	

BINDERS-CHELATORS-ANTIDOTES-OVERDOSE AGENTS

PROGLYCEM

CALCIUM CHANNEL BLOCKING AGENTS

ADALAT CC	NORVASC
CALAN	PROCARDIA
CALAN SR	PROCARDIA XL
CARDIZEM	TIAZAC
CARDIZEM CD	

CARDIOVASCULAR AGENTS MISCELLANEOUS

BIDIL	LANOXIN
DILATRATE-SR	MINITRAN
ISORDIL	NITRO-DUR
ISORDIL TITRADOSE	RANEXA

CORTICOSTEROIDS-IMMUNE MODULATORS

CORTEF

DIABETES NON-INSULIN

ACTOPLUS MET	GLYSET
ACTOPLUS MET XR	JANUMET
ACTOS	JANUMET XR
AMARYL	JANUVIA
BYDUREON	JENTADUETO
BYETTA	PRANDIMET
DIABETA	PRANDIN
DUETACT	PRECOSE
GLUCOPHAGE	RIOMET
GLUCOPHAGE XR	STARLIX
GLUCOTROL	SYMLIN
GLUCOTROL XL	TRADJENTA
GLUCOVANCE	VICTOZA
GLYNASE	

DIURETICS

ALDACTAZIDE	EDECRIN
ALDACTONE	INSPRA
DEMADEX	LASIX
DIAMOX	MAXZIDE
DIURIL	MICROZIDE
DYAZIDE	NEPTAZANE
DYRENIUM	ZAROXOLYN

ELECTROLYTE-MINERAL-TRACE ELEMENT REPLACEMENT

EFFER-K	K-TAB ER
KLOR-CON	

ENDOCRINE AGENTS MISCELLANE(

DDAVP	STIMATE
HECTOROL	ZEMPLAR
SANDOSTATIN	

ESTROGENS AND ESTROGEN-ANDROGEN COMBINATIONS

ACTIVELLA	ESTROGEL
ALORA	FEMHRT
ANGELIQ	FEMRING
CLIMARA	MENEST
CLIMARA PRO	MENOSTAR
COMBIPATCH	MINIVELLE
DIVIGEL	PREFEST
ELESTRIN	PREMARIN
ENJUVIA	PREMPHASE
ESTRACE	PREMPRO
ESTRASORB	VAGIFEM
ESTRING	VIVELLE-DOT

GASTROINTESTINAL-1 AGENTS	
APRISO	DIPENTUM
AZULFIDINE	LIALDA
CANASA	LOTRONEX
DELZICOL	
GASTROINTESTINAL-2 AGENTS	
URSO	URSO FORTE
GLAUCOMA AGENTS	
ALPHAGAN P	LUMIGAN
BETAGAN	PHOSPHOLINE IODIDE
BETOPTIC S	TIMOPTIC
COMBIGAN	TIMOPTIC OCUDOSE
COSOPT	TIMOPTIC-XE
COSOPT PF	TRUSOPT
IOPIDINE	XALATAN
ISOPTO CARPINE	
GROWTH STIMULATING AGENTS	
NORDITROPIN FLEXPRO	NUTROPIN AQ NUSPIN
NUTROPIN	SAIZEN
NUTROPIN AQ	
GYNECOLOGICAL AGENTS MISCELLANEOUS	
AYGESTIN	PROVERA
PROMETRIUM	
HEMATOLOGICAL AGENTS MISCELLANEOUS	
AGRYLIN	
HEPATITIS C AGENTS	
COPEGUS	PEGINTRON
INTRON A	REBETOL
PEGASYS	
IMMUNOLOGICAL AGENTS MISCELLANEOUS	
NEUMEGA	
INSULINS	
APIDRA	LEVEMIR
APIDRA SOLOSTAR	NOVOLIN 70/30
HUMALOG	NOVOLIN 70-30
HUMALOG MIX 50-50	NOVOLIN N
HUMALOG MIX 75-25	NOVOLOG
HUMULIN 70/30	NOVOLOG MIX 70-30
HUMULIN N	RELION 70/30
LANTUS	RELION N
LANTUS SOLOSTAR	

LAXATIVES-CATHARTICS-STOOL SOFTENERS	
KRISTALOSE	
LEUKOTRIENE MODIFYING AGENTS	
ACCOLATE	SINGULAIR
LUTEINIZING HORMONE-RELEASING HORMONE AGONISTS-ANTAGONISTS	
ELIGARD	LUPRON DEPOT-PED
LUPRON DEPOT	TRELSTAR
METABOLIC REPLACEMENT AGENTS MISCELLANEOUS	
CARNITOR	
MULTIPLE SCLEROSIS AGENTS	
AVONEX	GLATOPA
BETASERON	REBIF
COPAXONE	
MYDRIATICS	
CYCLOGYL	ISOPTO ATROPINE
CYCLOMYDRIL	MYDRIACYL
NEUROLOGICAL AGENTS MISCELLANEOUS	
EVOXAC	MESTINON
EXELON	
ONCOLOGICAL AGENTS	
DAPSONE	TARCEVA
GLEEVEC	TARGRETIN
SPRYCEL	TEMODAR
SUTENT	XELODA
OPHTHALMIC AGENTS MISCELLANEOUS	
RESTASIS	
OSTEOPOROSIS AGENTS	
BONIVA	FOSAMAX
EVISTA	FOSAMAX PLUS D
FORTEO	
OVERACTIVE BLADDER AGENTS	
DETROL	DITROPAN XL
DETROL LA	VESICARE
PAIN AGENTS	
ANAPROX	MOBIC
ANAPROX DS	NALFON
CELEBREX	NAPROSYN
DAYPRO	VIMOVO
EC-NAPROSYN	VOLTAREN
FELDENE	VOLTAREN-XR

PARKINSONS AGENTS	
AZILECT	REQUIP
COMTAN	REQUIP XL
ELDEPRYL	SINEMET
LODOSYN	SINEMET CR
MIRAPEX	STALEVO
MIRAPEX ER	TASMAR
NEUPRO	ZELAPAR
PHOSPHODIESTERASE-5 INHIBITOI	
VIAGRA	
PROTON PUMP INHIBITORS	
NEXIUM	PROTONIX
PRILOSEC	
PULMONARY-1 AGENTS	
ADVAIR DISKUS	FLOVENT HFA
ADVAIR HFA	PULMICORT
FLOVENT DISKUS	VOSPIRE ER
PULMONARY-2 AGENTS	
ANORO ELLIPTA	LUFYLLIN
ATROVENT HFA	SEREVENT DISKUS
BROVANA	SPIRIVA
FORADIL	TUDORZA PRESSAIR
RED BLOOD CELL STIMULANTS	
ARANESP	PROCRIT
EPOGEN	
RENIN-ANGIOTENSIN ANTIHYPERTENSIVES	
ACCUPRIL	LOTENSIN
ACCURETIC	LOTENSIN HCT
ACEON	LOTREL
ALTACE	MAVIK
AMTURNIDE	MICARDIS
ATACAND	MICARDIS HCT
ATACAND HCT	PRINIVIL
AVALIDE	TARKA
AVAPRO	TEKTURNA
AZOR	TEKTURNA HCT
BENICAR	TEVETEN
BENICAR HCT	TEVETEN HCT
COZAAR	TWYNSTA
DIOVAN	UNIRETIC
DIOVAN HCT	UNIVASC
EDARBI	VASERETIC

RENIN-ANGIOTENSIN ANTIHYPERTENSIVES (Continued)	
EDARBYCLOR	VASOTEC
EXFORGE	ZESTORETIC
EXFORGE HCT	ZESTRIL
HYZAAR	
RESPIRATORY AGENTS MISCELLANEOUS	
PULMOZYME	
SKELETAL MUSCLE RELAXANTS AND COMBINATIONS	
DANTRIUM	ZANAFLEX
TARGETED IMMUNOMODULATORY BIOLOGICS	
HUMIRA	SIMPONI ARIA
KINERET	STELARA
OTEZLA	XELJANZ
SIMPONI	
THYROID AND ANTITHYROID AGEI	
ARMOUR THYROID	TAPAZOLE
CYTOMEL	TIROSINT
SYNTHROID	
URINARY AGENTS MISCELLANEOU	
UROCIT-K	
VITAMINS	
NASCOBAL	ROCALTROL
POTABA	
WHITE BLOOD CELL STIMULANTS	
LEUKINE	NEUPOGEN
NEULASTA	

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2015	**Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors Subclass**	UF class review	▪ BCF: None (BCF selections from the non-insulin diabetes drug classes include metformin IR, metformin ER, glipizide, glyburide, glyburide micronized, sitagliptin, and sitagliptin/ metformin)	Uniform Formulary and step-preferred: ▪ Empagliflozin (Jardiance) ▪ Empagliflozin/linagliptin (Glyxambi)	Nonformulary and non step-preferred: ▪ Canagliflozin (Invokana) ▪ Canagliflozin/ metformin (Invokamet) ▪ Dapagliflozin (Farxiga) ▪ Dapagliflozin/ metformin ER (Xigduo XR)	Pending singing of the minutes / 90 days	▪See comments	▪Must try metformin and at least one drug from 2 additional oral non-insulin diabetes drug classes first before any SGLT2 inhibitor in new users. ▪Must try an empagliflozin-containing product first before Invokana, Invokamet, Farxiga, or Xigduo XR in all new and current users. (See Appendix C)
Aug 2015	**Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	UF class review Previously reviewed Nov 2012	BCF and step preferred: ▪ Exenatide once weekly (Bydureon)	Uniform Formulary and step-preferred: ▪ Albiglutide (Tanzeum)	Nonformulary and non step-preferred: ▪ Liraglutide (Victoza) ▪ Dulaglutide (Trulicity) ▪ Exenatide BID (Byetta)	Pending singing of the minutes / 90 days	▪See comments	▪ Must try metformin or a sulfonylurea first before a GLP1RA. Must try Bydureon and Tanzeum first before Victoza, Trulicity, or Byetta in all new and current users. (See Appendix C)

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Aug 2015	**Chronic Myelogenous Leukemia (CML)**	UF class review	None	▪ Imatinib (Gleevec) ▪ Dasatinib (Sprycel) ▪ Nilotinib (Tasigna) ▪ Bosutinib (Bosulif) ▪ Ponatinib (Iclusig)	None	Pending signing of the minutes	N/A	-
Aug 2015	**Long Acting Narcotic Analgesics**	UF subclass review	▪ Morphine sulfate extended release (MS Contin, generics)	▪ Fentanyl transdermal system (Duragesic, generics) ▪ Hydrocodone ER (Hysingla ER, Zohydro ER) ▪ Hydromorphone ER (Exalgo, generics) ▪ Morphine ER (Avinza, Kadian, generics) ▪ Morphine ER/naltrexone (Embeda) ▪ Oxycodone (Oxycontin) ▪ Oxymorphone ER (Opana ER) ▪ Tapentadol ER (Nucynta ER)	▪ None	Pending singing of the minutes	▪ High potency opioid PA: patients receiving a high potency opioid cannot be opioid-naive	▪ This is the high potency subclass of the Narcotic Analgesics Drug Class, for which immediate release morphine sulfate (MSIR, generics) and controlled release morphine sulfate (MS Contin, generics) are designated BCF.

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2015	**Pulmonary II–Chronic Obstructive Pulmonary Disease: Long-Acting Muscarinic Agents**	New Drug Class previously reviewed May 2013	▪ Tiotropium (Spiriva HandiHaler)	**LAMAs** ▪ **Umeclidinium (Incruse Ellipta) Aug 2015** ▪ Aclidinium (Tudorza) May 2013 LAMA/LABAs ▪ Umeclidinium/ vilanterol (Anoro Ellipta) Nov 2014	▪ None	Pending signing of the minutes	QLs apply (See Appendix D)	-
Aug 2015	**Targeted Immunologic Biologics (TIBs)**	New Drug Class previously reviewed Aug 2014	▪ Adalimumab (Humira)	**Uniform Formulary and non step preferred** **August 2015** ▪ **Secukinumab (Cosentyx)** **August 2014** ▪ Apremilast (Otezla) ▪ Golimumab (Simponi) ▪ Tofacitinib (Xeljanz) ▪ Ustekinumab (Stelara)	Non formulary and Non step preferred **August 2014** ▪ Abatacept (Orencia) ▪ Anakinra (Kineret) ▪ Certolizumab (Cimzia) ▪ Etanercept (Enbrel) ▪ Tocilizumab (Actemra)	Pending singing of the minutes	▪Step therapy required; see comments ▪Quantity Limits apply; see Formulary Search Tool	▪ Must try Humira first in all new users before the other TIBs. (See Appendix C) ▪ See TRICARE Formulary Search Tool for Cosentyx PA criteria ▪ TIBs are no longer an ECF class; Humira now BCF

TRICARE Formulary Search tool: *https://www.express-scripts.com/static/formularySearch/2.0.4/#/formularySearch/drugSearch?accessLink=FSTResults*
IR: immediate release
ER: extended release

Appendix G—Table of Abbreviations

A1c	hemoglobin A1c
ADHD	attention deficit hyperactivity disorder
AE	adverse event
ASCVD	atherosclerotic cardiovascular disease
BCF	Basic Core Formulary
BIA	budget impact analysis
BID	twice daily
BLA	Biologic License Application
CF	cystic fibrosis
CFR	Code of Federal Regulations
CFTR	cystic fibrosis transmembrane conductance regulator
CK	creatinine kinase
CMA	cost minimization analysis
CML	chronic myelogenous leukemia
COPD	chronic obstructive pulmonary disease
CV	cardiovascular
DCS	Defense Collaboration Services
DHA	Defense Health Agency
DM	diabetes mellitus
DoD	Department of Defense
DPN	diabetic peripheral neuropathy
DPP-4	dipeptidyl dipeptidase-4 inhibitor
ECF	Extended Core Formulary
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FEV_1	forced expiratory volume in one second
FY	fiscal year
GLP1RA	glucagon-like peptide-1 receptor agonist
HDL	high-density lipoprotein
HeFH	heterozygous familial hypercholesterolemia
HoFH	homozygous familial hypercholesterolemia
ICS	Inhaled Corticosteroids Drug Class
IPF	idiopathic pulmonary fibrosis
IL-17A	interleukin-17A
IR	immediate release
LA	long acting
LABA	long-acting beta2-adrenergic agonist
LAMA	long-acting muscarinic antagonist
LDL	low-density lipoprotein
LDL-C	low-density lipoprotein cholesterol
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDA	New Drug Application
NDAA	National Defense Authorization Act

NF	nonformulary
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PCSK9	proprotein convertase subtilisin/kexin type 9 inhibitors
PMP	Prescription Monitoring Program
POS	points of service
Project ECHO	Extension for Community Healthcare Outcomes
QLs	quantity limits
SC	subcutaneous
SGLT2	sodium-glucose co-transporter 2 inhibitor
SL	sublingual
SU	sulfonylurea
T2DM	type 2 diabetes mellitus
TFL	TRICARE for Life
TIBs	targeted immunomodulatory biologics
TKIs	tyrosine kinase inhibitors
TZD	thiazolidinedione
UF	Uniform Formulary
ULN	upper limit of normal