DEPARTMENT OF DEFENSE

PHARMACY AND THERAPEUTICS COMMITTEE
MINUTES AND RECOMMENDATIONS

August 2014

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 13, 2014, at the Defense Health Agency (DHA) Pharmacoeconomic Branch, Fort Sam Houston, 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 for the May 2014 DoD P&T Committee meeting on September 12, 2014.

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 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.

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

A. Non-Insulin Diabetes Drugs—Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA): Albiglutide (Tanzeum)

Background—Albiglutide (Tanzeum) is the fourth GLP1RA and the second product with once weekly dosing. Similar to the other GLP1RAs [(exenatide once weekly (Bydureon), liraglutide (Victoza), and exenatide twice daily (Byetta)], albiglutide has beneficial effects on reducing hemoglobin A1c, blood pressure, weight, and improving lipid lab profiles. Albiglutide has a lower incidence of nausea and vomiting compared to Bydureon, Victoza, or Byetta. However, it has a slightly higher incidence of diarrhea. All four GLP1RAs have the same warnings and contraindications for the risk of serious adverse effects, including medullary thyroid cancer, multiple endocrine neoplasia syndrome type 2, and pancreatitis. There are currently no long-term cardiovascular outcome studies published with any GLP1RA.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the main benefit of albiglutide is its once weekly dosing regimen and lower incidence of nausea compared to the other GLP1RA drugs. The GLP1RAs will be re-reviewed at an upcoming meeting for UF and potential BCF placement.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization (CMA) was performed to evaluate albiglutide (Tanzeum) with the other GLP1RA agents. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that albiglutide (Tanzeum) is cost-effective compared with other GLP1RA agents on the UF.

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

2. ***COMMITTEE ACTION: PRIOR AUTHORIZATION (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. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) PA criteria for albiglutide, requiring a trial of metformin or a sulfonylurea in all new and current users of albiglutide (Tanzeum), consistent with the PA requirements for the other GLP1RAs. Use of albiglutide is approved only for patients with Type 2 diabetes mellitus, consistent with the FDA-approved indication. (See Appendix C for full criteria.)

3. ***COMMITTEE ACTION***: ***PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation period in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is December 10, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

B. Attention Deficit Hyperactivity Disorder (ADHD) Stimulants Subclass: Methylphenidate Extended Release (ER) Oral Suspension (Quillivant XR)

Background—Quillivant XR is FDA-indicated for the treatment of ADHD in children six years of age or older; it is dosed once daily. Quillivant XR delivers medication directly via a suspension, instead of opening capsules and mixing the beads or powder with food, which is required with other long-acting stimulants (e.g., Metadate CD, Ritalin LA, Adderall XR). There are no head-to-head studies comparing Quillivant XR to other ADHD medications. Current clinical practice guidelines suggest that all stimulant compounds indicated for ADHD

have very few differences among them in their ability to improve symptoms, their tolerability profiles, or risk of adverse events.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that although Quillivant XR offers the convenience of an oral suspension of methylphenidate ER, it failed to demonstrate clinically compelling advantages over existing UF agents for ADHD. Other long-acting stimulant preparations with alternative dosing formulations (e.g., sprinkles) are available on the UF.

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed to evaluate methylphenidate ER suspension (Quillivant XR) with other long-acting methylphenidate agents on the UF. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) that Quillivant XR was not cost-effective compared with other long-acting methylphenidate agents on the UF.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) methylphenidate ER oral solution (Quillivant XR) be designated NF due to the lack of compelling clinical advantages and cost disadvantages compared to the UF products.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for methylphenidate ER oral solution (Quillivant XR). (See Appendix B for the full criteria.)

3. ***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 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 18, 2014.

Director, DHA, Decision: ☒ Approved □ Disapproved

Approved, but modified as follows:

V. UF DRUG CLASS REVIEWS

A. Targeted Immunomodulatory Biologics (TIBs)

Relative Clinical Effectiveness—The P&T Committee evaluated the relative clinical effectiveness of the TIBs Drug Class, which is comprised of the following injectable and oral medications:

- **Anti-tumor necrosis factor (TNF) biologics**: adalimumab (Humira), certolizumab (Cimzia), etanercept (Enbrel), and golimumab (Simponi)
- **Non-TNF biologics**: abatacept (Orencia), anakinra (Kineret), apremilast (Otezla), tocilizumab (Actemra), tofacitinib (Xeljanz), and ustekinumab (Stelara)

The TIBs are FDA-approved for a variety of indications, including rheumatologic, dermatologic, and gastrointestinal inflammatory conditions. The TIBs were reviewed for UF placement in November 2007 and adalimumab (Humira) was recommended as the only multi-indication TIB on the Extended Core Formulary (ECF). Since the 2007 class review, several new TIBs have been marketed. Two oral therapies, tofacitinib (Xeljanz) and apremilast (Otezla) are now available.

Relative Clinical Effectiveness Conclusion—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following conclusions for the TIBs, based on FDA-approved indications:

1. All the TIBs (adalimumab, etanercept, certolizumab, golimumab, abatacept, tocilizumab, tofacitinib, anakinra, ustekinumab and apremilast) are highly effective for their FDA indications versus placebo, based on randomized controlled trials (RCTs).

2. There are few direct head-to-head trials between the TIBs; the majority of studies are non-inferiority trials. Comparative effectiveness is primarily determined though network meta-analysis (NMA) and indirect comparison; i.e., number needed to treat (NNT). The strength of evidence is typically low.

3. For rheumatoid arthritis, the available evidence is insufficient to clearly show superiority of one TIB over another with regard to the American College of Rheumatology 50 (ACR50) endpoint for response to treatment.

   In three systematic reviews, there was a trend favoring etanercept over the other TIBs in terms of efficacy. The same reviews found anakinra had a statistically significant lower mean response when compared to etanercept and adalimumab, but the strength of evidence was low.

4. For juvenile inflammatory arthritis, there is insufficient evidence to suggest clinically relevant differences between adalimumab and etanercept, the two TIBs approved in pediatric patients.

5. For psoriatic arthritis, due to the lack of head-to-head clinical trials and heterogeneous study populations, there is insufficient evidence to determine comparative efficacy between the four anti-TNFs (adalimumab, certolizumab, etanercept, and golimumab), and the non-TNFs (ustekinumab, and apremilast). Indirect comparisons from RCTs suggest similar NNTs for these drugs.

6. For psoriasis, three products are approved, adalimumab, etanercept, and ustekinumab. In one head-to-head RCT, ustekinumab was superior to etanercept

in achieving response, based on the Psoriasis Activity and Severity Index 75 (PASI 75) score. NMA demonstrated similar efficacy for adalimumab and ustekinumab.

7. For Crohn's disease, a NMA demonstrated that adalimumab and certolizumab are both effective for the induction of response and maintenance of remission and maintenance of response. The same analysis showed adalimumab is superior to certolizumab for induction of remission.

8. For ulcerative colitis, adalimumab and golimumab are effective for inducing clinical response, clinical remission, and mucosal healing. There is insufficient data for direct comparison of these agents.

9. With regard to safety, the overall rates of adverse events (AEs) are similar between the TIBs. In short-term trials, adalimumab and abatacept had a lower risk of serious AEs (serious infections, malignancies, lymphomas, withdrawals and other AEs) compared to other TIBs.

10. Evidence from indirect comparisons of two systematic reviews and one NMA shows the rate of serious infections is higher with certolizumab than the other TIBs. A subgroup analysis from one systematic review and a NMA showed the risk of serious infections was not increased with etanercept, in contrast to the increased risk seen with the other anti-TNF drugs, compared to controls.

11. The risk of tuberculosis (TB) is increased with the TIBs as a group. There is evidence (low strength) that suggests an increased risk with adalimumab, compared with etanercept.

12. The evidence (low strength) from indirect comparisons suggesting a safety benefit with etanercept in terms of serious infections and TB compared to the other anti-TNFs, must be weighed against its lack of efficacy for gastrointestinal conditions (Crohn's disease and ulcerative colitis).

13. Although the strength of evidence is low, there does not appear to be an elevated risk of malignancy with the TIBs. However, the risk of nonmelanoma skin cancer is increased with adalimumab and etanercept, compared to controls.

14. Concurrent use of a TIB with another TIB results in increased AEs and is not recommended by current practice guidelines.

15. Unique safety concerns with the non-TNF biologics include the following:

    - abatacept: Increased risk of chronic obstructive pulmonary disease (COPD) exacerbation in adults with COPD
    - tocilizumab and tofacitinib: gastrointestinal perforation and lab abnormalities, including elevated lipids and transaminases

- apremilast: psychiatric adverse effects such as depression and suicidal ideations

16. Overall, adalimumab has the highest clinical utility within the Military Health System (MHS) given its seven FDA-approved indications and wide spectrum of clinical coverage.
17. Inclusion of a non-TNF biologic on the formulary is required for patients who do not respond to an anti-TNF biologic.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and budget impact analysis (BIA) were performed to evaluate the TIBs used to treat rheumatologic (stratified by rheumatoid arthritis and psoriatic arthritis), dermatologic, and gastrointestinal (stratified by Crohn's disease and ulcerative colitis) inflammatory conditions. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

1. CMA results for the TIBs showed the following:
    - For rheumatoid arthritis, adalimumab (Humira) was the most cost-effective TIB, followed by certolizumab (Cimzia), anakinra (Kineret), tofacitinib (Xeljanz), golimumab (Simponi), etanercept (Enbrel), abatacept (Orencia), and tocilizumab (Actemra).
    - For psoriatic arthritis, adalimumab was the most cost-effective drug, followed by apremilast (Otezla), certolizumab, golimumab, etanercept, and ustekinumab (Stelara).
    - For dermatologic conditions, adalimumab was the most cost-effective TIB, followed by etanercept, and ustekinumab.
    - For gastrointestinal conditions (Crohn's disease), adalimumab was the most cost-effective agent, followed by certolizumab. For ulcerative colitis, adalimumab was the most cost-effective agent, followed by golimumab.
2. A BIA was performed to evaluate the potential impact of scenarios, with selected agents designated step-preferred and UF or non-preferred and NF.

Robust BIA results showed the scenario with adalimumab designated as formulary and step preferred on the UF; apremilast, golimumab, tofacitinib, and ustekinumab designated as formulary and non-preferred; and, abatacept, anakinra, certolizumab, etanercept, and tocilizumab designated as NF and non-step preferred, was the most cost-effective option for the MHS.

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

- UF and step-preferred ("in front of the step"): adalimumab (Humira)
- UF and non-preferred ("behind the step"): apremilast (Otezla), golimumab (Simponi), tofacitinib (Xeljanz), and ustekinumab (Stelara)
- NF and non-preferred: abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), and tocilizumab (Actemra)
- This recommendation includes step therapy, which requires a trial of adalimumab for all new users of a TIB.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent), adalimumab (Humira) be designated BCF upon signing of the minutes. The TIBs are now classified as a BCF rather than an ECF drug class. Military Treatment Facilities (MTFs) that do not currently have adalimumab on formulary are required to add it to their local formularies and make it available to beneficiaries on the same basis as any other BCF agent.

3. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), and tocilizumab (Actemra). (See Appendix B for full MN criteria.)

4. ***COMMITTEE ACTION: PA CRITERIA***—Existing manual PA criteria currently apply to all the TIBs. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) automated (step therapy) criteria for all new users of the non-preferred TIBs [abatacept (Orencia), anakinra (Kineret), apremilast (Otezla), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), tocilizumab (Actemra), tofacitinib (Xeljanz), and ustekinumab (Stelara)], requiring a trial of adalimumab (Humira) before the non-step preferred drugs.

   A trial of Humira is not required if:

   - Contraindications exist to Humira
   - The patient has had an inadequate response to Humira, and requires a different anti-TNF biologic or a non-TNF biologic
   - The patient has experienced adverse reactions to Humira which are not expected to occur with the requested non-preferred TIB
   - There is no formulary alternative for the following:
     - Enbrel: Patient is a child younger than four years of age or the patient has hepatitis C virus

- Non-TNF TIB (Orencia, Actemra, Xeljanz, Kineret, Stelara, and Otezla): Patient has symptomatic chronic heart failure
- Actemra, Orencia or Simponi: Patient has been stable on an intravenous formulation, with continuous use in the past three months and needs to transition to the subcutaneous formulation

The P&T Committee also recommended manual PA criteria for all users of Humira or a non-preferred TIB. Coverage for the TIBs is only allowed for the FDA-approved indications, and coverage is not approved for concomitant use of a TIB with other biologics. (See Appendix C for full criteria.)

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—QLs currently apply to the TIBs. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) to continue the current QLs for abatacept, adalimumab, anakinra, apremilast, certolizumab, etanercept, golimumab, tofacitinib, tocilizumab, and ustekinumab, at a maximum of a 28-day supply in the Retail Network and maximum of a 56-day supply in the Mail Order Pharmacy.

6. ***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 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 18, 2014.

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

VI. BCF CHANGES

A. Non-Insulin Diabetes Drugs—Sulfonylureas: MTF Request for Glyburide Deletion from the BCF

The P&T Committee reviewed a MTF request to delete glyburide from the BCF. Two sulfonylureas, glyburide (Diabeta, Glynase, generics) and glipizide (Glucotrol, generics) have been maintained on the BCF since 1998. Two other sulfonylureas, glimepiride (Amaryl, generics) and glipizide XL (Glucotrol XL, generics) are designated UF. Glipizide is safer to use than glyburide in diabetic patients with renal insufficiency.

However, glyburide is the sulfonylurea of choice for treating pregnant women, based on an article in the New England Journal of Medicine from 2000. P&T Committee members were concerned about the availability of glyburide for pregnant patients at all MTFs if it was removed from the BCF.

1. ***COMMITTEE ACTION: GLYBURIDE DELETION FROM THE BCF***
   The P&T Committee recommended (0 for, 17 opposed, 0 abstained, 0 absent) to remove glyburide on the BCF. Glyburide will be retained on the BCF. Providers are cautioned about the risk of renal insufficiency with glyburide.

B. Contraceptives Agents (Triphasics): Ethinyl Estradiol (EE) 25 mcg; Norgestimate 0.18/0.215/0.25mg (Ortho Tri-Cyclen Lo, generics) Deletion from the BCF

The P&T Committee reviewed trends in utilization and spend for the Contraceptives Agents. Multiple generic entrants, product discontinuations, and pricing changes frequently occur for the various products. Eleven contraceptive subclasses are on the BCF, including six monophasic, one triphasic, and one progestogen-only formulation; all the contraceptive subclasses have designated UF products.

The triphasic product EE 25 mcg with 0.18/0.215/0.25mg norgestimate (Ortho Tri-Cyclen Lo) has been maintained on the BCF since May 2006. An increase in the Ortho Tri-Cyclen Lo price has been noted over the past two years. Other triphasic products with EE 25 mcg, containing a different progestin (e.g., desogestrel in the formulations of Cyclessa and Velivet) and norgestimate-containing products with EE 35 mcg (e.g., Ortho Tri-Cyclen and Trinessa) are available on the UF at significant cost savings.

1. ***COMMITTEE ACTION: EE 25 MCG; 0.18/0.215/0.25MG NORGESTIMATE (ORTHO TRI-CYCLEN LO) DELETION FROM THE BCF***—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 0 absent) removing EE 25 mcg; 0.18/0.215/0.25mg norgestimate (Ortho Tri-Cyclen Lo) from the BCF upon signing of the minutes; the drug remains UF.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VII. UTILIZATION MANAGEMENT

A. PA and QLs

1. **Valeritas V-Go Insulin Delivery Device**—V-Go is a disposable insulin delivery device approved for patients with Type 2 diabetes mellitus. Unlike an insulin pump, V-Go does not require any tubing or catheters. The device is filled daily with rapid acting insulin, allowing for continuous administration of basal insulin. After 24 hours, the

device is discarded and replaced with a new unit. Advantages of V-Go include convenience to the patient desiring increased control over their blood glucose levels and elimination of the need for multiple daily insulin injections. Additionally, V-Go may reduce prandial glycemic excursions compared to multiple insulin injections. Potential disadvantages of V-Go include the risk of hypoglycemia and infection, the requirement for daily manual filling of the device with insulin, non-adjustable preset basal rates, and the potential for wastage.

The P&T Committee considered PA criteria for V-Go, consistent with the product labeling, including the capacity and purpose of the system (a maximum allowable dose of insulin of 76 units per day), and the meal time bolus insulin dose capability (no less than 2 unit increments of insulin).

a) ***COMMITTEE ACTION: V-GO MANUAL PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual prior authorization criteria for all new users of V-Go. Coverage will be approved if the patient meets all of the following criteria:

(1) Patient has Type 2 diabetes mellitus; AND

(2) Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily; AND

(3) Patient does not need less than 2 unit increments of bolus dosing; AND

(4) Patient has been maintained on stable basal insulin for at least three months (at dosages of 20U, 30U, or 40U); AND

(5) Patient has been using prandial insulin for at least three months.

b) ***COMMITTEE ACTION: V-GO QLS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) QLs of 30 units per 30 days, consistent with the product labeling of 1 unit used daily.

c) ***V-GO PA IMPLEMENTATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) implementation of the PA upon signing of the minutes.

2. **Newer Sedative Hypnotics (SED-1s): Tasimelteon (Hetlioz)**—Tasimelteon is a melatonin receptor agonist that is approved for treating blind patients who have non-24 hours sleep-wake disorder and have no light perception. It will be reviewed as a new drug at an upcoming meeting. Automated PA (step therapy) currently applies to the SED-1s Drug Class, where a trial of generic zolpidem immediate release (IR) or zaleplon is required first.

a) ***COMMITTEE ACTION: TASIMELTEON (HETLIOZ) PA CRITERIA***
The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) PA criteria for all new users of tasimelteon (Hetlioz) who are blind and have non-24 hour sleep-wake disorder. PA criteria will require a trial of generic zolpidem IR or zaleplon before Hetlioz. (See Appendix C for full criteria.)

b) ***COMMITTEE ACTION: TASIMELTEON (HETLIOZ) PA IMPLEMENTATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of no later than the first Wednesday after a 30-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is December 10, 2014.

3. **Metastatic Melanoma Medications: Trametinib (Mekinist) and Dabrafenib (Tafinlar) Manual PA Criteria**—Mekinist and Tafinlar are oral kinase inhibitors approved for treating patients with unresectable or metastatic melanoma who have documented BRAF V600E or V600K mutations as detected by an FDA-approved test. PA criteria currently apply to other oral kinase inhibitors for this diagnosis.

   a) ***COMMITTEE ACTION: TRAMETINIB (MEKINIST) AND DABRAFENIB (TAFINLAR) PA CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria should apply to all new users of Mekinist and Tafinlar, consistent with the FDA-approved product labeling. The PA will ensure that candidates likely to respond to Mekinist and Tafinlar are identified prior to initiating therapy. (See Appendix C for full criteria.)

4. **Seizure Medications: Topiramate ER capsules (Trokendi XR and Qudexy XR) Manual PA Criteria**—Trokendi XR and Qudexy XR are branded ER formulations of topiramate that are dosed once daily. Generic formulations of topiramate IR have been marketed since 1996, and include both tablets and capsules. Generic topiramate IR is FDA-approved for treating patients with seizures, down to the age of two years, and migraine headache. Topiramate is sometimes used off –label for weight loss.

   Trokendi XR and Qudexy XR are indicated for the treatment of seizures, but are only approved for patients down to the age of six or ten years, depending on the diagnosis.

   a) ***COMMITTEE ACTION: TOPIRAMATE ER (TROKENDI XR AND QUDEXY XR) PA CRITERIA***—The P&T Committee recommended (16 for, 1 opposed, 0 abstained, 0 absent) PA criteria for all new users of Trokendi XR and Qudexy XR consistent with the product's labeling for treatment of seizures, due to the potential for off-label use. Patients will be required to try generic topiramate IR first, unless there is a contraindication or adverse reaction with the generic product. (See Appendix C for full criteria.)

b) ***COMMITTEE ACTION: TOPIRAMATE ER (TROKENDI XR AND QUDEXY XR) PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date no later than the first Wednesday after a 30-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is December 10, 2014.

5. **Oral Chemotherapy Agents: Ibrutinib (Imbruvica), Idealisib (Zydelig), and Everolimus (Afinitor Disperz)**—QLs currently apply to the oral chemotherapy agents.

a) ***COMMITTEE ACTION: IBRUTINIB (IMBRUVICA), IDEALISIB (ZYDELIG,) AND EVEROLIMUS (AFINITOR DISPERZ)—QLs***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following QLs, consistent with the products' packaging and labeling:

(1) Ibrutinib (Imbruvica): A maximum allowable quantity at the retail network POS of 60 tablets (30-day supply) and 120 tablets at the Mail Order Pharmacy (60-day supply)

(2) Idealisib (Zydelig): A maximum allowable quantity at the retail network POS of 60 tablets (30-day supply) and 120 tablets at the Mail Order Pharmacy (60-day supply)

(3) Everolimus (Afinitor Disperz): A maximum allowable quantity at the retail network POS of a 28-day supply, and a 56-day supply at the Mail Order Pharmacy.

Director, DHA, Decision: ☒ Approved ☐ Disapproved

Approved, but modified as follows:

VIII. SECTION 716 OF THE NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FISCAL YEAR 2013 PILOT PROGRAM FOR REFILLS OF MAINTENANCE MEDICATIONS FOR TRICARE FOR LIFE BENFICIARIES THROUGH THE TRICARE MAIL ORDER PROGRAM

A. Medication Drug List for the Pilot Program: Updates—The Medication Drug list for the Pilot Program for TRICARE for Life beneficiaries was recommended at the November 2013 P&T Committee meeting. An update to the drug list is required due to some products being discontinued from the market, availability issues, and to ensure consistency within the drug classes. (See the November 2013 P&T Committee meeting minutes, Appendix F, found at

http://pec.ha.osd.mil/PT_min_charter.php?submenuheader=5
or the TRICARE Formulary Search Tool at
http://pec.ha.osd.mil/TFL_maintenance_drug_list.php for the full medication drug list.)

1. ***COMMITTEE ACTION: MAINTENANCE MEDICATION PROGRAM DRUG LIST UPDATE***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following changes to the list of covered maintenance medications for the Section 716 pilot program. Implementation will occur upon signing of the minutes.

   - Remove from list due to manufacturer discontinuation: Cardizem 90 mg tablet; Dilacor XR 240 mg capsule; Estraderm 0.05 mg patch; Exelon 2 mg/mL solution; Lantus 100 units/mL cartridge; Lufyllin-GG elixir; Namenda 5mg–10 mg titration pack; Parcopa 10 mg–100 mg orally dissolving tablet (ODT); Parcopa 25 mg–100 mg ODT; Parcopa 25 mg–250 mg ODT; Potaba 500 mg tablet; Questran Light packet; Sanctura XR 60 mg capsules; Teveten 400 mg tablets; Uniretic 15mg–25 mg tablet
   - Remove from list due to noncompliance with the Trade Agreements Act: Isopoto carpine 2% eye drops; Lopid 600 mg tablet; Pepcid 40 mg tablet
   - Remove from list due to availability issues: Theo24
   - Add to list, due to consistency with the drug class: Humulin 70/30 Kwikpen; Humilin 100 units/mL Kwikpen; Pegasys 180 mcg/0.5 mL syringe
   - Add to list due to consistency with the class and UF changes recommended at the August 2014 P&T Committee meeting: TIBs formulary drugs—Otezla, Simponi, Stelara, and Xeljanz

   Director, DHA, Decision: ☒ Approved ☐ Disapproved

   Approved, but modified as follows:

IX. LINE EXTENSIONS

A. Formulary Status Clarification—The P&T Committee clarified the formulary status for one product line extension ("follow-on product") by the original manufacturer. Line extensions have the same FDA indications and pricing as the "parent" drug. The product is a new dosage strength of buprenorphine transdermal system (Butrans).

1. ***COMMITTEE ACTION: LINE EXTENSIONS FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) clarifying the formulary status of the following product to reflect

the current formulary status and step therapy/PA criteria of the parent compound. Implementation will occur upon signing of the minutes.

- Buprenorphine patch (Butrans) 7.5 mcg/hour patch: UF with PA, similar to Butrans patch 5, 10, 15, and 20 mcg/hour

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

X. FISCAL YEAR 2008 NDAA, Section 703

The P&T Committee reviewed drugs from manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs are not in compliance with the Fiscal Year 2008 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, these drugs will be designated NF on the UF and will require pre-authorization prior to use in the Retail POS and medical necessity in the MTFs. These NF drugs will remain available in the Mail Order POS without preauthorization.

1. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) that the following products be designated NF on the UF:

Auxilium Pharma:	Robaxin 750, Robaxin, Levatol
Bluepoint Lab:	Nitrofurantoin Mono-M; Nitrofurantoin
Eli Lilly:	Livalo
Kowa:	Livalo
Major Pharma:	sulfasalazine, methotrexate
Orexo:	Zubsolv
Purdue:	Dilaudid, Intermezzo
VistaPharm:	sucralfate
Xenoport:	Horizant
Zylera:	Ulesfia

2. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following pre-authorization criteria for the drugs recommended NF above: 1) obtaining the product by home delivery would be detrimental to the patient; and, 2) for branded products with AB generic availability, use of the generic product would be detrimental to the patient. These pre-authorization criteria do not apply to any POS other than retail network pharmacies.

3. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD FOR PRE-AUTHORIZATION CRITERIA***—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 the Retail Network; and, 2) DHA send a letter to beneficiaries affected by these decisions. Based on the P&T Committee's recommendation, the effective date is February 18, 2014.

4. ***COMMITTEE ACTION: DRUG DESIGNATED FORMULARY***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) retaining the following drugs, due to their unique clinical niches: oxycodone 5 mg/mL solution (VistaPharm); nitrogen mustard topical gel for the treatment of mycosis fungoides-type cutaneous T-cell lymphoma (Valchlor; Actelion); and, typhoid vaccine live oral (Vivotif; Berne Products Crucell).

Director, DHA, Decision: ☑ Approved ☐ Disapproved

Approved, but modified as follows:

XI. ITEMS FOR INFORMATION

A. Specialty Medications—The P&T Committee was briefed on an initial plan for specialty medications, including a discussion of a proposed definition of a specialty agent. DHA's goal is to provide a standardized means to measure utilization and spend of specialty agents, and to evaluate patient outcomes. Other aspects include providing tools to assist patients, providers, and MTFs in the course of managing drug and associated therapy for these complex disease states. The P&T Committee will receive updates and will review specialty agents eligible for contractor-provided clinical pharmacy services at future meetings.

XII. ADJOURNMENT

The meeting adjourned at 1730 hours on August 13, 2014. The next meeting will be in November 2014.

Appendix A—Attendance: August 2014 P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

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

Appendix E—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

13 Nov 2014
Date

Appendix A—Attendance: August 2014 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Dr. George Jones	Chief, DHA Pharmacy Operations Division
LTC Robert Conrad, MS	Chief, DHA Pharmacoeconomic Branch (Recorder)
COL John Spain, MS	Army, Pharmacy Officer
Col Scott Sprenger, BSC	Air Force, Pharmacy Officer
CAPT Deborah Thompson, USCG	Coast Guard, Pharmacy Officer
CAPT Derrik Clay for CAPT Edward Norton, MSC	Navy, Pharmacy Officer (Pharmacy Consultant BUMED)
COL Ted Cieslak, MC	Army, Physician at Large
Col Michael Wynn, MC	Army, Family Practice Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Brian King, MC	Navy, Internal Medicine Physician
COL Jack Lewi, MC	Army, Internal Medicine Physician
CDR Shaun Carstairs, MC	Navy, Physician at Large
Lt Col William Hannah, MC	Air Force, Internal Medicine Physician
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Dr. Miguel Montalvo	TRICARE Regional Office-South, Chief of Clinical Operations Division and Medical Director
Voting Members Absent	
Col Michael Spilker, BSC	DHA Deputy Chief, Pharmacy Operations Division
Mr. Joe Canzolino	U.S. Department of Veterans Affairs
Nonvoting Members Present	
Mr. David Hurt	Associate General Counsel, DHA
CDR Brandon Hardin by phone	Medical Logistics Division, DLA
Guests	
Lt Col Dan Castiglia	Defense Logistics Agency Troop Support
Capt Richard Caballero	Defense Logistics Agency Troop Support

Appendix A—Attendance (continued)

Guests—(continued)	
LCDR Robert Selvester, MC	VA/DoD Evidence-Based Practice Guideline Work Group
Mr. Alexander Quinones	Defense Logistics Agency Troop Support
CDR Matthew Baker	Indian Health Service
CDR Brandon Hardin via DCO	Medical Logistics Division, DLA
Ms. Nancy Misel via DCO	Air Force, Pharmacy Officer
CAPT Brittany Latimer via DCO	Army, Pharmacy Officer
MAJ Kevin Ridderhoff via DCO	DHA, Pharmacy Operations Division
LT Kendra Jenkins via DCO	DHA, Pharmacy Operations Division
Others Present	
CAPT Walter Downs, MC	DHA Pharmacoeconomic Branch
CDR Joshua Devine, USPHS	DHA Pharmacoeconomic Branch
CDR Edward Vonberg, BSC	DHA Pharmacoeconomic Branch
LCDR Marisol Martinez, USPHS	DHA Pharmacoeconomic Branch
Maj David Folmar, BSC	DHA Pharmacoeconomic Branch
MAJ Misty Cowan, MC	DHA Pharmacoeconomic Branch
Maj Ronald Khoury, MC	DHA Pharmacoeconomic Branch
Dr. David Meade	DHA Pharmacoeconomic Branch
Dr. Angela Allerman	DHA Pharmacoeconomic Branch
Dr. Eugene Moore	DHA Pharmacoeconomic Branch
Dr. Shana Trice	DHA Pharmacoeconomic Branch
Dr. Teresa Anekwe via DCO	DHA Pharmacoeconomic Branch
Dr. Amy Lugo via DCO	DHA Pharmacoeconomic Branch
Dr. Brian Beck	DHA Pharmacoeconomic Branch
Mr. Kirk Stocker	DHA Pharmacoeconomic Branch contractor
Ms. Deborah Garcia	DHA Pharmacoeconomic Branch contractor
Dr. Esmond Nwokeji	DHA Pharmacoeconomic Branch contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
• Abatacept (Orencia) • Anakinra (Kineret) • Certolizumab (Cimzia) • Etanercept (Enbrel) • Tocilizumab (Actemra) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira) is contraindicated • The patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) resulted or is likely to result in therapeutic failure. • The patient previously responded to the nonformulary agent and changing to adalimumab (Humira) would incur unacceptable risk • No alternative formulary agent applies only to: 1. Abatacept (Orencia): The patient is transitioning from IV abatacept or has symptomatic congestive heart failure CHF. 2. Anakinra (Kineret): The patient has neonatal onset multisystem inflammatory disease (NOMID), a subtype of cryopyrin associated periodic syndrome (CAPS). 3. Etanercept (Enbrel): The patient is less than 4 years of age or has hepatitis C infection. 4. Tocilizumab (Actemra): The patient is transitioning from IV abatacept or has symptomatic CHF. **Formulary alternative:** adalimumab (Humira)
• Methylphenidate ER oral suspension (Quillivant XR) **Attention Deficit Hyperactivity Disorder Stimulants**	• The formulary agents resulted in therapeutic failure. • No alternative formulary agent — patient has a G-tube. **Formulary alternatives:** Methylphenidate immediate release, sustained release, or extended release

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• Adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs)**	Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy, and when other systemic therapies are medically less appropriate • Moderate to severely active Crohn's disease following an inadequate response to conventional therapy, loss of response to Remicade, or an inability to tolerate Remicade • Moderate to severely active ulcerative colitis following inadequate response to immunosuppressants Coverage approved for pediatric patients (age 4-17 years) with: • Moderate to severe active polyarticular juvenile idiopathic arthritis Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Golimumab (Simponi) **Targeted Immunomodulatory Biologics (TIBs)**	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 me, coverage is approved for Simponi if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira is not expected with requested non-step preferred TIB • Patient has been stable on IV Simponi with continuous use in last 3 months and needs to transition to the SC formulation of Simponi AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis in combination with methotrexate • Active psoriatic arthritis or active ankylosing spondylitis • Moderately to severely active ulcerative colitis with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy Rheumatoid arthritis patients require an active methotrexate script. Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)

Drug / Drug Class	Prior Authorization Criteria
• Certolizumab (Cimzia) **Targeted Immunomodulatory Biologics (TIBs)**	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 Cimzia if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderately to severely active Crohn's disease following an inadequate response to conventional therapy. Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Etanercept (Enbrel) **Targeted Immunomodulatory Biologics (TIBs)**	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 Enbrel if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative (Enbrel is prescribed for children < 4years of age; Enbrel is prescribed for a patient with hepatitis C virus) AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis • Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy Coverage approved for pediatric patients (age 2–17) with: • Moderate to severe active polyarticular Juvenile Idiopathic Arthritis Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)

Drug / Drug Class	Prior Authorization Criteria
• Anakinra (Kineret) **Targeted Immunomodulatory Biologics (TIBs)**	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 Kineret if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative (Kineret for pediatric patient with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryoprin Associated Period Syndrome (CAPS) NOMID • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis, who have failed ≥ 1 disease modifying anti-rheumatic drugs (DMARDs) Coverage approved for pediatric patients (all ages) with: • Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryoprin Associated Period Syndrome (CAPS) Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Abatacept (Orencia) **Targeted Immunomodulatory Biologics (TIBs)**	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 Orencia if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Patient has been stable on IV Orencia with continuous use in last 3 months and needs to transition to the SC formulation of Orencia AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis • Subcutaneous Orencia is not approved for use in systemic or polyarticular Juvenile Idiopathic Arthritis

Drug / Drug Class	Prior Authorization Criteria
	Abatacept (Orencia)—continued Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Tocilizumab (Actemra) **Targeted Immunomodulatory Biologics (TIBs)**	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 Actemra if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to the SC formulation of Actemra AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs) • Subcutaneous Actemra is not approved for use in systemic or polyarticular Juvenile Idiopathic Arthritis Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Tofacitinib (Xeljanz) **Targeted Immunomodulatory Biologics (TIBs)**	Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Xeljanz if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non-step preferred TIB • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF AND Coverage approved for patients ≥ 18 years with: • Moderate to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

Drug / Drug Class	Prior Authorization Criteria
	Tofacitinib (Xeljanz)—continued Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Apremilast (Otezla) **Targeted Immunomodulatory Biologics (TIBs)**	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 Otezla if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Adverse reactions to Humira not expected with requested non-step preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• Ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Stelara if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Adverse reactions to Humira not expected with requested non-step preferred TIB AND Coverage approved for patients ≥ 18 years with: • Active psoriatic arthritis • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

Drug / Drug Class	Prior Authorization Criteria
	Ustekinumab (Stelara)—continued Coverage is NOT provided for concomitant use 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), or rituximab (Rituxan)
• albiglutide once weekly (Tanzeum) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new and current users of albiglutide (Tanzeum) are required to try metformin or a sulfonylurea (SU) before receiving Tanzeum. Automated PA criteria: The patient has received a prescription for metformin or SU at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days, AND Manual PA criteria: If automated criteria are not met, albiglutide (Tanzeum) 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 sulfonylurea: 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
• Valeritas V-Go Insulin Delivery Device (V-Go) **Insulins**	PA criteria apply to all new users of the V-Go device. Manual PA criteria: (1) Patient has Type 2 diabetes mellitus AND (2) Patient does not need more than 40 units of basal insulin daily AND the patient does not need more than 36 units of bolus insulin daily AND (3) Patient does not need less than 2 unit increments of bolus dosing AND (4) Patient has been maintained on stable basal insulin for at least 3 months (at dosages of 20U, 30U, or 40U) AND (5) Patient has been using prandial insulin for at least 3 months.
• Tasimelteon (Hetlioz) **Newer Sedative Hypnotic-1s**	PA criteria apply to all new users of tasimelteon (Hetlioz). A trial of generic zolpidem IR or zaleplon is required before Hetlioz. Automated PA: The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA: If automated criteria are not met, tasimelteon (Hetlioz) is approved (e.g., trial of zolpidem immediate release or zaleplon is NOT required) if the patient meets criterion #1 below, and one of the other criteria (#2, #3, or #4).

Drug / Drug Class	Prior Authorization Criteria
	Tasimelteon (Hetlioz)—continued (1) The patient is totally blind and has no light perception. AND (2) The patient has received a trial of zolpidem IR or zaleplon and had an inadequate response. OR (3) The patient received a trial of zolpidem IR or zaleplon but was unable to tolerate it due to adverse effects. OR (4) Treatment with zolpidem IR or zaleplon is contraindicated for this patient (e.g., due to hypersensitivity, aberrant behaviors, or intolerable rebound insomnia).
• Trametinib (Mekinist) and Dabrafenib (Tafinlar) **Metastatic Melanoma Medications**	Manual PA criteria apply to all new users of trametinib (Mekinist) and dabrafenib (Tafinlar) Mekinist: • Coverage approved for treatment of patients alone or in combination with dabrafenib (Tafinlar) in patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. • Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy Tafinlar: • Coverage approved as a single agent for treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. • Combination use with Mekinist in the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test. • Not approved for patients with wild-type BRAF melanoma
• Topiramate ER (Trokendi XR and Qudexy XR) **Seizure Medications**	Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR: • Coverage approved for o Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years o Lennox-Gastaut seizures in patients ≥ 6 years • Coverage not approved for o Non-FDA approved indications, including migraine headache and weight loss • Patient is required to try topiramate first, unless the following has occurred: o Inadequate response not expected to occur with Trokendi XR or Qudexy XR o Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR

Appendix D—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 2014	**Targeted Immunologic Biologics**	UF class review Previously reviewed	▪ Adalimumab (Humira)	▪ Apremilast (Otezla) ▪ Golimumab (Simponi) ▪ Tofacitinib (Xeljanz) ▪ Ustekinumab (Stelara)	▪ Abatacept (Orencia ▪ Anakinra (Kineret) ▪ Certolizumab (Cimzia) ▪ Etanercept (Enbrel) ▪ Tocilizumab (Actemra)	Pending singing of the minutes / 90 days	▪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) ▪ TIBs are no longer an ECF class; Humira now BCF

TRICARE Formulary Search tool: *http://www.pec.ha.osd.mil/formulary_search.php*

Appendix E—Table of Abbreviations

A1c	hemoglobin A1c
ACR50	American College of Rheumatology 50
ADHD	attention deficit hyperactivity disorder
AE	adverse event
BCF	Basic Core Formulary
BIA	budget impact analysis
CAPS	Cryoprin Associated Period Syndrome
CEA	cost-effectiveness analysis
CHF	congestive heart failure
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
DCO	Defense Connect Online
DHA	Defense Health Agency
DMARDs	disease modifying anti-rheumatic drugs
DoD	Department of Defense
DR	delayed release
EE	ethinyl estradiol
ER	extended release
ECF	Extended Core Formulary
FDA	U.S. Food and Drug Administration
GLP1RA	glucagon-like peptide-1 receptor agonist
IR	immediate release
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NF	nonformulary
NDAA	National Defense Authorization Act
NOMID	Neonatal-Onset Multisystem Inflammatory Disease
NMA	network meta-analysis
NNT	number needed to treat
P&T	Pharmacy and Therapeutics
PA	prior authorization
PASI 75	Psoriasis Activity and Severity Index 75
POS	points of service
RCTs	randomized controlled trials
QLs	quantity limits
SED-1s	Newer Sedative Hypnotics Drug Class
SU	sulfonylurea
TB	tuberculosis
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
UF	Uniform Formulary