DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 8 and 9, 2017, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2016 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2016 DoD P&T Committee meeting on February 2, 2017.

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

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

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly-approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5) (previously known as "innovator drugs"), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

Nonformulary medications are generally restricted to the mail order program according to amended section 199.21, revised paragraphs (h)(3)(i) and (ii), effective August 26, 2015.

IV. UF DRUG CLASS REVIEWS

A. Hepatitis C Virus (HCV) Drugs: Direct-Acting Antivirals (DAAs) Subclass

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

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

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

  Note that sofosbuvir is not used as monotherapy.

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

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

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

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

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

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

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

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

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

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

- **NF:** No products

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

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

   A trial of Harvoni is not required if:

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

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

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

B. Antibiotics: Tetracycline Drugs Subclass

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period and, 2) DHA send letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is August 9 2017.

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

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

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

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

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

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

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

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

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

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

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

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

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

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

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

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

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

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

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

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

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

B. Quantity Limits (QLs)

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

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

C. PA and QLs Implementation Periods

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

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

VII. LINE EXTENSIONS

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

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

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

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

VIII. FORMULARY STATUS UPDATE: ANTILIPIDEMIC-1s

A. Step Therapy: Rosuvastatin

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

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

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

For more information about The Expanded MTF/Mail Pharmacy Initiative (EMMPI) and the statutory and regulatory mandate that NF pharmaceutical agents are generally not available at MTFs or the Retail Network, but are available in the Mail Order program, refer to the August 2015 DoD P&T Committee meeting minutes, available at http://www.health.mil/PandT. See Appendix F for the mail order status of medications designated NF during the February 2017 P&T Committee Meeting.

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

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

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

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

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

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

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

X. ITEMS FOR INFORMATION

A. TRICARE Mail Order Pharmacy Auto-Refill Program Update

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

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

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

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

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

XI. ADJOURNMENT

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

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

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

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

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

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

Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☑ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

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

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

3.

☐ concurs with the recommendations, except for the following:

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

4 May 2017
Date

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

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

Appendix A—Attendance (continued)

Others Present	
CAPT Walter Downs, MC	Chief, P&T Section, DHA Formulary Management Branch
Lt Col Ronald Khoury, MC	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
LCDR Christina Andrade	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Dean Valibhai, PharmD, MBA	DHA Purchased Care Branch
LT Teisha Robertson via telephone	DHA Purchased Care Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
David Meade, PharmD via telephone	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via telephone	DHA Integrated Utilization Branch
Maj Gregory Palmrose, BSC	University of Texas PhD student
Barbara Bustamante	Pharmacy Student, University of Incarnate Word
Gallissara Agavatpanitch	Pharmacy Student, University of Texas

Appendix B—Table of Medical Necessity (MN) Criteria

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Drug / Drug Class	Prior Authorization Criteria

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

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

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

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

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

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

Drug / Drug Class	Prior Authorization Criteria
• palbociclib (Ibrance) **Oral Oncologic Agents**	**Changes from February 2017 meeting are in BOLD** Manual PA criteria apply to all new users of Ibrance. Manual PA criteria—Ibrance is approved if: A. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND B. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND C. The patient meets ONE of the following criteria (i, ii, iii, or iv): i. The patient is a postmenopausal woman and Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR ii. The patient is a premenopausal or perimenopausal woman and meets the following conditions (a and b): a. The patient is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]), surgical bilateral oophorectomy, or ovarian irradiation; AND b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR iii. The patient is a man and meets the following conditions (a and b): a. The patient is receiving a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin]); AND b. Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole. OR **iv. The patient is a pre-, peri-, or post-menopausal woman and has disease progression following endocrine therapy and is using palbociclib in combination with fulvestrant (Faslodex).** Other Non-FDA approved uses are not approved. Prior Authorization does not expire. .

Drug / Drug Class	Prior Authorization Criteria
• topiramate ER (Trokendi XR) **Anticonvulsants and Anti-Mania Agents**	**February 2017 updates are in BOLD** Manual PA criteria apply to all new users of Trokendi XR and Qudexy XR: • Coverage approved for o Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years o Lennox-Gastaut seizures in patients ≥ 6 years for Trokendi ER and age ≥ 2 years for Qudexy XR o Adjunctive therapy for partial onset seizure or primary generalized tonic clonic seizure in patients 2 years of age or older (Qudexy XR) or 6 years and older (Trokendi XR). o **Migraine prophylaxis in adults (Trokendi XR)** • Coverage not approved for o Non-FDA approved indications, including weight loss and migraine headache (for Qudexy XR only) • Patient is required to try topiramate first, unless the following has occurred: o Inadequate response not expected to occur with Trokendi XR or Qudexy XR o Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR Prior Authorization does not expire.
• testosterone 2% gel pump (Fortesta) **Testosterone Replacement Therapies (Step-preferred product)**	**February 2017 updates are in BOLD** Manual PA criteria apply to all users of transdermal and buccal testosterone replacement products. • Coverage approved for male patients if: o Patient is male over the age of 17 years AND o Patient has a diagnosis of hypogonadism as evidenced by 2 or more morning total testosterone levels below 300 ng/dL AND o The patient is experiencing symptoms usually associated with hypogonadism • **Coverage approved for female-to-male gender reassignment (endocrinologic masculinization) if:** o **Patient is an adult, or is 16 years or older who has experienced puberty to at least Tanner stage 2; AND** o **Patient has a diagnosis of gender dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the DSM; AND** o **Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment); AND** o **Patient has a documented minimum of three months of real-life experience (RLE) and/or three months of continuous psychotherapy addressing gender transition as an intervention for gender dysphoria; AND** o **For gender dysphoria biological female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding.** Prior authorization does not expire.

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

Appendix D—Table of Quantity Limits

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

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

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

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

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

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

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

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
				UF –Not Subject to Step ▪ doxycycline calcium/ monohydrate 25 mg/5 mL, 50 mg/5 mL suspension (generic) ▪ tetracycline 250 mg, 500 mg caps ▪ demeclocycline HCl 150 mg, 300 mg caps (generic)	IR/DR (Oracea and generics) ▪doxycycline monohydrate (Monodoxyne NL) ▪doxycycline monohydrate (Adoxa) ▪doxycycline monohydrate (Monodox) ▪minocycline ER 45 mg, 90 mg, 135 mg ER (generics) ▪minocycline ER 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn)			

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

Appendix H—Table of Abbreviations

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