DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2019

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 8 and 9, 2019, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of February 2019 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the February 2019 DoD P&T Committee meeting on April 25, 2019.

2. **Clarification of Previous Minutes**

   a) **November 2018 Meeting—Auto-Refill Requirements for Self-Monitoring Blood Glucose Test Strips and Lancets and the Gastrointestinal-2 Chronic Idiopathic Constipation/Irritable Bowel Syndrome Drugs Implementation:** Removal of the these products from the Auto-Refill program managed by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy will be implemented on June 12, 2019. Letters will be sent to affected beneficiaries.

   b) **November 2018 Meeting—Targeted Immunomodulatory Biologics (TIBs):** The implementation date for the updates to the TIBs Prior Authorization and Medical Necessity criteria occurred on April 24, 2019. Additionally for tildrakizumab (Ilumya), prior authorization will apply to new users only.

   c) **February 2019 Meeting—Tier 4 Implementation Dates:** Implementation for Tier 4 status for Glumetza, Vimovo, and Lexette foam will occur on August 28, 2019, with letters mailed to beneficiaries at 60 days and 30 days prior to implementation.

   d) **February 2019 Meeting—Brand over Generic Authorization for Dihydroergotamine Spray/Pump (Migranal Nasal Spray):** The brand over generic authorization for Migranal Nasal Spray was removed on April 9, 2019.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. All Uniform Formulary (UF), Basic Core Formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year 2018. 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. Proton Pump Inhibitors – Capsules and Tablets and Alternative Dosage Form Subclasses

Background—The P&T Committee evaluated the relative clinical effectiveness of the Proton Pump Inhibitors (PPIs), including omeprazole (Prilosec), pantoprazole (Protonix), rabeprazole (Aciphex), dexlansoprazole (Dexilant), lansoprazole (Prevacid), omeprazole/sodium bicarbonate (Zegerid), esomeprazole (Nexium), and esomeprazole strontium. Generic formulations of all the products are marketed, except for Dexilant and esomeprazole strontium. Over-the-counter (OTC) formulations of Nexium, Prevacid, Prilosec, and their generics are also available.

The Alternative Dosage Form subclass was also evaluated for UF status and is comprised of 6 products: Prilosec, Protonix, Nexium, and Zegerid packets for oral suspension, Aciphex sprinkle, and Prevacid orally dissolving tablet (ODT; Prevacid Solutab). There are no generic PPI alternative dosage forms.

The Committee reviewed new clinical data available since the original class review in May 2007. Nexium was designated NF at the most recent class review in February 2017.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- The May 2007 drug class review concluded that PPIs have similar efficacy in treating a wide range of acid-related disorders and are highly therapeutically interchangeable. The P&T Committee did not find new clinical efficacy data that would change the original conclusion.
- The 2013 American College of Gastroenterology (ACG) Gastroesophageal Reflux Disease (GERD) Guidelines also support the May 2007 conclusion in their statement that there are no major differences in efficacy between the different PPIs for symptom relief and healing of erosive esophagitis.
- Several recent meta-analyses and systematic reviews state the PPIs do not have clinically significant differences in efficacy (e.g., 2009 Oregon Health & Science University Drug Effectiveness Review Project; 2018 Utah Medicaid P&T Committee).

- A recent network meta-analysis evaluated the comparative efficacy of PPIs for erosive esophagitis and concluded that at equipotent doses the PPIs do not exhibit superiority of one product over the other (Medicine 2017).
- Head-to-head trials between the PPIs are limited in that comparisons of equipotent doses are not always included.
- Differences in pharmacokinetic properties between the PPIs, such as release mechanism (e.g., delayed release or dual release), salt form (e.g., magnesium strontium or sodium bicarbonate), and chirality (e.g., R- vs. R- and S-enantiomers) have little to no clinical impact.
- With regard to the individual PPIs, the P&T Committee concluded the following:
  - Dexlansoprazole (Dexilant) contains the R enantiomer of lansoprazole.
  - Although dexlansoprazole provides two releases of medication with peak concentrations at 2 and 5 hours, the link between dual release and therapeutic benefit is not known. Dexlansoprazole is only approved for patients 12 years and older and is not manufactured in an alternative dosage form.
  - FDA approval for dexlansoprazole was based on two Phase 3 randomized controlled trials showing non-inferiority to lansoprazole. Dexlansoprazole displayed a higher discontinuation rate due to adverse effects in comparison to lansoprazole.
  - The 2009 FDA Review noted that although dexlansoprazole was effective for the requested indications, there was no convincing evidence of additional benefit over existing therapies, and the benefit-to-risk profile for dexlansoprazole was unfavorable.
  - The 2017 network meta-analysis also found that dexlansoprazole was the PPI with the highest discontinuation rate in comparison to all other products.
  - There is no new data to change the May 2009 conclusion that Dexilant does not have a significant clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other PPI drugs currently included on the UF.
  - Esomeprazole strontium contains a different salt formulation from esomeprazole magnesium (Nexium) and is not available in an alternative dosage form.
    - FDA approval was based on the data with Nexium, and no clinical trials were conducted with this formulation. Strontium is incorporated into bone and is not recommended for use in children or during pregnancy due to safety. Esomeprazole strontium is also not recommended in patients with severe renal impairment.
    - Esomeprazole strontium offers no clinically compelling advantages in comparison to esomeprazole magnesium (Nexium) or the other PPIs.
  - Omeprazole/sodium bicarbonate (Zegerid) is only approved for adults. FDA approval was granted based on the original omeprazole studies. Due to the

sodium bicarbonate component, it is contraindicated in patients with metabolic alkalosis, hypocalcemia, respiratory alkalosis or those on salt restricted diets (it contains 300 to 400 mg of sodium per tablet). Zegerid offers no compelling clinical advantages over the other PPIs.

  - Lansoprazole has the largest number of FDA-approved indications; however, there is robust evidence for off-label use for all PPIs for all indications. The alternative dosage form of Prevacid ODT contains phenylalanine and should be avoided in patients with phenylketonuria. Lansoprazole is approved for patients as young as 12.
  - Pantoprazole provides an option for flexible mealtime dosing and does not require dosage adjustment for hepatic impairment. It has an alternative dosage form for treating patients down to the age of 5.
  - Rabeprazole also provides an option for those who require flexible mealtime dosing but is not available in a formulation for use in PEG or NG tubes. The Aciphex sprinkle formulation is approved for children down to the age of 12 years.
  - Esomeprazole and omeprazole have a long history of use, are available OTC, are compatible with NG/PEG tube administration, and the alternative dosage forms carry the youngest FDA-approved age range down to 1 month.

- The 2013 ACG GERD Guidelines and 2017 American Gastroenterological Association (AGA) Best Practices agree that high-quality evidence recommend 4 weeks to 8 weeks of PPI therapy for GERD. Patients with uncomplicated GERD who respond to short-term PPIs should subsequently attempt to stop or reduce PPI use.
- Unless otherwise clinically necessary, PPIs should be used for the shortest period possible per label indication. Indications for longer-term PPI use include refractory GERD, erosive esophagitis, Zollinger-Ellison syndrome, NSAID-induced ulcer history, Barret's Esophagus, and chronic anticoagulation after an Upper GI Bleed.
- With the exception of high discontinuation rates associated with dexlansoprazole, there are no important safety differences in long-term findings between PPI agents, but studies are observational in nature.
- Studies have shown PPIs are not benign and long-term use has been associated with adverse events. FDA safety alerts in 2011, 2012, and 2016 reported that prescription PPIs may cause nutrient malabsorption (vitamin B12, iron, magnesium, calcium) resulting in osteoporosis, hypomagnesemia, vitamin B12 deficiency, and increased infection risk (*Clostridium difficile infections*,, salmonella, campylobacter, and pneumonia). Furthermore, hypomagnesemia, increased risk of bone fracture, increased risk of drug-induced cutaneous and systemic lupus erythematosus.
- The updated Beers Criteria published by the American Geriatrics Society in January 2019 reaffirms the 2015 recommendation to avoid prolonged use of PPIs beyond 8 weeks in adults age 65 years or older, unless there is a justified reason to continue use.

- PPI deprescribing campaigns suggest tapering patients, emphasizing therapeutic lifestyle modification, using rescue therapy such as calcium carbonate antacids or histamine blockers (e.g., ranitidine, famotidine), or attempting on-demand or de-escalation of dosing.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the PPIs. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

Tablets and Capsules Subclass

- CMA results for the Tablets and Capsules subclass showed that esomeprazole strontium, dexlansoprazole, and omeprazole/bicarbonate were substantially less cost-effective than the remainder of the class.
- BIA was performed for the Tablets and Capsules subclass to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating omeprazole (Prilosec, generics) and pantoprazole (Protonix, generics) as formulary and step-preferred, esomeprazole (Nexium, generics) and rabeprazole (Aciphex, generics) as UF and non-step-preferred, lansoprazole (Prevacid, generics) and omeprazole/sodium bicarbonate (Zegerid, generics) as NF and non-step-preferred, and dexlansoprazole (Dexilant) and esomeprazole strontium as Tier 4 demonstrated significant cost avoidance for the Military Health System (MHS).

Alternative Dosage Form Subclass

- CMA results for the Alternative Dosage Form subclass showed that the 6 PPIs available in these formulations had relatively similar cost-effectiveness when adjusted for utilization.
- BIA results for the PPI Alternative Dosage Forms showed that designating Nexium packets, Prilosec packets, Protonix packets, and Aciphex sprinkles as UF, and Prevacid ODT and Zegerid packets as NF demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: TABLETS AND CAPSULES AND ALTERNATIVE DOSAGE FORMS UF/TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following formulary recommendations for the Proton Pump Inhibitors as outlined below, based on clinical and cost-effectiveness.

   When considering the PPI candidates for Tier 4/not covered status, the P&T Committee considered the information outlined in the interim rule, Section 702(b)(10) of the NDAA 2018 published on December 11, 2018, and found at: https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. The interim rule allows for complete exclusion of drugs from TRICARE pharmacy benefit coverage when certain

criteria are met. Tier 4 status will apply to all users of the recommended candidates.

Capsules and Tablets Subclass

- UF and step-preferred
  - omeprazole 20 mg and 40 mg capsules (Prilosec, generics)
  - pantoprazole tablets (Protonix, generics)
- UF and non-step-preferred
  - rabeprazole tablets (Aciphex, generics)
  - esomeprazole capsules (Nexium, generics)
- NF and non-step-preferred
  - lansoprazole capsules (Prevacid, generics)
  - omeprazole/sodium bicarbonate capsules (Zegerid, generics)
- This recommendation includes step therapy in new users, which requires a trial of omeprazole or pantoprazole before esomeprazole or rabeprazole, and a trial of all the UF step-preferred and non-step preferred products (omeprazole, pantoprazole, rabeprazole and esomeprazole) before lansoprazole or omeprazole/sodium bicarbonate. See PA section below.
- Tier 4/Not Covered
  - dexlansoprazole (Dexilant)—The P&T Committee concluded that dexlansoprazole provides very little to no additional clinical effectiveness relative to the other PPIs; that the risk of use may outweigh any potential benefit including a higher discontinuation rate; and that the FDA reviewer expressed concerns regarding the benefit to risk profile. Overall the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other PPIs.
  - esomeprazole strontium—The P&T Committee concluded that the esomeprazole strontium has little clinical data to support its use; has very little or no additional clinical effectiveness relative to the other PPIs and that the needs of TRICARE beneficiaries can be met by the other PPIs.

Alternative Dosage Form Subclass

- UF
  - esomeprazole (Nexium) packet for suspension
  - omeprazole (Prilosec) packet for suspension
  - pantoprazole (Protonix) packet for suspension
  - rabeprazole (Aciphex) sprinkle
- NF
  - lansoprazole ODT (Prevacid Solutab)

        - omeprazole/sodium bicarbonate (Zegerid) packet for suspension
    - Note that step therapy does not apply to the PPI Alternative Dosage Forms.

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining omeprazole 10 and 20 mg capsules and pantoprazole tabs on the BCF and adding omeprazole 40 mg to the BCF. Note that an Alternative Dosage Form PPI was not added to the BCF.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—The PPI class currently has step therapy requirements. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated PA criteria for the PPIs. PA criteria are not required for omeprazole or pantoprazole. Updated manual and automated step therapy PA criteria were recommended in new users for rabeprazole and esomeprazole, requiring a trial of either of the preferred products (omeprazole or pantoprazole) first.

   Additionally, the manual PA criteria for new users of lansoprazole and omeprazole/sodium bicarbonate were updated to require a trial of all of the UF products (omeprazole, pantoprazole, rabeprazole, and esomeprazole) first. Use of the non-preferred PPI is allowed if there is a contraindication, inadequate response, or adverse reaction to all of the preferred PPIs. See Appendix C for the full criteria.

   The current PA criteria for the Alternative Dosage Forms were also updated. PA criteria will now no longer be required for the packets for oral suspension formulations of, Nexium, or Protonix, or the Aciphex sprinkles; Prilosec packets do not currently require PA. Manual PA criteria are recommended for Prevacid ODT and Zegerid packets for oral suspension in all new and current users older than age 18. The provider must state why the patient needs an alternative dosage form and why they cannot take all of the formulary alternative dosage forms. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for lansoprazole (Prevacid, generics), lansoprazole ODT (Prevacid Solutab), omeprazole/sodium bicarbonate (Zegerid, generics), and omeprazole/sodium bicarbonate (Zegerid) packets for suspension. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: PROTON PUMP INHIBITOR MHS GENESIS QUANTITY AND REFILL PROGRAM DEFAULT***

RECOMMENDATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) setting an MHS GENESIS quantity and refill default for all PPIs (omeprazole, omeprazole/sodium bicarbonate, esomeprazole, esomeprazole strontium, lansoprazole, pantoprazole, rabeprazole, and dexlansoprazole) of sixty capsules/tablets with zero refills. The provider may change the quantity or number of refills manually. These recommendations are not quantity limits for the MTFs, Mail Order, or retail network. These recommendations will not apply to CHCS MTF sites, although these sites are encouraged to set the same defaults in their local CHCS drugs files.

6. ***COMMITTEE ACTION: PROTON PUMP INHIBITOR AUTO-REFILL PROGRAM RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing omeprazole, omeprazole/sodium bicarbonate, esomeprazole, lansoprazole, pantoprazole, and rabeprazole from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy. Reasons for removal include the large volume of patient requests, potential long-term safety concerns, and the fact that clinical practice guidelines recommend avoiding use beyond 8 weeks in most patients.

7. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—*** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining branded and non-formulary PPIs on the Select Maintenance Drug list, with the exception that esomeprazole strontium and dexlansoprazole (Dexilant) will be removed from the list when Tier 4/not covered status is implemented.

8. ***COMMITTEE ACTION: OTC OMEPRAZOLE UF RECOMMENDATION—***OTC omeprazole and omeprazole magnesium tablets and capsules have been included on the TRICARE Pharmacy benefit since the August 2015 DoD P&T Committee meeting, under provisions of 32 CFR 199.21(h)(5). The P&T Committee reviewed the cost and utilization of the OTC PPIs, including omeprazole, at the three points of service (POS). OTC omeprazole is not cost-effective compared to generic prescription formulations of omeprazole and pantoprazole. Low-cost OTC omeprazole is readily available for purchase at several venues (retail pharmacies, commissary, grocery stores, etc.).

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing OTC omeprazole and omeprazole magnesium capsules and tablets from the UF, based on cost-effectiveness.

9. ***COMMITTEE ACTION: STATUS OF OTC PPIs ON THE MHS GENESIS OTC LIST***—OTC PPIs currently on the MHS GENESIS OTC List include omeprazole magnesium 20.6 mg (Prilosec OTC), lansoprazole 15 mg (Prevacid 24h, generics), and omeprazole/sodium bicarbonate 20-1100 cap (Zegerid OTC, generics). MTFs dispensed only 248 prescriptions for any of the OTC PPIs during 2QFY19.

   The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) removing all OTC PPIs from the MHS GENESIS OTC List, on the basis of low utilization and the availability of multiple prescription alternatives. The Committee also recommended that PPI step therapy lookback criteria should be set up to include OTC lansoprazole on the list of qualifying drugs that would allow patients to bypass the requirement to use a preferred PPI first. Refer to Section X for more information about the MHS GENESIS OTC List.

10. ***COMMITTEE ACTION: UF/TIER 4, PA, MN, AUTO REFILL, MHS GENESIS QUANTITY AND REFILL PROGRAM DEFAULT IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday 120 days after signing of the P&T minutes at all points of service, and 2) DHA send letters to beneficiaries who are affected by the auto-refill removal and Tier 4/not covered recommendations and those affected by the removal of OTC omeprazole and omeprazole magnesium from the UF. Note that the BCF addition of omeprazole 40 mg will occur on the first Wednesday two weeks after signing of the minutes. Based on the P&T Committee's recommendation, the effective date is November 27, 2019.

B. Pulmonary Arterial Hypertension (PAH) Agents – Prostacyclins, Endothelin Receptor Antagonists (ERAs), and Nitric Oxide Drugs

Background—The P&T Committee reviewed the clinical effectiveness of the PAH agents, which are divided into the three subclasses outlined below. The class was last reviewed in February 2015. The intravenous prostacyclins (e.g., Flolan and Remodulin) and PDE-5 inhibitors indicated for erectile dysfunction (e.g., Viagra and Cialis) were not included in the review.

- **Endothelin Receptor Antagonists (ERAs)**: bosentan (Tracleer), ambrisentan (Letairis, generics), and macitentan (Opsumit);
- **Prostacyclins**: treprostinil nebulized solution (Tyvaso), iloprost nebulized solution (Ventavis), treprostinil extended-release oral tablets (Orenitram ER), and selexipag tablets (Uptravi);
- **Nitric Oxide Drugs**: the soluble guanylate cyclase stimulator, riociguat (Adempas) and the PDE-5 inhibitors sildenafil (Revatio, generics) and tadalafil (Adcirca, Alyq, generics).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Guidelines

- Guidelines from the 6th World Symposium on PAH were updated in 2019. Key findings include the following:
    - Utilizing risk assessment to determine whether to start initial monotherapy or combination therapy in treatment-naïve patients.
    - Initial combination therapy is recommended for most patients with World Health Organization (WHO) Group 1 PAH; however, initial monotherapy may be considered for select patients.
    - Clinical trial design in PAH is shifting primary endpoints from a short-term correlate such as six-minute walk distance (6MWD) to long-term clinical efficacy measures such as clinical worsening or clinical failure.
- There are no head-to-head studies between the PAH agents in the individual drug subclasses. Comparative efficacy is limited to indirect comparisons, systematic reviews, and meta-analyses.

Endothelin Receptor Antagonists (ERAs)

- There is insufficient evidence to suggest one ERA is superior to another in terms of efficacy.
- Ambrisentan and macitentan have the advantage of once daily dosing, while bosentan is dosed twice daily.
- Generic formulations of ambrisentan are available.
- Data supporting combination therapy with an ERA and a PDE-5 inhibitor is available with ambrisentan in treatment-naïve patients (AMBITION trial) and macitentan in treatment-experienced patients (SERAPHIN trial). Benefits of combination therapy include an improvement in the composite endpoint of time to clinical failure (AMBITION trial), and reduced morbidity/mortality versus placebo or reduced hospitalization versus background therapy (SERAPHIN trial).
- Ambrisentan may cause peripheral edema, while bosentan has a higher risk of hepatic impairment and requires liver function test (LFT) monitoring.
- All of the ERAs require a Risk Evaluation and Mitigation Strategies (REMS) program for embryo-fetal toxicity (pregnancy category X rating).

Prostacyclins

- There is insufficient evidence to suggest one oral prostacyclin is superior to another in terms of efficacy. The oral prostacyclins (Uptravi and Orenitram) have advantages over the inhaled agents (Tyvaso and Ventavis), including ease of administration and less frequent dosing, which has resulted in reduced MHS utilization of the inhaled agents.

- Oral selexipag (Uptravi) in the GRIPHON trial showed a 40% reduction in the occurrence of the primary composite endpoint, which included mortality.
- Results from the FREEDOM-EV study showed that early addition of oral treprostinil (Orenitram ER) in patients receiving one oral background PAH agent significantly delayed disease progression.
- An Agency for Healthcare Research and Quality (AHRQ) systematic review (2013) evaluated the association of adverse reactions (ADRs) with the various PAH drug classes. Inhaled prostacyclins are likely to be associated with ADRs such as headaches, cough, jaw pain, and flushing. With the exception of cough, similar ADRs are seen with the oral prostacyclins.

Nitric Oxide Drugs

- The PAH nitric oxide agents differ in indication, dosing frequency, and pregnancy risk.
- Riociguat (Adempas) is the only soluble guanylate cyclase stimulator, is dosed three times daily, has an additional indication for chronic thromboembolic pulmonary hypertension (CTEPH), and requires a REMS due to a pregnancy category X rating.
- For the PDE-5 inhibitors, sildenafil 20 mg is dosed three times daily and tadalafil is dosed as two 20 mg tablets once daily.
- A Cochrane review (2016) of riociguat (Adempas) showed improved 6MWD; however, the results were not statistically significant. Riociguat did reduce pulmonary artery pressures. No significant differences were seen in the endpoints of mortality, change in functional class, or clinical worsening.
- Concomitant use of riociguat (Adempas) and the PDE-5 inhibitors should be avoided due to additive adverse reactions.

Overall Conclusion

- The choice of the PAH drug depends on a variety of factors including FDA-approved indication, labeling, mechanism of action, route of administration, side effect profile, drug interactions, patient preference, and physician experience.

Relative Cost-Effectiveness Analysis and Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results by formulary subclass showed that ambrisentan (Letairis) was the most cost-effective ERA followed by macitentan (Opsumit) and bosentan (Tracleer); riociguat (Adempas) was the least cost-effective nitric oxide drug; treprostinil (Tyvaso) was the most cost-effective nebulized prostacyclin, followed by iloprost (Ventavis); and treprostinil (Orenitram ER) was the most cost-effective oral prostacyclin followed by selexipag (Uptravi).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or non-formulary on the uniform formulary. BIA results found that designating all the PAH drugs as formulary on the uniform formulary demonstrated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following for the PAH agents, as outlined below, based on clinical and cost-effectiveness:

   Prostacyclins

   - UF
     - treprostinil nebulized solution (Tyvaso)
     - iloprost nebulized solution (Ventavis)
     - treprostinil extended-release oral tablets (Orenitram ER)
     - selexipag (Uptravi)

   Endothelin Receptor Antagonists (ERAs)

   - UF
     - bosentan (Tracleer)
     - ambrisentan (Letairis, generics)
     - macitentan (Opsumit)

   Nitric Oxide Drugs

   - UF and step-preferred
     - sildenafil 20 mg tablets (Revatio, generics)
   - UF and non-step-preferred
     - tadalafil 20 mg (Adcirca, Alyq, generics)
     - riociguat (Adempas)

   - For the nitric oxide drugs, note that this recommendation will continue to require step therapy, which requires a trial of sildenafil 20 mg generic in all new users of tadalafil (Adcirca, Alyq, generics) or riociguat (Adempas). See PA section below.
   - Note that sildenafil 10 mg/mL oral suspension is also UF, but not part of the step therapy requirements for the other nitric oxide drugs.

- Note that for all the PAH drugs, no products were recommended for NF Status.

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) not to add any PAH agent to the BCF. Sildenafil 20 mg generic tablets remain on the Extended Core Formulary (ECF).

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) new manual PA criteria in new users for the ERAs (bosentan [Tracleer], ambrisentan [Letairis], and

macitentan [Opsumit]) and the prostacyclins (inhaled iloprost [Ventavis], inhaled treprostinil [Tyvaso], oral treprostinil [Orenitram ER], and selexipag [Uptravi]).

Updated step therapy and manual PA criteria were recommended in new users for riociguat (Adempas) and tadalafil (Adcirca, Alyq, and generics). For both Adempas and all tadalafil formulations, updated criteria will require the prescription to be written by a cardiologist or pulmonologist, and will continue to require a trial of sildenafil 20 mg. For Adempas, patients are also required to try generic tadalafil. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT FOR AMBRISENTAN (LETAIRIS) AND PA CRITERIA—***TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Letairis is more cost-effective than the AB-rated generic formulations for ambrisentan, which were launched in March 2019. Therefore, branded Letairis will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy).

   The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) requiring brand Letairis over generic ambrisentan in all new and current users, based on cost effectiveness. The prescriber will provide patient-specific justification as to why branded Letairis cannot be used. The Tier 1 (generic) copayment will apply to brand Letairis. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. See Appendix C for the full PA criteria for generic ambrisentan.

5. ***COMMITTEE ACTION: BRAND LETAIRIS COPAYMENT CHANGE—*** The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) lowering the current cost-share for the endothelin receptor antagonist Letairis to the generic Tier 1 cost-share.

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

   > [W]hen a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 90 days after the signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is October 23, 2019.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 2019 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION*—**The P&T Committee recommended (group 1: 17 for, 0 opposed, 0 abstained, 1 absent; group 2: 18 for, 0 opposed, 0 abstained, 0 absent; Tirosint-SOL: 10 for, 7 opposed, 1 abstained, 0 absent) the following:

- UF:
  - cladribine (Mavenclad) – Multiple Sclerosis Agents: Oral Agents
  - epinephrine injection (Symjepi) – Respiratory Agents Miscellaneous
  - levodopa inhalation powder (Inbrija) – Parkinson's Agents
  - levothyroxine sodium oral solution (Tirosint-SOL) – Thyroid and Antithyroid Agents
  - loteprednol etabonate 0.38% ophthalmic gel (Lotemax SM) – Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Anti-inflammatory Agents
  - netarsudil 0.02%/latanoprost 0.005% ophthalmic solution (Rocklatan) – Glaucoma Agents
  - siponimod (Mayzent) – Multiple Sclerosis Agents: Oral Miscellaneous
  - stiripentol (Diacomit) – Anticonvulsants-Antimania Agents
  - tacrolimus oral suspension (Prograf) – Immunosuppressives

- NF:
  - benzhydrocodone/acetaminophen (Apadaz) – Narcotic Analgesics and Combinations
  - estradiol 1 mg/progesterone 100 mg capsules (Bijuva) – Gynecological Agents Miscellaneous
  - meloxicam ODT (Qmiiz ODT) – Pain Agents: NSAID
  - prucalopride (Motegrity) – Gastrointestinal-2 Agents: Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome Constipation-Predominant (IBS-C)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (group 1: 17 for, 0 opposed, 0 abstained, 1 absent; group 2: 18 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Apadaz, Bijuva, Qmiiz ODT, and Motegrity. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (group 1: 17 for, 0 opposed, 0 abstained, 1 absent; group 2: 18 for, 0 opposed, 0 abstained, 0 absent; Tirosint-SOL: 10 for, 7 opposed, 1 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Applying the same manual PA criteria for Rocklatan in new users as is currently in place for Rhopressa.
- Applying manual PA criteria to new and current users of Mavenclad, Mayzent, Motegrity, and Qmiiz ODT.
- Applying manual PA criteria to new users of Inbrija.
- Applying an automated age edit to new and current users of Tirosint-SOL and new users of Prograf solution. Patients younger than 6 years for Tirosint solution and younger than 12 years for Prograf solution will not be subject to the PA.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (group 1: 17 for, 0 opposed, 0 abstained, 1 absent; group 2: 18 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service, on August 14, 2019.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

a) NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5): Antihistamine-1: First generation and combinations – Carbinoxamine maleate 6 mg tablets (Ryvent, generics) and Carbinoxamine maleate 4 mg/5 mL ER oral suspension (Karbinal ER)

Carbinoxamine 6 mg tablets and 4 mg/5 mL ER oral suspension are new drugs approved via the Abbreviated New Drug Application (ANDA) pathway and thus do not qualify for review by the DoD P&T Committee under the innovator program or new drug reviews. These ANDA-approved products contain ingredients that are currently available in generic products or were included in formulations previously removed from the market. (See February 2019 DoD P&T Committee meeting minutes.)

Carbinoxamine maleate is a first-generation antihistamine and is available in 4 mg and 6 mg generic tablets, 6 mg brand tablets (Ryvent), 4 mg/5 mL immediate release oral solution, and a 4 mg/5 mL ER suspension (Karbinal ER). The 6 mg brand and generic tablets and 4 mg/5 mL ER suspension are not cost-effective relative to the generic 4 mg tablets and 4 mg/5 mL IR oral solution. Cost-effective generic formulations of carbinoxamine 4 mg oral tablets and IR solution are available on the UF without a PA required, and low-cost OTC tablet formulations for diphenhydramine, fexofenadine, or dimenhydrinate tablets and low-cost OTC liquid formulations for diphenhydramine, fexofenadine, or loratadine are widely available.

COMMITTEE ACTION: ANTIHISTAMINE-1: FIRST GENERATION AND COMBINATIONS CARBINOXAMINE MALEATE TABLETS AND SUSPENSION (KARBINAL ER) MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for carbinoxamine 6 mg tablets (Ryvent and generics) and carbinoxamine 4 mg/5 mL ER oral suspension (Karbinal ER) in new and current users, due to the significant cost differences and lack of clinically compelling benefits over generic alternatives. See Appendix C for the full criteria.

b) Insulins: Rapid Acting Agents: generic insulin lispro (authorized generic for Humalog)

An authorized generic for Humalog entered the market in April 2019. An "authorized generic" is the brand company's own product repackaged and marketed as a generic drug. An authorized generic is considered therapeutically equivalent to the name brand drug because it is the same drug. The FDA does not consider authorized generics as AB-rated generic formulations.

COMMITTEE ACTION: GENERIC INSULIN LISPRO MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the authorized generic insulin lispro in new and current users, requiring a trial of branded Humalog, due to cost-effectiveness. The PA requirement will be removed when it is no longer cost advantageous. See Appendix C for the full criteria.

c) Oral Oncologic Agents: niraparib (Zejula), olaparib (Lynparza), and rucaparib (Rubraca)

PA criteria have not previously been required for the ovarian cancer drugs (PARP inhibitors). The P&T Committee reviewed three oral oncologic agents, Zejula, Lynparza, and Rubraca. PA criteria were recommended for these three products in new users, in order to assure prescribing in accordance with FDA-approved indications or a National Comprehensive Cancer Network (NCCN) Guideline-endorsed indication.

COMMITTEE ACTION: NIRAPARIB (ZEJULA), OLAPARIB (LYNPARZA), AND RUCAPARIB (RUBRACA) MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new users. See Appendix C for the full criteria.

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

   a) **Corticosteroids: Immune Modulators – Atopic Dermatitis Subclass – dupilumab (Dupixent)—**Manual PA criteria were originally recommended for Dupixent for Atopic Dermatitis during the May 2017 P&T Committee meeting. The Dupixent PA was then updated to reflect the additional FDA-approved indication for asthma in November 2018. In February and May 2019, the FDA lowered the age for both asthma and atopic dermatitis down to 12 years. The P&T Committee updated the PA to reflect the lower age allowance and also lowered the baseline eosinophils requirement from 300 cells/mcL to 150 cells/mcL, as some benefit was seen at the lower range in the clinical trial.

   b) **Oral Oncologic Agents**—Ibrutinib (Imbruvica) is an oral oncology agent that was designated as UF prior to the Innovator Rule established in August 2015. In May 2018, the P&T Committee recommended PA criteria for both the tablets and capsules. The committee reviewed the NCCN Guidelines and updated the PA to include an allowance for an additional indication that carries a Grade 1, 2A, or 2B recommendation from the NCCN Guidelines.

   c) **Targeted Immunomodulatory Biologics (TIBs): certolizumab (Cimzia) and adalimumab (Humira)—**Cimzia was granted a new FDA indication in March 2019 for non-radiographic axial spondyloarthritis with objective signs of inflammation (nr-ax SpA). Nr-ax SpA is a subtype of spondyloarthritis, a spectrum of disease that also includes ankylosing spondylitis. Guidelines from the Assessment of SpondyloArthritis international Society (ASAS)/European League Against Rheumatism (EULAR) recommend the TNF inhibitors adalimumab (Humira), certolizumab (Cimzia), etanercept (Enbrel), and golimumab (Simponi) for nr-ax SpA, and state that the price of the TNF inhibitor should influence therapy. The P&T Committee updated the Cimzia PA for this additional indication. Although Humira is not approved for treating nr-ax SpA in the United States, clinical trial data is available and it carries this approval by foreign drug regulatory agencies. Based on the ASAS/EULAR guidelines and clinical trial data, the Humira PA was also updated to allow treatment for nr-ax SpA. Patients with nr-ax SpA will still be required to try Humira prior to Cimzia.

   d) **Targeted Immunomodulatory Biologics (TIBs): tofacitinib citrate (Xeljanz/Xeljanz XR)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Xeljanz was

originally approved for treating rheumatoid arthritis; the indication was later expanded to include psoriatic arthritis and ulcerative colitis in adults. The committee reviewed the new FDA safety alert for increased risk for pulmonary embolism and death in patients taking a 10 mg twice daily dose for rheumatoid arthritis. This dosage is only approved for patients with ulcerative colitis. The P&T Committee updated the PA to limit the 10 mg twice daily dose for the labeled indication of ulcerative colitis.

e) Weight Loss Agents—The P&T Committee recommended updates to the manual PA criteria for the branded weight loss agents to provide additional clarity regarding step therapy. Patients must first try generic phentermine before use of any of the non-phentermine branded drugs for weight loss. All updated PA criteria apply to new users. Medical necessity criteria were also updated accordingly.

f) Weight Loss Agents: topiramate extended-release/phentermine (Qsymia)— The P&T Committee recommended updates to the manual PA criteria for Qsymia to include safety concerns regarding pregnancy risk and the REMS program.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Qsymia, the weight loss agents, Dupixent, Xeljanz/Xeljanz XR, Cimzia, Humira, and Imbruvica as well as updates to the MN criteria for the weight loss agents. All updated PA criteria apply to new users of these agents. (See Appendices B and C for the full criteria.)

B. QLs

1. General QLs: QLs were reviewed for 11 drugs from several classes where there are existing QLs, including various respiratory agents. QLs were also recommended for the opioid benzhydrocodone/acetaminophen (Apadaz), limiting therapy to 14 days as included in the package insert, and for oxiconazole cream due to several transactions in which quantities higher than would be clinically expected were dispensed.

   COMMITTEE ACTION: QLs—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) QLs for Apadaz, oxiconazole cream, Pulmicort, Combivent Respimat, Breo Ellipta, Asmanex, QVAR Redihaler, Xopenex nebulized solution, albuterol sulfate nebulized solution 2.5 mg/0.5 mL, and albuterol sulfate nebulized solution 2.5-, 0.63- and 1.25 mg/3 mL. See Appendix D for the QLs.

2. Injectable sumatriptan: The Committee was also briefed on the utilization and cost trends for injectable sumatriptan since the class review in August 2016. A review of the clinical appropriateness of injectable triptan use in relation to cluster headache was also provided. Quantity limit overrides will be granted for injectable sumatriptan in patients with cluster headache.

COMMITTEE ACTION: QUANTITY LIMITS FOR INJECTABLE SUMATRIPTAN—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) that a quantity limit override be granted for patients with a diagnosis of cluster headaches who are concurrently receiving injectable sumatriptan.

C. PAs with Renewal Criteria and Definition

The majority of PAs are approved indefinitely; however, there are some drugs where the PA does expire, with specific renewal criteria required for continuing therapy. Drugs where renewal criteria apply include drugs with significant safety issues (e.g., desmopressin acetate [Nocdurna, Noctiva]), those with continuing monitoring requirements (e.g., oncology drugs), or for circumstances where adherence or a documented response to therapy is required (e.g., PCSK-9 inhibitors for hypercholesterolemia, CGRP inhibitors for migraine headache prophylaxis, or dupilumab for atopic dermatitis or asthma).

The P&T Committee clarified that the intent of PAs with renewal criteria will require the patient to have satisfied the initial PA criteria.

1. ***COMMITTEE ACTION: DEFINITION OF RENEWAL PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) the definition of renewal PA criteria as follows: In order to go through the renewal criteria, the patient must have satisfied the initial PA criteria. If a PA has expired within 6 months (or otherwise specified by the Government), the patient is eligible for the renewal pathway. However, if the original PA has been expired for a period longer than what is specified above, then the patient must go through the initial PA criteria.

D. PA and QLs Implementation Periods

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

    - (18 for, 0 opposed, 0 abstained, 0 absent) New PAs for carbinoxamine 6 mg tablets (Ryvent, generics), Karbinal ER suspension, Rubraca, Lynparza, and Zejula become effective 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for carbinoxamine 6 mg tablets (Ryvent, generics) and Karbinal ER if applicable, as new and current users will be subject to the PA.
    - (18 for, 0 opposed, 0 abstained, 0 absent) Updates to the current PA criteria for Qsymia, the weight loss agents, Dupixent, Xeljanz/Xeljanz XR, Cimzia, Humira, and Imbruvica in new users become effective 30 days after the signing of the minutes.
    - (18 for, 0 opposed, 0 abstained, 0 absent) The QLs for the 11 drugs listed in section VI B above, and in Appendix D, become effective on the first Wednesday two weeks after the signing of the minutes in all POS.

VII. BRAND OVER GENERIC AUTHORIZATION FOR FLUTICASONE/SALMETEROL (ADVAIR DISKUS)

Pricing for the branded Advair Diskus product is more cost-effective than the AB-rated generic formulations for fluticasone/salmeterol, which were launched in March 2019. Therefore, the branded Advair Diskus product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Advair Diskus as outlined in Section IV B 4 on page 13. The "brand over generic" requirement for Advair Diskus will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

A. ***COMMITTEE ACTION: ADVAIR DISKUS BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) implementing the requirement to prefer the branded Advair product over generic formulations. Manual PA criteria are required for generic fluticasone/salmeterol in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded fluticasone/salmeterol product cannot be used.

B. ***COMMITTEE ACTION: ADVAIR DISKUS BRAND COPAYMENT CHANGE—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) that the brand (Tier 2) formulary cost-share for Advair Diskus in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost-share.

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for 3 product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) clarifying the formulary status of the following 3 products to reflect the current formulary status and applicable step therapy, PA criteria, MN criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- Antipsychotic Agents—Atypical: pimavanserin (Nuplazid) is now available in capsules. Nuplazid in the original tablet formulation was reviewed as a new drug in August 2016 with PA criteria due to safety concerns surrounding a black box warning of increased risk of death in elderly patients with dementia-related psychosis. The P&T Committee recommended designating Nuplazid capsules as NF with the same manual PA requirements as the Nuplazid tablets.

- Hematological Agents—White Blood Cell Stimulant filgrastim-aafi (Nivestym) is now available in a vial version. Nivestym in the original syringe formulation was reviewed by the Committee for formulary status in November 2018 and is currently designated as NF. The new Nivestym vial formulation will be designated as NF, and also added to the EMMPI program, the same as the parent agent.

- TIBs—the new formulation of guselkumab (Tremfya) autoinjector pen will be designated as NF and non-step-preferred, with the same MN, PA, and QLs (day supply limit) as the Tremfya prefilled syringe. Tremfya autoinjector will also be added to the EMMPI program.

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

See Appendix F for the mail order status of medications designated UF, NF, or Tier 4/Not Covered during the May 2019 P&T Committee meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the non-formulary to mail requirement. The implementation date for all EMMPI recommendations from the May 2019 meeting, including the newly approved drugs affected by the EMMPI, will be effective upon the first Wednesday two weeks after the signing of the minutes.

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

The P&T Committee recommended (group 1: 17 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 1 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI program, for the reasons outlined in the table.

X. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OVER-THE-COUNTER (OTC) FORMULARIES AT MTFS: PAIN AGENTS

Background—At the retail pharmacy network and mail order pharmacy, OTC products are limited to those explicitly included in the TRICARE pharmacy benefit (e.g., diabetic supplies, tobacco cessation agents, inhaler spacers, needles/syringes) and those medications added to the Uniform Formulary and covered by TRICARE under provisions of 32 CFR 199.21(h)(5) as being cost-effective and clinically effective compared with other drugs in the same therapeutic class. The OTC products currently on the UF include omeprazole, loratadine, cetirizine, fexofenadine, levonorgestrel 1.5 mg (Plan B One-Step and its generics), and doxylamine 25 mg. As of this meeting, omeprazole OTC formulations will be removed from UF status.

There are variations in the coverage of OTC products across the MTFs. On a recent survey of MTF providers and pharmacy personnel, 72% to 84% of 309 responders indicated that they wanted the DoD P&T Committee to develop a standardized list of OTC drugs and medical supplies that would be allowed on local MTF formularies.

The MHS GENESIS OTC List, which was implemented on March 29, 2018, was developed as a technical testing list and has not yet been reviewed from a clinical perspective. The DoD P&T Committee will review the list by drug class over the next few years in order to develop a streamlined, standardized list, with the goal of providing a uniform and consistent OTC drug benefit across MTFs. The MHS GENESIS OTC List ensures successful adjudication of identified OTCs at MHS GENESIS sites. Although the MHS GENESIS OTC List does not directly impact non-GENESIS (i.e., CHCS) sites through the adjudication process, MTFs are expected to participate in development of the list and implement the newly standardized drug categories at their own sites.

Individual MTFs may recommend changes to the MHS GENESIS OTC List through their local P&T Committees, and then subsequently forward the completed "MTF Drug Review Request Form" to the POD Formulary Management Branch. The form is available at https://health.mil/PandT.

OTC Pain Agents Clinical Review—The OTC pain agents class represents the first drug class evaluated for placement on the MHS GENESIS OTC List. The DoD P&T Committee's evaluation included comparative utilization and patterns of utilization across MTFs, clinical considerations, the availability of legend alternatives, and results of a survey of MTF providers and pharmacy personnel specifically addressing OTC pain agents. The pain agents were divided into 3 groups: 1) OTC analgesics and NSAIDs, 2) topical analgesics, and 3) topical irritants/counter-irritants.

1) *Analgesics and NSAIDs:*

- Most acetaminophen prescriptions dispensed by MTFs are for 325 mg tablets, liquid formulations, and 500 mg tablets. All acetaminophen products are OTC; there are no legend products.
- Ibuprofen 200 mg tablet dispensing at MTFs is substantially lower than the prescription strengths of ibuprofen. Liquid ibuprofen use is lower than both acetaminophen liquid and oral ibuprofen, but is still commonly dispensed. OTC ibuprofen chewable tablets are infrequently dispensed.
- Naproxen is available both as naproxen and naproxen sodium, with a single OTC strength of naproxen sodium (220 mg, equivalent to 200 mg of naproxen) dispensed at low volumes at MTFs. Legend naproxen formulations are available in 250, 375, and 500 mg tablets or delayed release tablets, and as naproxen sodium 275 and 550 mg tablets (equivalent to 250 and 500 mg of naproxen, respectively). The higher strengths of naproxen/naproxen sodium account for the vast majority of MTF prescriptions.
- No legend alternative exists for the OTC aspirin/acetaminophen/caffeine (Excedrin Migraine, generics); the closest comparator is butalbital/acetaminophen/caffeine 50-325-40 mg capsules. While clinical literature is sparse, treatment of mild to moderate

migraine with either simple analgesics or combination analgesics with caffeine is supported. Combination analgesics with caffeine offer more efficacy but increased adverse effects compared to products solely containing analgesics. The OTC product is not any less likely to cause medication overuse headaches compared to prescription alternatives. In addition, the OTC Excedrin formulation is readily available for purchase, at minimal cost.

- Removing acetaminophen 500 mg tablets, 650 mg ER tablets, acetaminophen liquid in unit-of-use cups or syringes, and acetaminophen rapidly dissolving tablets from the MHS GENESIS OTC List is expected to have little to no impact at the current GENESIS sites or the next wave of GENESIS sites expected to implement in September 2019 (Mountain Home, Lemoore, Monterey, and Travis).

A. COMMITTEE ACTION: STATUS OF OTC ANALGESICS AND NSAIDS ON THE MHS GENESIS OTC LIST—The P&T Committee recommended (16 for, 1 opposed, 1 abstained, 0 absent) the following:

- removing the following products from the MHS GENESIS OTC List: acetaminophen 500 mg tablets, 650 mg ER tablets, acetaminophen liquid in unit-of-use cups or syringes, and acetaminophen rapidly dissolving tablets;
- retaining acetaminophen 325 mg tablets, 160 mg/5 mL liquid formulations (all products: elixirs, liquids, oral suspension, and solutions), acetaminophen chewable tablets (as an option for children), and acetaminophen suppositories; and
- retaining all three OTC ibuprofen options (tablets, chewable tablets, and liquid), based on utilization and to provide chewable tablets as an option for children.
- The P&T Committee did not recommend addition of OTC naproxen 220 tablets or aspirin/acetaminophen/caffeine, which are not currently on the MHS GENESIS List.

B. COMMITTEE ACTION: IMPLEMENTATION—The P&T Committee recommended (16 for, 1 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday 120 days following signing of the minutes.

2) *Topical Irritants/Counter-irritants:*

- Benzocaine/menthol aerosol (Dermoplast) is approved for temporary relief of pain and itching; no viable legend alternative formulated as a spray or aerosol is available. OB/GYN specialists and survey respondents indicated that it is widely used postpartum for external perineal pain, for which an aerosol or spray is preferable compared with a lotion or ointment, and that it is best practice to send a new mother home with all necessary medications.
- Dibucaine ointment is approved for use both topically (for dermal pain and itching) and rectally (for hemorrhoids). Providers responding to the survey indicated that it is dispensed postpartum, but also used for other purposes, including joint pain, hemorrhoids, and as pain control during initial herpes outbreaks.

- Lidocaine 4% cream
    - Clinical evidence for topical lidocaine is sparse: a Cochrane review reported no good evidence to support treatment in neuropathic pain, although individual studies supported efficacy for pain relief. While one study showed OTC lidocaine was non-inferior to legend lidocaine patch for low back pain, there is inadequate evidence that legend lidocaine patch is effective for low back pain. OTC lidocaine is as effective for alleviating pain from venipuncture as legend alternatives. However, OTC lidocaine is not included in osteoarthritis guidelines, which recommend topical NSAIDs and capsaicin.
    - Topical lidocaine is available OTC in a wide variety of strengths and formulations, but lidocaine 4% cream was the only OTC lidocaine product dispensed by MTFs during 2QFY19. MTFs more commonly dispense the legend lidocaine 5% ointment and legend lidocaine 5% patch. Prescription alternatives also include lidocaine/prilocaine combinations.
    - Providers responding to the survey indicated lidocaine 4% cream was used for large joint arthritis and back pain, and when patches won't remain in place; for vulvodynia; for superficial nerve pain, rash, itch, multiple insect bites, etc.; and to numb skin prior to injections or procedures.
    - Removal of lidocaine 4% cream from the MHS GENESIS OTC List is expected to have minimal impact at the current MHS GENESIS sites or the next wave of MHS GENESIS sites.

    A. COMMITTEE ACTION: STATUS OF TOPICAL IRRITANT/COUNTER IRRITANTS ON THE MHS GENESIS OTC LIST—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

        - removing lidocaine 4% cream from the MHS GENESIS OTC List;
        - retaining benzocaine/menthol aerosol for postpartum use; and
        - retaining dibucaine for now, but readdressing it along with other hemorrhoid products at a later date.

    B. COMMITTEE ACTION: IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 120 days following signing of the minutes.

3) *Irritants/Counter-irritants:*

- Capsaicin cream has no viable legend alternative (Qutenza is a legend 8% capsaicin patch that falls under the TRICARE medical benefit as it requires administration by a healthcare professional). Capsaicin cream is included in clinical guidelines as being probably effective for reducing peripheral diabetic neuropathic pain (American Academy of Neurology) and is conditionally recommended for hand osteoarthritis (American College of Rheumatology). The majority of MTF prescriptions are for the 0.025% strength, followed by 0.1%, with negligible use of the 0.075% strength.

- Muscle Rubs/Rubefacients (e.g., Myoflex, Icy Hot, Bengay Ultra, Tiger Balm, etc.) are used topically for temporary relief of minor aches and pains. Clinical evidence is limited. A 2014 Cochrane review did include 7 studies of salicylate-containing rubefacients in acute pain and 3 in chronic pain. The quality of studies was considered poor, and reviewers concluded that the evidence did not support the use of topical rubefacients containing salicylate for either acute injuries or chronic conditions. The products were well tolerated in the short term.
- Medications in this category dispensed by MTFs during 2QFY19 include trolamine salicylate 10% cream, methyl salicylate cream and ointment, menthol/camphor lotion and ointment, and menthol 2% gel, 5% gel, and patch. There are no legend alternatives. Across the MHS, 41 of 90 MTF hosts dispensed any of these medications during 2QFY19, with 23 sites dispensing more than 1 of the 4 different formulations.
- The P&T Committee noted that while it is normally preferable that OTC medications be listed on patient profiles, muscle rubs present little concern about drug interactions. Those military commands wanting muscle rubs available for trainees should have them available, similar to other OTC products such as sunscreens
- Removal of methyl salicylate/menthol cream and ointment, menthol/camphor lotion and ointment, and capsaicin 0.075% cream from the MHS GENESIS OTC List is expected to have minimal impact at the current MHS GENESIS sites or the next wave of GENESIS sites.

A. COMMITTEE ACTION: STATUS OF IRRITANTS/COUNTER IRRITANTS ON THE MHS GENESIS OTC LIST—The P&T Committee recommended (14 for, 3 opposed, 1 abstained, 0 absent) the following:

- removing all muscle rubs from the MHS GENESIS OTC List, including methyl salicylate/menthol cream and ointment and menthol/camphor lotion and ointment;
- retaining capsaicin cream 0.025% and 0.1% cream; and
- removing the 0.075% strength of capsaicin cream

~~B.~~ COMMITTEE ACTION: IMPLEMENTATION—The P&T Committee recommended (14 for, 3 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday 120 days following signing of the minutes.

XI. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS

Management of the TRICARE pharmacy benefit requires a wide variety of actions, with various levels of involvement of the DoD P&T Committee, the Beneficiary Advisory Panel (BAP), and the Director, DHA. In May 2005 when the UF Rule was implemented, the P&T Committee developed a comprehensive list of the functions associated with formulary

management and categorized each into one of three decision pathways, depending on the level of involvement required. Operations are categorized according to the following processes: administrative functions (day-to-day maintenance not requiring DoD P&T Committee review); formulary recommendations requiring DoD P&T Committee review and approval by the Director, DHA; and formulary changes requiring DoD P&T Committee review and approval of the Committee's recommendations by the Director, DHA, after considering comments from the Beneficiary Advisory Panel (BAP).

The Committee reviewed the list of previously approved functions/actions that was last updated in May 2017 to manage the benefit. The updated list of functions includes direction for handling drugs designated as Tier 4 and also drugs included on the Clinical Services Drug List (from the February 2019 DoD P&T Committee meeting). (See Appendix G.)

XII. ITEMS FOR INFORMATION

A. Veteran's Administration Continuity of Care List

The P&T Committee was briefed on the updated DoD/VA Continuity of Care Drug List, a joint list of medications for pain, sleep disorders, psychiatric, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by FY16 NDAA, Section 715. Additions, deletions, and clarifications to the list were based on FY18 Active Duty prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The updated list will now go to the VA for review and will be posted on www.health.mil when finalized.

B. MHS and Commercial Pharmacy Trends

The Committee was briefed on various aspects of MHS prescribing including overall trends and spends, the effect of co-pay changes on utilization patterns, the top 25 drug classes, and the continued increases in use and cost of specialty drugs. Comparisons between the MHS and commercial health plans in these trends was discussed.

XIII. ADJOURNMENT

The meeting adjourned at 1630 hours on May 9, 2019. The next meeting will be in August 2019.

Appendix A—Attendance: May 2019 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 During the May 2019 DoD P&T Committee Meeting
Appendix G—DoD P&T Committee Processes and Recommendations/ Approval Authorities
Appendix H—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary
Appendix I—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

26 JULY 2019
Date

Appendix A—Attendance: May 2019 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner for Mr. David Bobb	Chief, Pharmacy Operations Division (POD)
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder) POD
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Peter Cole, MC	Navy, Physician at Large
CDR Bradey Gotto for CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
CDR Michael Smiley for LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Benjamin Keller for CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
COL Clayton Simon, MC	TRICARE Regional Office Representative
Kelly Echevarria, PharmD for Jennifer Zacher, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. David Hurt for Mr. Brian Wheeler	DHA, Associate General Counsel
Lt Col Derek Underhill, BSC	DLA Troop Support
Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Ms. Alexia Ray	DHA Contract Operations Division
LCDR Joshua Blackborn, MSC	DHA Medical Education and Training Campus
CAPT Matthew Clark	Indian Health Service
CDR Matt Miller	Indian Health Service

Appendix A—Attendance (continued)

Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Christina Andrade, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
Robert Conrad, PharmD	DHA Formulary Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Brian Beck, PharmD	DHA Purchased Care Branch
CDR Eric Parsons, MSC	DHA Purchased Care Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Cortney Raymond	DHA Formulary Management Branch Contractor

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• lansoprazole capsules (Prevacid, generics) • omeprazole/sodium bicarbonate capsules (Zegerid, generics) **Proton Pump Inhibitors: Capsules and Tablets**	• Use of EACH formulary PPI is contraindicated. • Patient has experienced significant adverse effects from EACH formulary PPI. • Use of EACH PPI has resulted in therapeutic failure. **Formulary Alternatives:** omeprazole capsules, pantoprazole tablets, esomeprazole capsules, rabeprazole tablets
• lansoprazole ODT (Prevacid Solutab) **Proton Pump Inhibitors: Alternative Dosage Forms**	• Use of EACH formulary agent is contraindicated. • No alternative formulary agent – patient requires an ODT dosage form due to swallowing difficulties (e.g., stroke, developmental delay, exceptional family member). **Formulary Alternatives:** omeprazole packet for suspension, pantoprazole packet for suspension, esomeprazole packet for suspension, rabeprazole sprinkle
• omeprazole/sodium bicarbonate packet for suspension (Zegerid) **Proton Pump Inhibitors: Alternative Dosage Forms**	• Use of EACH formulary PPI is contraindicated. **Formulary Alternatives:** omeprazole packet for suspension, pantoprazole packet for suspension, esomeprazole packet for suspension, rabeprazole sprinkle
• benzhydrocodone/ acetaminophen (Apadaz) **Narcotic Analgesics & Combinations**	• Patient has had therapeutic failure of at least two combination narcotic analgesics. **Formulary Alternatives:** oxycodone/APAP, oxycodone/ASA, hydrocodone/APAP
• estrogen/progesterone (Bijuva) **Gynecological Agents Miscellaneous**	• Patient has experienced significant adverse effects from formulary agents. **Formulary Alternatives:** Combipatch, Climara Pro, FemHRT, Activella, PremPro, Angeliq
• meloxicam orally disintegrating tablets (ODT) (Qmiiz ODT) **Pain Agents: NSAID**	• Patient has or is expected to experience significant adverse effects from at least three formulary agents. **Formulary Alternatives:** ibuprofen, indomethacin, celecoxib, diclofenac, naproxen, diflunisal, etodolac, fenoprofen, flurbiprofen, ketoprofen, ketorolac, meclofenamate, nabumetone, oxaprozin, piroxicam, sulindac, tolmetin
• prucalopride (Motegrity) **Gastrointestinal-2 Agents: CIC/IBS-C**	• All 3 formulary agents have resulted in therapeutic failure. **Formulary Alternatives:** Linzess, Trulance, Amitiza

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• esomeprazole capsules (Nexium, generics) • rabeprazole tablets (Aciphex, generics) **Proton Pump Inhibitors: Capsules and Tablets**	Note that Prior Authorization is not required for omeprazole capsules or pantoprazole tablets. Manual and Automated PA criteria apply to all new users of esomeprazole (Nexium, generics) and rabeprazole (Aciphex, generics). Automated PA Criteria: The patient has filled an Rx for generic omeprazole **OR** generic pantoprazole product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 365 days. Manual PA Criteria: Coverage is approved if all criteria are met: • Provider acknowledges that omeprazole and pantoprazole are the DoD's preferred agents • Provider acknowledges that omeprazole and pantoprazole are Uniform Formulary and do not require prior authorization • The patient has a contraindication to omeprazole and pantoprazole OR • The patient has had an inadequate response or had an adverse reaction to omeprazole OR • The patient has had an inadequate response or had an adverse reaction to pantoprazole Non-FDA-approved uses are not approved. PA does not expire.

• lansoprazole capsules (Prevacid)
• omeprazole/sodium bicarbonate capsules (Zegerid)
 	
Proton Pump Inhibitors: Capsules and Tablets
	Manual PA and Automated PA criteria apply to all new users of lansoprazole (Prevacid, generics) and omeprazole/sodium bicarbonate (Zegerid, generics).
	
	Automated PA Criteria: The patient has filled an Rx for generic omeprazole **AND** generic pantoprazole **AND** generic esomeprazole **AND** rabeprazole product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 365 days.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Provider acknowledges that omeprazole and pantoprazole are the DoD's preferred agents
	• Provider acknowledges that omeprazole and pantoprazole are Uniform Formulary and do not require prior authorization
	• And the patient meets all four of the following criteria:
	  • Has a contraindication, had an inadequate response, or had an adverse reaction to omeprazole
	  AND
	  • Has a contraindication, had an inadequate response, or had an adverse reaction to pantoprazole
	  AND
	  • Has a contraindication, had an inadequate response, or had an adverse reaction to esomeprazole
	  AND
	  • Has a contraindication, had an inadequate response, or had an adverse reaction to rabeprazole
	
	Non-FDA-approved uses are not approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• lansoprazole ODT (Prevacid Soutab) • omeprazole/sodium bicarbonate packet for suspension (Zegerid) **Proton Pump Inhibitors: Alternative Dosage Forms**	Age edit applies: Patients 18 years and older will be subject to the PA. Manual PA criteria apply to all new and current users of Prevacid Solutab and Zegerid packet for suspension. <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Provider acknowledges that omeprazole and pantoprazole tablets and capsules are Uniform Formulary and do not require prior authorization • Provider acknowledges that omeprazole, esomeprazole, and pantoprazole packets for suspension and rabeprazole sprinkles are Uniform Formulary and do not require prior authorization • Provider most document patient-specific clinical rationale of why the patient cannot take ALL alternative PPI agents Non-FDA-approved uses are not approved. PA does not expire.
• ambrisentan (Letairis) brand and generic products • macitentan (Opsumit) **Pulmonary Arterial Hypertension Agents (PAH) – Endothelin Receptor Antagonist (ERA) Subclass**	Manual PA criteria apply to new users of Letairis or Opsumit. <u>Manual PA Criteria:</u> Letairis or Opsumit is approved if all criteria are met: • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of World Health Organization (WHO) group 1 PAH • Patient and provider are enrolled in the Letairis or Opsumit REMS program • Patient is not pregnant • Women of childbearing potential must use adequate contraception • Patient has no history of liver function test (LFT) elevations on previous endothelin receptor antagonist (ERA) therapy accompanied by signs or symptoms of liver toxicity or increases in bilirubin greater than two times the upper limit of normal • Patient does not have moderate or severe liver impairment (e.g., Child-Pugh Class B or C) Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• bosentan (Tracleer) brand and generic products **Pulmonary Arterial Hypertension Agents (PAH) – Endothelin Receptor Antagonist (ERA) Subclass**	Manual PA criteria apply to new users of Tracleer. Manual PA Criteria: Tracleer is approved if all criteria are met: • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has diagnosis of WHO group 1 or 4 (see below) • Patient has documented diagnosis of WHO group 1 – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of WHO group 1 OR • Patient has documented diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO group 4) and the patient has tried Adempas or has a contraindication to Adempas • Patient and provider are enrolled in the Tracleer REMS program • Patient is not pregnant • Women of childbearing potential must use adequate contraception • Patient does not have baseline elevated aminotransferases greater than three times the upper limit of normal due to difficulty in monitoring for hepatotoxicity • Patient does not have moderate or severe liver impairment (e.g., Child-Pugh Class B or C) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• iloprost inhalation (Ventavis) • treprostinil inhalation (Tyvaso) **Pulmonary Arterial Hypertension Agents (PAH) – Prostacyclin Subclass**	Manual PA criteria apply to new users of Ventavis or Tyvaso. Manual PA Criteria: Ventavis or Tyvaso is approved if all criteria are met: • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 PAH – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH Non-FDA-approved uses are not approved. Prior authorization does not expire.
• selexipag (Uptravi) • treprostinil oral (Orenitram ER) **Pulmonary Arterial Hypertension Agents (PAH) – Prostacyclin Subclass**	Manual PA criteria apply to new users of Uptravi or Orenitram ER. Manual PA Criteria: Uptravi or Orenitram ER is approved if all criteria are met: • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 PAH – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH • Patient meets one of the following criteria: – The patient has tried one oral therapy for PAH from one of the three following different categories (either alone or in combination) each for ≥ 60 days: one PDE-5 inhibitor (tadalafil or sildenafil), one ERA (Letairis, Opsumit, or Tracleer), or Adempas; *OR* – The patient has tried one prostacyclin therapy (oral, IV, or nebulized) Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• riociguat (Adempas) **Pulmonary Arterial Hypertension Agents (PAH) – Nitric Oxide Subclass**	Updates from the February 2015 meeting are in **bold** Note that the previous automation for the step therapy has been removed. Manual PA criteria apply to new users of Adempas. Manual PA Criteria: Adempas is approved if all criteria are met: • **Prescribed by or in consultation with a cardiologist or a pulmonologist** • Patient has a documented diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) WHO Group 4 PAH OR • Patient has documented diagnosis of WHO group 1 PAH – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH • Patient has had an adequate trial of sildenafil 20 mg (Revatio, generics) and failed or did not respond to therapy AND • **Patient has had an adequate trial of tadalafil 40 mg (Adcirca, generics) and failed or did not respond to therapy AND** • Patient is not receiving PDE-5 inhibitors or nitrates concomitantly Non-FDA-approved uses are not approved. Prior authorization does not expire.
• tadalafil 20 mg (Adcirca, Alyq, generics) **Pulmonary Arterial Hypertension Agents (PAH) – Nitric Oxide Subclass**	Updates from the February 2015 meeting are in **bold** Manual PA criteria apply to new users of tadalafil 20 mg (Adcirca, generics) and Alyq. Manual PA Criteria: Tadalafil 20 mg (Adcirca, generics) or Alyq is approved if all criteria are met: • **Prescribed by or in consultation with a cardiologist or a pulmonologist** • **Patient has documented diagnosis of WHO group 1 PAH** – **Patient has had a right heart catheterization (documentation required)** – **Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH** • Patient has had an adequate trial of sildenafil 20 mg (Revatio, generics) and failed or did not respond to therapy and • Patient is not receiving other PDE-5 inhibitors, nitrates, or riociguat (Adempas) concomitantly Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria

• cladribine (Mavenclad)
 	
Multiple Sclerosis Agents: Oral Miscellaneous
	Manual PA criteria apply to all new and current users of Mavenclad.
	
	Manual PA Criteria: Coverage will be approved if all criteria are met:
	• Prescribed by a neurologist
	• Patient has a documented diagnosis of one of the following:
	  • Relapsing-Remitting Multiple Sclerosis
	  • Active Secondary Progressive Multiple Sclerosis
	• Patient is not currently using a disease-modifying therapy (DMT)
	• Patient has failed another DMT
	• Mavenclad is not used in patients with:
	  • Current malignancy
	  • Pregnant women or breastfeeding
	  • Men and women of reproductive potential who do not plan to use effective contraception during treatment and 6 months after the last dose
	  • Active chronic infection (e.g., hepatitis, tuberculosis, or HIV infection)
	• Monitoring for hematological and lymphocytic parameters will occur before, during, and after treatment
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.

• levodopa inhalation powder (Inbrija) **Parkinson's Agents**	Manual PA criteria apply to all new users. Manual PA Criteria: Inbrija will be approved if all criteria are met: • Age ≥ 18 years • Patient has a diagnosis of Parkinson's disease • Inbrija is prescribed by or in consultation with a neurologist • Patient continues to experience wearing off periods, despite optimizing carbidopa/levodopa therapy (e.g., increasing the dose or increasing the frequency of dosing) • Patient is currently taking and will continue taking carbidopa-levodopa therapy • Inbrija is not being used concomitantly with, or within 2 weeks of, a non-selective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine, isocarboxazid, hydracarbazine) • Patient does not have chronic underlying pulmonary disease (e.g., asthma, COPD) Non-FDA-approved uses are not approved. Prior authorization expires in one year. Renewal Criteria: PA will be renewed indefinitely if the patient: • Has had a documented reduction in motor symptoms associated with "off" periods of Parkinson's disease, and • Is not taking an MAO inhibitor, and does not have a chronic underlying pulmonary disease (e.g., asthma, COPD).

Drug / Drug Class	Prior Authorization Criteria
• levothyroxine sodium solution (Tirosint-SOL) **Thyroid and Antithyroid Agents**	**PA does not apply to patients younger than 6 years of age (age edit)** PA criteria apply to all new and current users of Tirosint-SOL 6 years of age and older. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is not able to chew a levothyroxine tablet • Patient is not able to swallow a capsule or tablet • Drug is prescribed by or in consultation with an endocrinologist Non-FDA-approved uses are not approved. PA expires after 12 months. No renewal allowed; must fill out a new PA.
• meloxicam orally disintegrating tablets (ODT) (Qmiiz ODT) **Pain Agents: NSAID**	Manual PA criteria apply to all new and current users of Qmiiz. Manual PA Criteria: Coverage for Qmiiz will be approved if: • Note: Multiple formulary NSAIDs, including meloxicam oral tablets, are available for DoD beneficiaries without a PA. • The provider must state the clinical rationale of why patient cannot take any of the formulary NSAIDs: _____ (blank write in) Non-FDA-approved uses are not approved. Prior authorization expires in one year. Renewal criteria – No renewal criteria. PA will be renewed for an additional year if a new PA form is completed.

• netarsudil 0.02%/ latanoprost 0.005% ophthalmic solution (Rocklatan)
 	
Glaucoma Agents
	Manual PA criteria apply to all new users of Rocklatan.
	
	Manual PA Criteria: Coverage will be approved if all criteria are met:
	• Written by an ophthalmologist or an optometrist
	• Patient has had a trial of appropriate duration of 2 different formulary options from different drug classes in combination or separately and has not reached intraocular pressure (IOP) target goals
	  • Prostaglandin analogs
	  • Beta-blockers
	  • Alpha 2-adrenergic agonists
	  • Topical carbonic anhydrase inhibitors
	• Combination therapy of Rocklatan and Rhopressa is not allowed
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria

• prucalopride (Motegrity)
 	
Gastrointestinal-2 Agents: CIC/IBS-C
	Manual PA criteria apply to all new and current users of Motegrity.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Patient is ≥ 18 years of age
	• Patient has tried and failed all formulary agents including Amitiza, Linzess, and Trulance
	• Patient has documented symptoms for ≥ 3 months
	• Patient has diagnosis of chronic idiopathic constipation (CIC)
	• Patient does not have a GI obstruction
	• Patient has no history of suicidal ideation
	• Patient has low cardiovascular risk
	• Patient has documentation of failure of an increase in dietary fiber/dietary modification
	• Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes defined as
	  • osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)
	  • bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids;
	  • stool softener (e.g., docusate);
	  • stimulant laxative (e.g., bisacodyl, sennosides)
	• Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Trulance, Symproic, Relistor, Movantik)
	
	Non-FDA-approved uses are not approved.
	Initial Expiration date: 1 year; Renewal PA (continuation): 1 year
	
	Renewal PA Criteria: Motegrity will be approved for an additional 12 months if the following are met:
	• Patient has had improvement in constipation symptoms
	• Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Trulance, Symproic, Relistor, Movantik)
	• Patients are monitored for suicidal risk

Drug / Drug Class	Prior Authorization Criteria

• siponimod (Mayzent)
 	
Multiple Sclerosis Agents: Oral Miscellaneous
	Manual PA criteria apply to all new and current users of Mayzent.
	
	Manual PA Criteria: Coverage will be approved if all criteria are met:
	• Prescribed by a neurologist
	• A documented diagnosis of one of the following:
	  • Clinically Isolated Syndrome
	  • Relapsing-Remitting Multiple Sclerosis
	  • Active Secondary Progressive Multiple Sclerosis
	• Patient is not currently using another disease-modifying therapy (DMT)
	• Patient has not failed an adequate course of fingolimod (Gilenya)
	• All recommended Mayzent monitoring has been completed, and patient will be monitored throughout treatment as recommended in the label. Monitoring includes complete blood count (CBC), liver function tests (LFT), varicella zoster virus (VZV) antibody serology, genotyping of CYP2C9, electrocardiogram (ECG), and macular edema screening.
	• In patients with CYP2C9 *1/*3 or *2/*3 maintenance dosing will be 1 mg daily
	• Mayzent will not be used in patients with a CYP2C9 *3/*3 genotype
	• Mayzent will not be used in patients with significant cardiac history, including:
	  • Patients with a recent history (within the past 6 months) of class Ill/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization
	  • Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless a functioning pacemaker is inserted
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.

• tacrolimus oral suspension (Prograf) **Immunosuppressives**	**PA does not apply to patients younger than 12 years of age (age edit).** PA criteria apply to all new users of Prograf solution 12 years of age and older. Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by or in consultation with a transplant specialist AND • Has severe dysphagia (e.g., severe esophagitis, mucositis) or is completely unable to swallow (e.g., has G-tube) OR • Patient is < 18 years old and has difficulty swallowing tablets/capsules **Applies to new users (grandfathering allowed).** **PA does not expire.**

Drug / Drug Class	Prior Authorization Criteria
• carbinoxamine 6 mg tablets (Ryvent and generics) • carbinoxamine ER oral suspension (Karbinal ER) **Antihistamine I: First Generation and Combinations**	Manual PA criteria apply to all new and current users of carbinoxamine 6 mg tablets (Ryvent brand and generics) and 4 mg/5 mL ER oral suspension (Karbinal ER). Note: Carbinoxamine generic IR liquid and 4 mg tablets are available without a PA; providers are encouraged to consider changing the prescription to generic IR liquid or 1 or 2 of the 4 mg tablets. Manual PA Criteria: Coverage for carbinoxamine 6 mg tablets (Ryvent brand and generics) or Karbinal ER suspension will be approved if: • This agent has been identified as having cost-effective alternatives. Please describe why this drug is required as opposed to available alternatives. _____ (blank write in) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• insulin lispro (Humalog authorized generic) **Rapid acting insulins**	Manual PA criteria apply to all new and current users of insulin lispro (authorized generic for Humalog). Manual PA Criteria: Coverage is approved if all criteria are met: • Note: Brand Humalog is the preferred insulin lispro product in the DoD. If the prescription is for Humalog, prior authorization is not required. • Please provide a patient-specific justification as to why the brand Humalog product cannot be used _____ (blank write in) Non-FDA-approved uses are not approved. PA does not expire.
• ibrutinib (Imbruvica) tablets and capsules **Oral Oncologic Agents**	**May 2019 criteria specific to Imbruvica are in BOLD.** Manual PA criteria apply to all new users of Imbruvica tablets and capsules. Manual PA Criteria: Coverage will be approved if all criteria are met: • Imbruvica capsules are the Department of Defense's preferred formulation for Imbruvica. • Imbruvica is prescribed by or in consultation with a hematologist/oncologist • If the prescription is for Imbruvica capsules, please continue to the questions below. • If the prescription is for Imbruvica tablets, documentation must be provided as to why the capsule formulation cannot be used, and then continue with the questions below. • The provider must document why can't the patient take the capsule formulation of Imbruvica: _____ • The patient is ≥ 18 years old • The patient has laboratory evidence of and pathologic confirmation of 1 of the following: – Mantle Cell Lymphoma – Marginal Zone Lymphoma – Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with or without 17p deletion – Waldenström's macroglobulinemia – Chronic Graft versus Host Disease – **Non-germinal center diffuse large B-cell lymphoma as a second or greater line therapy in transplant non-candidates** – **The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.** Other non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• niraparib (Zejula) **Oral Oncologic Agents: Ovarian Cancer**	Manual PA criteria apply to all new users of Zejula. Manual PA Criteria: Coverage will be approved if all criteria are met: • Zejula is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test • Niraparib will be prescribed as a maintenance therapy for one of the following diagnoses: • Platinum-sensitive, relapsed, high-grade, ovarian cancers: OR • Recurrent epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer AND • Patient has received 2 or more lines of platinum-based chemotherapy AND • Patient was in objective response (either complete or partial) to most recent treatment regimen AND • Zejula will not be combined with bevacizumab (Avastin) OR – The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis: _____. • Female patients are not pregnant or planning to become pregnant and will take highly effective contraception while taking Zejula and for 6 months after the last dose. Other non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• olaparib (Lynparza) **Oral Oncologic Agents: Ovarian Cancer**	Manual PA criteria apply to all new users of Lynparza. Manual PA Criteria: Coverage will be approved if all criteria are met: • Olaparib is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test • Patient will use olaparib as either treatment or maintenance therapy: for one or more of the following diagnoses: a) Recurrent or Stage IV Triple negative breast cancer b) Recurrent or Stage IV hormone receptor (+) (ER, PR, or both) HER2 (-) breast cancer AND was either: -Previously treated with prior endocrine therapy OR -Was not an appropriate candidate for endocrine therapy c) Recurrent advanced ovarian cancers (platinum-sensitive or platinum-resistant), fallopian tube or primary peritoneal cancers AND -Patient has received at least 3 prior lines of therapy AND -Olaparib will be used as a single agent • Patient will use olaparib as a maintenance therapy for one of the following diagnoses: a) Platinum-sensitive, relapsed, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND -Patient has received 2 or more lines of platinum-based chemotherapy -Patient was in objective response (either complete or partial) to most recent treatment regimen -Olaparib will not be combined with bevacizumab (Avastin) OR b) Newly diagnosed, advanced, high-grade, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND -Patient has had a complete or partial response to primary therapy with a platinum-based therapy -Olaparib will not be combined with bevacizumab (Avastin) OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • Female patients are not pregnant or planning to become pregnant and will take highly effective contraception while taking Lynparza and for 6 months after the last dose. Other non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rucaparib (Rubraca) **Oral Oncologic Agents: Ovarian Cancer**	Manual PA criteria apply to all new users of Rubraca. Manual PA Criteria: Coverage will be approved if all criteria are met: • Rucaparib is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has a deleterious BRCA mutation as detected by an FDA-approved test • Rubraca will be prescribed for one of the following: a) Treatment of recurrent, high-grade, epithelial ovarian cancer (platinum-sensitive or platinum-resistant), fallopian tube or primary peritoneal cancer AND – Patient has received at least 2 prior lines of therapy AND – Rubraca will be used as a single agent b) Maintenance of relapsed platinum-sensitive ovarian cancer, fallopian tube or primary peritoneal cancer AND – Patient has received 2 or more lines of platinum-based chemotherapy AND – Patient was in objective response (either complete or partial) to most recent treatment regimen AND – Rubraca will not be combined with bevacizumab (Avastin) c) Newly diagnosed, advanced, high-grade, ovarian cancer, fallopian tube or primary peritoneal cancer AND – Patient has had a complete or partial response to primary therapy with a platinum-based therapy AND – Rubraca will not be combined with bevacizumab (Avastin) OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • Female patients are not pregnant or planning to become pregnant and will take highly effective contraception while taking Rubraca and for 6 months after the last dose. Other non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• dupilumab (Dupixent) **Corticosteroids – Immune Modulators: Atopic Dermatitis Subclass**	Prior authorization criteria originally approved May 2017 and updated August 2018 and November 2018. **May 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Dupixent. Manual PA Criteria: Coverage will be approved for initial therapy for 6 months if all criteria are met: • Patient has moderate to severe or uncontrolled atopic dermatitis • Patient must be ~~18 years~~ **12 years** of age or older • Prescribed by a dermatologist, allergist, or immunologist • Patient has a contraindication to, intolerability to, or failed treatment with at least ONE high potency/class 1 topical corticosteroid • Patient has a contraindication to, intolerability to, or failed treatment with at least ONE systemic immunosuppressant • Patient has a contraindication to, intolerability to, inability to access treatment, or failed treatment with Narrowband UVB phototherapy • ~~**The 200 mg/1.14 mL dosing is NOT approved for atopic dermatitis**~~ **OR** • Patient has moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma • Patient must be 12 years of age or older • Prescribed by a pulmonologist, asthma specialist, allergist, or immunologist • **Patient has baseline eosinophils ~~≥300 cells/mcL~~ ≥ 150 cells/mcL** • Patient's symptoms are not adequately controlled on stable high-dose inhaled corticosteroid AND either a Long-Acting Beta Agonist or a Leukotriene Receptor Antagonist for at least 3 months • Will not be used for relief of acute bronchospasm or status asthmaticus • Dupixent will be only used as add-on therapy to other asthma controller medications Non-FDA-approved uses are not approved. PA expires after 6 months. Renewal PA Criteria: Coverage will be approved indefinitely for continuation of therapy if: 1. **Atopic Dermatitis:** The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1) 2. **Asthma: The patient has had a positive response to therapy with a decrease in exacerbations, improvements in FEV_1, or decrease in oral corticosteroid use.**

Drug / Drug Class	Prior Authorization Criteria
• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs) – Tumor Necrosis Factor (TNF) Inhibitors**	Prior authorization criteria originally approved August 2014 and implemented February 18, 2015. PA updated November 2015, November 2016, November 2018, and February 2019 to reflect indication changes. **May 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Humira. <u>Manual PA Criteria</u>: Coverage is approved for Humira if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy. • Moderate to severely active Crohn's disease (CD). • Moderate to severely active ulcerative colitis (UC). • Moderate to severe hidradenitis suppurativa (HS). • Non-infectious intermediate, posterior, and panuveitis. • **Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation.** Coverage approved for pediatric patients ≥ 6 years with: • Moderate to severely active Crohn's disease. Coverage approved for pediatric patients ≥ 12 years with: • Moderate to severe hidradenitis suppurativa (HS). Coverage approved for pediatric patients 2-17 years with: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA). • Non-infectious intermediate, posterior, and panuveitis. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? • AS only: Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Coverage for non-FDA-approved uses not listed above. Please provide diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Drug / Drug Class	Prior Authorization Criteria
• certolizumab (Cimzia) **Targeted Immunomodulatory Biologics (TIBs) – Tumor Necrosis Factor (TNF) Inhibitors**	Prior authorization criteria originally approved August 2014 and updated November 2018. **<u>Changes from the May 2019 meeting are in BOLD.</u>** **Manual PA criteria apply to all new users of Cimzia.** <u>Manual PA Criteria</u>: Coverage is approved for Cimzia if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. • Moderately to severely active Crohn's disease (CD). • **Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation with evidence of elevated CRP and/or MRI evidence of sacroiliitis and Ankylosing Spondylitis Disease Activity Score (ASDAS) ≥ 2.1** • Humira is the Department of Defense's preferred targeted biologic agent. The patient has tried Humira. • The patient has a contraindication to Humira (adalimumab) OR • The patient had an inadequate response to Humira. OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent. • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Cimzia. Is the prescriber aware of this? • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • AS **and nr-axSpA only:** Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are not approved. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: adalimumab (Humira), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Drug / Drug Class	Prior Authorization Criteria

• tofacitinib (Xeljanz/Xeljanz XR)
 	
Targeted Immunomodulatory Biologics (TIBs) – Miscellaneous
	Prior authorization criteria originally approved August 2014 and updated May 2016 to reflect XR formulation, February 2018, August 2018, and November 2018 to reflect indication changes.
	
	<u>Changes from the May 2019 meeting are in BOLD.</u>
	
	Step therapy and manual PA criteria apply to all new users of Xeljanz/Xeljanz XR.
	
	<u>Automated PA Criteria</u>: 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
	
	<u>Manual PA Criteria</u>:
	If automated criteria are not met, coverage is approved for Xeljanz/Xeljanz XR if:
	Coverage approved for patients ≥ 18 years with:
	• Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate.
	  ◦ **This prescription for 5 mg BID or 11 mg daily.**
	• Active psoriatic arthritis (PsA).
	  ◦ **This prescription for 5 mg BID or 11 mg daily.**
	• Moderately to severely active ulcerative colitis (UC). **(Will allow doses up to 10 mg BID).**
	
	• Humira is the Department of Defense's preferred targeted biologic agent. The patient has tried Humira.
	• The patient has a contraindication to Humira (adalimumab) OR
	• The patient had an inadequate response to Humira. OR
	• The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent.
	
	• The patient is not receiving potent immunosuppressants (for example, azathioprine and cyclosporine) concomitantly
	• Patient hemoglobin (Hgb) must be > 9 g/dL.
	• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed).
	• The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])?
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.
	
	Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), rituximab (Rituxan), **secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya)**.

Drug / Drug Class	Prior Authorization Criteria
• phentermine/topiramate ER (Qsymia) **Weight Loss Agents**	**May 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Qsymia. <u>Manual PA Criteria:</u> Agent approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • **Patient has tried and failed generic phentermine alone** • Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agent. • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy. • Patient is not pregnant. • **Prescriber will abide by and the patient has been informed of the REMS and safety concerns associated with this agent:** – **Use in combination with other products intended for weight loss has not been established** – **Use in patients with increased cardiovascular risk has not been established** – **Qsymia is pregnancy category X and is associated with increased risk of teratogenicity** • If patient has impaired glucose tolerance or diabetes, must have tried metformin first or is concurrently taking metformin. Non-FDA-approved uses are not approved. Prior authorization expires after 4 months. <u>Renewal PA Criteria</u>: Qsymia will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • For patients initially receiving Qsymia 7.5 mg/46 mg: discontinue Qsymia or escalate to 15 mg/92 mg if a 3% reduction in baseline body weight is not achieved at 12 weeks • For patients receiving Qsymia 15 mg/92 mg: discontinue if a 5% reduction in baseline body weight is not achieved at 12 weeks • The patient is not pregnant. Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy, AND will remain engaged throughout course of therapy.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• benzhydrocodone/ acetaminophen tablets (Apadaz) **Narcotic Analgesics and Combinations**	▪ Retail: 14-day supply ▪ MTF/Mail: 14-day supply
• albuterol sulfate 0.63 mg/ 3 mL, 1.25 mg/3 mL, and 2.5 mg/3 mL nebulized solution **Pulmonary-1 Agents: Short Acting Beta Agonists**	▪ Retail: 125 vials per fill ▪ MTF/Mail: 375 vials per fill
• albuterol sulfate 2.5 mg/ 0.5 mL solution **Pulmonary-1 Agents: Short Acting Beta Agonists**	▪ Retail: 120 vials per fill ▪ MTF/Mail: 360 vials per fill
• levalbuterol 2.5 mg/5 mL (Xopenex) nebulized solution **Pulmonary-1 Agents: Short Acting Beta Agonists**	▪ Retail: 120 vials per fill ▪ MTF/Mail: 360 vials per fill
• beclomethasone (QVAR Redihaler) **Pulmonary-1 Agents: Inhaled Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• budesonide 0.25 mg/2 mL nebulized solution (Pulmicort) **Pulmonary-1 Agents: Inhaled Corticosteroids**	▪ Retail: 60 ampules per fill ▪ MTF/Mail: 180 ampules per fill
• fluticasone/vilanterol (Breo Ellipta) **Pulmonary-1 Agents: Combinations**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• ipratropium/albuterol soft mist inhaler (Combivent Respimat) **Pulmonary-2: Chronic Obstructive Pulmonary Disease**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• mometasone furoate 110 mcg (Asmanex) • mometasone furoate 220 mcg (Asmanex) **Pulmonary-1 Agents: Inhaled Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill

Drug / Drug Class	Quantity Limits
• oxiconazole cream (generic and brand) **Antifungals**	▪ Retail: 90 grams per fill and 28 day supply ▪ MTF/Mail: 90 grams per fill and 28 day supply
• sumatriptan injectable (Imitrex, generics) **Migraine Agents: Triptans**	MTF/Mail/Retail: QL override allowed for patients with a diagnosis of cluster headache at all three points of service

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
benzhydrocodone/ acetaminophen (Apadaz)	Narcotic Analgesics & Combinations	• oxycodone/ acetaminophen • hydrocodone/ acetaminophen	Short-term **(≤ 14 days)** management of acute pain	• First combination narcotic containing an inactive prodrug of hydrocodone that requires *in vivo* enzymes for activation • Apadaz was approved through the 505(b)(2) pathway using bioequivalence studies, with no new efficacy studies completed. • Apadaz lacks the labeling for an abuse deterrent formulation found in other narcotics (e.g., OxyContin). • Administration is limited to only 14 days, per FDA indication. • Apadaz provides no compelling clinical advantages compared to the other UF and NF narcotic analgesics.	• NF • Do not add to EMMPI list
cladribine (Mavenclad)	Multiple Sclerosis Agents: Oral Misc	• dimethyl fumarate (Tecfidera) • fingolimod (Gilenya) • teriflunomide (Aubagio)	Multiple sclerosis (MS), relapsing-remitting MS (RRMS), secondary progressive MS (SPMS)	• Mavenclad is another option for treatment of relapsing-remitting MS and is the first MS therapy that provides long-term changes in immune function. • It is the second FDA-approved medication for secondary progressive MS (SPMS), although SPMS does not have an ICD-10 diagnosis code. • It is administered over 5 days, repeated one month after initial dosing, 43 weeks later, and then one month after the 3rd course. • Black box warnings include malignancy and teratogenicity. • Based on safety, Mavenclad should only be used second line after failure of another MS disease-modifying therapy (DMT). • Effects on long-term disability are unknown, as there was no difference between Mavenclad and placebo in Expanded Disability Status Scale (EDSS) scores. • While Mavenclad adds to the treatment options for patients with MS and has been studied and shown effective in those that progress to SPMS, the true benefit of the drug and place in therapy remains unclear.	• UF • Do not add to EMMPI list
epinephrine IM/SC injection (Symjepi)	Respiratory Agents Miscellaneous	• epinephrine, autoinjector (EpiPen, generics; AdrenaClick generic; Auvi-Q)	Anaphylactic emergencies	• Symjepi is a first prefilled, single-dose syringe for emergency self-treatment of Type 1 allergic reactions requiring manual injection and administration. The other epinephrine injection products (EpiPen or Auvi-Q) are autoinjectors. • Can be administered either intramuscularly (IM) or subcutaneously (SC); it requires manual administration, unlike the autoinjectors. • No new clinical trials were conducted. • One published human factor cohort study to assess ability of adolescents to safely use Symjepi versus EpiPen trainer devices found more user errors (4 out of 34 users) with EpiPen compared to Symjepi ($p<0.05$) but was sponsored by the Symjepi manufacturer. • Pediatric strength (0.15 mg) has not yet launched. • Symjepi is an alternative option to epinephrine autoinjectors for use in the community or clinic setting.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
estradiol 1 mg progesterone 100 mg capsules (Bijuva)	Gynecological Agents Miscellaneous	• estradiol/ norethindrone (Combipatch, FEMHRT, Vivelle) • estradiol/ levonorgestrel (Climara Pro) • Conjugated estrogen/ medroxy-progesterone (Prempro)	Moderate to severe vasomotor symptoms	• Bijuva is a new formulation of estradiol and progesterone in an oral capsule form that is FDA-approved for the treatment of vasomotor symptoms in women with a uterus. • Bijuva is the 7th available combination estrogen/progesterone agent and the 5th available oral agent. • Marketing claims state that Bijuva is the 1st product to contain bio-identical estrogen and progestin, but the FDA does not recognize the term "bio-identical hormone replacement." • Bijuva was evaluated in 1 placebo-controlled trial and outperformed placebo. • There are no head-to-head comparisons of Bijuva with other estradiol combinations or similar drugs with an indication for vasomotor symptoms. • Bijuva contains the same black box warnings as the other combination hormonal replacement therapies. Bijuva has little to no clinical benefit relative to other estradiol combination formulations for the treatment of vasomotor symptoms.	• NF • Add to EMMPI list
levodopa inhalation powder (Inbrija)	Parkinson's Agents	• entacapone (Comtan) • apomorphine (Apokyn) • safinamide (Xadago)	Intermittent treatment of off episodes in patients with Parkinson's disease treated with carbidopa/ levodopa	• Inbrija is the first orally inhaled form of levodopa, and it is indicated for intermittent treatment of off episodes in patients with Parkinson's disease who are receiving carbidopa/levodopa therapy. • FDA approval was based partly on existing efficacy data for levodopa and one pivotal placebo-controlled study indicating Inbrija was superior to placebo in reducing Unified Parkinson Disease Rating Scale (UPDRS) motor function score from pre-dose to 30 minutes post-dose. • However, no significant difference in reducing total time spent in off state has been shown. • Based on safety, Inbrija should not be used concomitantly with, or within 14 days, of MAO inhibitor use and/or in patients with chronic underlying lung disease (e.g., asthma, COPD). • Inbrija provides a therapeutic alternative to other available adjunct dopaminergic agents.	• UF • Do not add to EMMPI list
levothyroxine sodium solution (Tirosint-SOL)	Thyroid and Antithyroid Agents	• levothyroxine tablets (Synthroid) • levothyroxine capsule (Tirosint)	Hypothyroidism and TSH suppression – as adjunct to surgery and radioactive iodine (RAI) treatment in thyroid cancer	• Tirosint-SOL is a new oral solution formulation of levothyroxine and is the first FDA-approved levothyroxine solution. • Only pharmacokinetic studies were conducted showing bioequivalence to Tirosint capsules and Synthroid tablets. • No new clinical trials were completed. • Note that levothyroxine tablets may be chewed. • Other than providing ease in swallowing for patients with swallowing difficulties and pediatric patients unable to chew a tablet, this drug provides no compelling advantage over existing formulary agents.	• UF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
loteprednol etabonate 0.38% ophthalmic gel (Lotemax SM)	Anti-inflammatory Immuno-modulatory Ophthalmic Agents: Ophthalmic Anti-inflammatory Agents	• loteprednol 0.5% (Lotemax) QID • loteprednol 1% (Inveltys) BID • loteprednol 0.2% (Alrex) • prednisolone 1% (Pred Forte) QID	Treatment of post-operative inflammation and pain following ocular surgery	• Lotemax SM ophthalmic gel is the 4th formulation of loteprednol for post-surgery pain and inflammation. • SM stands for "submicron." The purported benefits of submicronization causing faster dissolution and enhanced penetration into the ocular surface have not been proven in a clinical trial. • Lotemax SM is superior to placebo vehicle in decreasing inflammatory cells and pain on day 8. No head-to-head trials with other ocular steroids are available. • Lotemax SM offers an advantage in that is administered TID, compared to Pred Forte, which is administered QID. The Inveltys loteprednol formulation is administered BID. • Provides little to no relative clinical benefit compared to available agents.	• UF • Do not add to EMMPI list
meloxicam ODT (Qmiiz ODT)	Pain Agents: NSAIDs	• Generic meloxicam 7.5 or 15 mg tablets • naproxen oral suspension • meloxicam submicronized (Vivlodex)	Osteoarthritis, rheumatoid arthritis, and juvenile rheumatoid arthritis	• Qmiiz is another formulation of meloxicam for osteoarthritis and rheumatoid arthritis. • Qmiiz was approved through the 505(b)(2) pathway, which showed bioequivalence to meloxicam tablets. There are no clinical trials. • Qmiiz can be administered without food or water. • Qmiiz provides little to no relative clinical benefit compared to available meloxicam tablets or the other NSAIDs.	• NF • Add to EMMPI list
netarsudil 0.02%/ latanoprost 0.005% ophthalmic solution (Rocklatan)	Glaucoma Agents	• netarsudil (Rhopressa) • latanoprost (Xalatan, generics)	Reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension	• First combination eye drop containing a rho kinase inhibitor and prostaglandin analog indicated for elevated IOP • Rocklatan was evaluated in 2 pivotal phase 3 studies, and both showed a minimally clinically important difference (MCID) of > 5 mmHg difference from baseline. One study showed continued efficacy out to 12 months. • Rocklatan was more effective than either latanoprost or netarsudil alone. • Conjunctival hyperemia incidence is over 50%, which is higher than other glaucoma agents. • Limitations include short duration of the studies.	• UF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
prucalopride (Motegrity)	GI-2: CIC/IBS-C Agents	• linaclotide (Linzess) • lubiprostone (Amitiza) • plecanatide (Trulance)	Chronic idiopathic constipation (CIC) in adults	• Motegrity is a new 5-HT_4 agonist approved for adults with chronic idiopathic constipation and is the 4th available agent for CIC. • Prucalopride has been approved for use in Europe since 2009. • Evaluated in 5 Phase III/IV studies; the primary endpoint was not statistically significant in comparison to placebo in 1 trial. • No head-to-head studies with other CIC agents • Most common ADRs included headache, nausea, diarrhea, abdominal pain/distension. • Worse side effect profile compared to other agents indicated for CIC due to the increased risk of suicidality • Motegrity provides no compelling advantages over existing agents for CIC on the formulary.	• NF • Add to EMMPI list
siponimod (Mayzent)	Multiple Sclerosis Agents: Oral Misc	• dimethyl fumarate (Tecfidera) • fingolimod (Gilenya) • teriflunomide (Aubagio)	Multiple sclerosis, clinically isolated syndrome (CIS), RRMS, SPMS	• Mayzent is another option for treatment of CIS and relapsing-remitting MS and is the second sphingosine 1-phosphate (S1P) receptor modulator (after fingolimod [Gilenya]). • First FDA-approved medication for the indication of active secondary progressive MS (SPMS), although SPMS does not have an ICD-10 diagnosis code. • There are no comparator trials to understand the true benefit of siponimod over fingolimod. • There are similar warnings and contraindications to fingolimod with the addition of siponimod requiring genotyping and dose adjustments based on those results. • Unknown effect on long-term disability as seen in the 25-foot walk test. • While Mayzent adds to the treatment options for patients with MS and has been studied and shown effective in those that progress to SPMS, the true benefit of the drug and place in therapy remains unclear.	• UF • Do not add to EMMPI list
stiripentol (Diacomit)	Anticonvulsants-Antimania agents	• topiramate (Topamax) • levetiracetam (Keppra) • cannabidiol (Epidiolex)	Treatment of seizures associated with Dravet syndrome in patients ≥ 2 years old taking clobazam; not for use as monotherapy	• Diacomit is a new molecular entity indicated for the rare disease, Dravet syndrome, and must be coadministered with clobazam. • Diacomit was evaluated in the STICLO – France and Italy study and was statistically superior to placebo. • Side effects are mostly related to metabolic interactions with co-medication. • Diacomit provides an additional add-on therapy for current treatment options in Dravet syndrome patients.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tacrolimus oral suspension (Prograf)	Immuno-suppressives	• tacrolimus (Astagraf XL) • tacrolimus (Envarsus XR) • tacrolimus (Prograf) • tacrolimus generic	Prophylaxis of organ rejection following allogenic heart, kidney, or liver transplant	• First and only oral solution formulation: preferred for young pediatric patients • Avoids dosing errors inherent to suspension from capsules/tablets • Offers lowest dose strength among all other formulations • PK parameters similar to other formulations	• UF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary, Nonformulary, or Tier 4 During the May 2019 DoD P&T Committee Meeting

<table>
<tr><th>DoD P&T Meeting</th><th>ADD to the Mail Order Requirement
(NOT Excepted from Mail Order Requirement)</th><th>Do NOT Add to the Mail Order Requirement
(Excepted from Mail Order Requirement)</th></tr>
<tr><td rowspan="2">May 2019</td><td>Proton pump inhibitors (remain on list):
▪ lansoprazole (Prevacid, generics)
▪ omeprazole/sodium bicarbonate (Zegerid, generics)

Newly Approved Drugs per 32 CFR 199.21(g)(5)

Designated UF:
Similar agents on list:
▪ netarsudil/latanoprost ophthalmic solution (Rocklatan)
▪ levothyroxine sodium solution (Tirosint-SOL)
Designated NF:
No reason to exempt from EMMPI requirement:
▪ estrogen/progesterone (Bijuva)
▪ meloxicam orally disintegrating tablets (Qmiiz ODT)
▪ prucalopride (Motegrity)

Line Extensions
Similar agents on list:
▪ guselkumab (Tremfya) autoinjector pen
▪ pimavanserin (Nuplazid) capsules</td><td>Newly Approved Drugs per 32 CFR 199.21(g)(5)
Designated UF:
Not yet clear if feasible to provide through mail order:
▪ cladribine (Mavenclad)
▪ siponimod (Mayzent)
▪ stiripentol (Diacomit)
▪ levodopa inhalation powder (Inbrija)

Drugs for acute or limited duration use:
▪ loteprednol etabonate 0.38% ophthalmic gel (Lotemax SM)
▪ epinephrine injection (Symjepi)

Drugs in classes not currently represented on the EMM list:
▪ tacrolimus oral suspension (Prograf)

Designated NF:
C-II exception applies:
▪ benzhydrocodone/acetaminophen (Apadaz)</td></tr>
<tr><td colspan="2">Remove from Select Maintenance List due to Tier 4 (not covered) status:
▪ esomeprazole strontium
▪ dexlansoprazole (Dexilant)</td></tr>
</table>

Appendix G—DoD P&T Committee Processes and Recommendations/Approval Authorities Updated May 8, 2019 (Updates from May 2019 meeting are in Bold)

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

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

Process	Function
	▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA "health.mil" website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ **Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting.**
Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments	▪ Classification of a medication as non-formulary on the Uniform Formulary (UF) and the implementation plan (including effective date). ▪ **Classification of a medications as Tier 4 (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and the implementation plan (including effective date).** ▪ Establishment of prior authorization requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and the implementation plan (including effective date). ▪ Changes to existing prior authorization (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of prior authorization requirements for a drug. ▪ Clarification of a medication as non-formulary due to NDAA Section 703 regulations and the implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as non-formulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as non-formulary (Tier 3 co-pay).

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

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2019	**Proton Pump Inhibitors: Capsules and Tablets Subclass**	UF Class Review Class most recently reviewed in February 2017	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ dexlansoprazole (Dexilant) ▪ esomeprazole strontium			Pending signing of the minutes / 120 days The effective date is November 27, 2019.	▪ MHS GENESIS quantity and refill limits: Default quantity of #60 and zero (0) refills will be standardized for all PPIs in MHS GENESIS sites	▪ No PA required for omeprazole or pantoprazole. ▪ Manual PA required for non-step-preferred products in new users; current users are grandfathered. ▪ See Appendix C for full PA criteria and step therapy requirements. ▪ New Tier 4/Not Covered recommendation for Dexilant and esomeprazole strontium applies to both new and current users. ▪ Note – OTC omeprazole and omeprazole magnesium removed from the UF.
			Step-preferred ▪ Omeprazole10, 20 mg and 40 mg capsules (Prilosec, generics) ▪ pantoprazole tablets (Protonix, generics)	*Non-step-preferred* ▪ esomeprazole (Nexium, generics) ▪ rabeprazole (Aciphex, generics)	*Non-step-preferred* ▪ lansoprazole (Prevacid, generics) ▪ omeprazole/sodium bicarbonate (Zegerid, generics)			

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2019	**Proton Pump Inhibitors: Alternative Dosage Form Subclass**	UF Class Review Class not previously reviewed	Note that no BCF selection was made for the Alternative Dosage Form subclass.	▪ omeprazole packet for oral suspension (Prilosec) ▪ pantoprazole packet for oral suspension (Protonix) ▪ esomeprazole packet for oral suspension (Nexium) ▪ rabeprazole sprinkle (Aciphex)	▪ lansoprazole orally dissolving tablet (Prevacid Solutab) ▪ omeprazole/ bicarbonate packet for oral suspension (Zegerid)	Pending signing of the minutes / 120 days The effective date is November 27, 2019.	▪ See Comments	▪ Note that step-therapy does not apply to the alternative dosage forms. ▪ PA does not apply to the UF alternative dosage forms. ▪ Manual PA required for Prevacid ODT and Zegerid in all new and current users. Patients 18 years and under are not subject to the PA. ▪ See Appendix C for the full criteria.

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2019	**Pulmonary Arterial Hypertension: Prostacyclin Subclass, Endothelin Receptor Antagonists Subclass, and Nitric Oxide Subclass**	UF Class Review Class previously reviewed in February 2015	▪ BCF: No PAH product selected ▪ ECF: sildenafil 20 mg tablets (Revatio generic) remains ECF	<u>Prostacyclins</u> ▪ treprostinil nebulized solution (Tyvaso) ▪ iloprost nebulized solution (Ventavis) ▪ treprostinil extended release (ER) tablets (Orenitram) ▪ selexipag tablets (Uptravi) <u>Endothelin Receptor Antagonists (ERAs)</u> ▪ bosentan tablets (Tracleer, generics) ▪ ambrisentan tablets (Letairis) ▪ macitentan tablets (Opsumit) <u>Nitric Oxide Drugs</u> *Step-preferred* ▪ sildenafil 20 mg tablets (Revatio generic) *Non-step-preferred* ▪ tadalafil 20 mg tablets (Adcirca generics, Alyq,) ▪ riociguat tablets (Adempas)	▪ None	Pending signing of the minutes / 90 days The effective date is October 23, 2019.	▪ Manual PAs required for all new users of all PAH agents	▪ Exempt from EMMPI list due to limited distribution ▪ See Appendix C for full PA criteria and step therapy requirements. ▪ Note that sildenafil 10 mg/mL oral suspension is also UF, but not part of the step therapy requirements for the other nitric oxide drugs.

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

Appendix I—Table of Abbreviations

Term	Definition	Term	Definition
6MWD	6-minute walk distance	CVD	Cardiovascular disease
ACG	American College of Gastroenterology	DHA	Defense Health Agency
AGA	American Gastroenterological Association	DMT	Disease-modifying therapy
ADR	adverse reaction	DoD	Department of Defense
AE	adverse event	ECF	Extended Core Formulary
AHRQ	Agency for Healthcare Research and Quality	ECG	electrocardiogram
ANDA	Abbreviated New Drug Application	EDSS	Expanded Disability Status Scale
AS	ankylosing spondylitis	EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ASAS	Assessment of SpondyloArthritis Society	ER	Estrogen receptor; extended release
ASDAS	Ankylosing Spondylitis Disease Activity Score	ERA	Endothelin receptor antagonist
AV	atrioventricular	EULAR	European League Against Rheumatism
BAP	Beneficiary Advisory Panel	FDA	U.S. Food and Drug Administration
BBW	Black box warning	FEV_1	forced expiratory volume in one second
BCF	Basic Core Formulary	FMB	Formulary Management Branch
BIA	budget impact analysis	FY	fiscal year
BMI	Body mass index	GERD	Gastroesophageal reflux disease
CBC	Complete blood count	GI	gastrointestinal
CD	Crohn's Disease	HIV	human immunodeficiency virus
CFR	Code of Federal Regulations	HS	hidradenitis suppurativa
CGRP	calcitonin gene-related peptide	IBS-C	Constipation-predominant irritable bowel syndrome
CHCS	Composite Health Care System	IM	intramuscular
CHF	chronic/congestive heart failure	IOP	Intraocular pressure
CIC	chronic idiopathic constipation	IR	Immediate release
CIS	Clinically isolated syndrome	ISGA	Investigator's Static Global Assessment
CMA	cost minimization analysis	IV	intravenous
COPD	Chronic obstructive pulmonary disease	LFT	Liver function tests
COR	Contracting Officer's Representative	MAO	Monoamine oxidase
CRP	C-reactive protein	MCID	Minimal clinically important difference
CTEPH	Chronic thromboembolic pulmonary hypertension	MCSC	Managed Care Support Contractors

Term	Definition	Term	Definition
MHS	Military Health System	PPI	Proton pump inhibitor
MN	Medical Necessity	PR	progesterone receptor
MRI	Magnetic resonance imaging	Ps	Plaque psoriasis
MS	Multiple Sclerosis	PsA	Psoriatic arthritis
MTF	Military Treatment Facility	QL	Quantity limits
NASH	Nonalcoholic steatohepatitis	RA	Rheumatoid arthritis
NCCN	National Comprehensive Cancer Network	RAI	Radioactive iodine
NDAA	National Defense Authorization Act	RCT	Randomized controlled trial
NF	Nonformulary	REMS	Risk Evaluation and Mitigation Strategies
NG	nasogastric	RRMS	Relapsing-remitting multiple sclerosis
nr-axSpA	non-radiographic axial spondyloarthritis	S1P	Sphingosine 1-phosphate
NSAID	Nonsteroidal anti-inflammatory drug	SC	subcutaneous
ODT	Orally dissolving tablet	SPMS	Secondary progressive multiple sclerosis
OTC	Over the counter	TB	tuberculosis
P&T	Pharmacy and Therapeutics	TIB	Targeted immunomodulatory biologic
PA	Prior authorization	TNF	Tumor Necrosis Factor
PAH	Pulmonary arterial hypertension	TSH	Thyroid-stimulating hormone
PARP	poly ADP-ribose polymerase	UC	Ulcerative colitis
PCSK-9	Proprotein convertase subtilisin/kexin type 9	UF	Uniform Formulary
PDE-5	Phosphodiesterase-5 inhibitor	UPDRS	Unified Parkinson Disease Rating Scale
PDTS	Pharmacy Data Transaction Service	VA	Veteran’s Affairs
PEG	Percutaneous endoscopic gastrostomy	VTE	Venous thromboembolism
pJIA	Polyarticular juvenile idiopathic arthritis	VZV	Varicella zoster virus
PK	pharmacokinetics	WHO	World Health Organization
POD	Pharmacy Operations Division	XR	Extended release
POS	Point of service		