DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 9 and 10, 2017, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May 2017 Minutes—**RADM Colin Chinn, MC, USN, Acting Deputy Director, DHA, approved the minutes from the May 2017 DoD P&T Committee meeting on July 27, 2017.

2. **Clarification to the May 2017 Minutes**

   a) **Update to Deutetrabenazine (Austedo) Manual Prior Authorization (PA) Criteria:** Concomitant use with another vesicular membrane transport type 2 (VMAT-2) inhibitor is not allowed.

   b) **Section 703, National Defense Authorization Act for Fiscal Year 2008** Immediately following the May 2017 P&T Committee meeting, the manufacturer for crofelemer (Mytesi) complied with Section 703 and the drug was designated with formulary status on the Uniform Formulary.

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

A. Basal Insulin Analogs

Background—The Basal Insulin Analogs were previously reviewed for UF status in February 2010. There are several new entrants to the class; however, there are no generic or biosimilar products available. The class is comprised of insulin glargine vials and pens (Lantus), insulin glargine 100 U/mL (Basaglar), insulin detemir vials and pen (Levemir), insulin degludec (Tresiba), and insulin glargine 300 U/mL (Toujeo). Manual prior authorizations (PAs) are currently in place for Toujeo and Tresiba.

Note that the combination products degludec/liraglutide (Xultophy) and degludec/lixisenatide (Soliqua) are part of the glucagon-like peptide-1 receptor agonists (GLP1RA) subclass, and were not included in the review. The formulary recommendations do not apply to neutral protamine Hagedorn (NPH) or 70/30 insulin preparations.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- Basal insulin analogs are dosed subcutaneously (SQ) once daily, and have similar initial dosing.
    - Insulin glargine (Lantus) was marketed in 2000, and was designated as BCF in 2010.
    - Insulin detemir (Levemir) may be dosed once or twice daily and has been marketed since 2005.
    - Insulin degludec (Tresiba) has a long duration of action of up to 42 hours, versus 24 hours for the other products. It also has flexibility with regard to time of administration, and is available in two concentrations (100 U/mL, 200 U/mL).
    - Basaglar is another insulin glargine identical to Lantus in terms of amino acid sequence and pH. It was approved using the FDA 505(b)(2) pathway, since it is a similar biologic version of Lantus.
    - Toujeo is a more concentrated version of Lantus containing 300 U/mL, and has an onset of action developing over 6 hours, compared to Lantus at 3 to 4 hours.
- Although the basal insulin analogs differ in their pharmacokinetic profiles, this variance does not translate into differences in glycemic control or hemoglobin A1c improvements when comparing one product to one another.
- When compared in head-to-head trials, there were no clinically relevant differences reported between the basal insulin analogs and their effect on glycemic control. Lantus was the active comparator in the majority of the non-inferiority trials.
- A 2016 meta-analysis from the Institute of Clinical and Economic Review evaluated eight trials comparing insulin degludec (Tresiba) with insulin glargine (Lantus) or insulin detemir (Levemir). For all eight trials, insulin degludec was non-inferior to the other insulins based on A1c results.

- Regarding hypoglycemia, it is difficult to conclude emphatically that one basal insulin analog is less likely to cause clinically relevant severe or nocturnal hypoglycemia events. This is due to the differences in the definitions of hypoglycemia used in the individual clinical trials, the open label study designs, and the different primary endpoints.
- For special populations, Lantus, Levemir, and Tresiba are approved for use in pediatrics. The basal insulin analogs are rated as pregnancy category C, with the exception of Levemir, which is rated as pregnancy category B.
- A survey of Military Health System (MHS) providers found that the majority of respondents (90%) stated a preference for Lantus in their clinical setting and that it should remain on the BCF, due to their familiarity with the product. Additionally, most clinicians responded that two basal insulins were required on the formulary. After Lantus, most providers stated a preference for Levemir, followed by Tresiba as a second available agent.
- The majority of MHS patients can be treated with Lantus, based on the lack of compelling advantages of the newer basal insulin analogs, existing MHS utilization patterns, and MHS provider opinion.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that glargine pens and vials (Lantus) were the most cost-effective basal insulin analogs followed by glargine 300 U/mL (Toujeo), detemir vial (Levemir), glargine 100 U/mL (Basaglar), detemir pen (Levemir), and degludec (Tresiba).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating glargine pens and vials (Lantus) as BCF and step-preferred, and designating detemir vials (Levemir) and glargine 300 U/mL (Toujeo) as UF and non step-preferred, with glargine 100 U/mL (Basaglar), detemir pen (Levemir), and degludec (Tresiba) as NF and non step-preferred, demonstrated a significant estimated cost avoidance for the MHS.

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

    - **UF and Step-Preferred:**
        - insulin glargine pen and vial (Lantus)
    - **UF and Non Step-Preferred**
        - insulin detemir vial (Levemir)
        - insulin glargine 300 U/mL (Toujeo)
    - **NF and Non Step-Preferred:**
        - insulin detemir pen (Levemir)

- insulin degludec (Tresiba)
- insulin glargine 100 U/mL (Basaglar)

Note that as part of this recommendation, all new users of a basal insulin analog are required to try Lantus first.

2. ***COMMITTEE ACTION: BCF***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) maintaining insulin glargine pens and vials (Lantus) on the BCF, due to provider opinion and clinical and cost effectiveness.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) step therapy for the basal insulin analogs, requiring a trial of Lantus in all new users, prior to use of the non step-preferred products (Basaglar, Levemir, Tresiba, and Toujeo). The step therapy requirement will be included in the manual PAs.

   The existing PAs for Tresiba and Toujeo currently include the requirement for a trial of Lantus first. The Tresiba PA criteria were updated to include use in pediatrics. New PA criteria for Levemir pens and vials, and Basaglar were recommended to incorporate the step therapy. In general, the non step-preferred product will only be allowed if the patient has tried and failed or is intolerant to Lantus, or in the pregnant population, if the patient cannot be treated with Lantus. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) maintaining the current MN criteria for insulin degludec (Tresiba), and insulin glargine 100 U/mL (Basaglar), and new criteria for insulin detemir pen (Levemir). See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) maintaining the basal insulins on the EMMPI list. See Appendix F.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
   The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation. Based on the P&T Committee's recommendation, the effective date is November 22, 2017.

B. Corticosteroids – Immune Modulators Drug Class: Hereditary Angioedema (HAE) Agents Subclass

Background—HAE is a rare disease characterized by lack of or dysfunction of C1 esterase inhibitor. The disease presents as frequent edema episodes affecting the gastrointestinal (GI) tract, extremities, face, and airway. HAE is mediated by bradykinin, and is unresponsive to typical therapy of steroids, epinephrine, and antihistamines.

The drugs in the HAE subclass include the C1 esterase inhibitors and the bradykinin B2 receptor antagonist icatibant (Firazyr). The C1 esterase inhibitors all contain the same active ingredient, but differ in manufacturing and source (plasma derived versus recombinant), FDA indications (treatment versus prophylaxis), and dosing (weight-based versus fixed dosing).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 1 absent) the following for the HAE drugs:

- Treatment
    - Berinert, Ruconest, and icatibant (Firazyr) are indicated for treatment of acute angioedema episodes, based on placebo-controlled trials. The C1 esterase inhibitors are self-administered via intravenous (IV) infusion, while Firazyr is administered by SQ injection. Berinert and icatibant (Firazyr) have FDA approval for treatment of laryngeal attacks, but clinical trial data is available with Ruconest.
    - There are no direct comparative studies between the products for treatment of HAE. However, indirect comparison shows that Berinert, Ruconest, and Firazyr start relieving symptoms within 30 to 90 minutes following administration.
- Prophylaxis
    - For long-term prophylaxis of HAE, guidelines recommend Cinryze and the attenuated androgen Danazol. Factors to consider for initiation of prophylaxis include attack frequency and severity, comorbid conditions, access to emergent treatment, patient experience and preference, and risk factors for adverse effects.
    - Evidence for efficacy of Danazol from a retrospective study showed a 94% response rate, with a decrease from 33.3 attacks per year pre-treatment to 5.4 attacks following Danazol administration.
- Safety
    - The C1 esterase inhibitors all contain warnings for thrombosis. The plasma-derived products (Berinert, Cinryze) carry a risk of blood-borne pathogens, while the recombinant product (Ruconest) has a risk for hypersensitivity reactions in patients allergic to rabbits. Differences between the products regarding the long-term risks of viral transmission and thrombosis remain to be determined.

- Attenuated androgens are rated Pregnancy Category X. Well-known risks of using androgens include virilization in females, stroke, myocardial infarction (MI), and venous thromboembolism.

- Other Factors
  - A survey of MTF and network providers who treat HAE patients commented that Danazol is recommended for prophylaxis but should be avoided in patients with contraindications and women of childbearing age.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (13 for, 0 opposed, 1 abstained, 1 absent) the following:

- CMA results showed that Berinert, Cinryze, Ruconest, and icatibant (Firazyr) were cost-effective agents.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating all four HAE agents (Berinert, Cinryze, Ruconest, and icatibant [Firazyr]) as formulary on the UF demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) the following, based on clinical and cost effectiveness:

   - **UF:**
     - plasma-derived human C1 esterase inhibitor IV (Cinryze)
     - plasma-derived human C1 esterase inhibitor IV (Berinert)
     - recombinant C1 esterase inhibitor IV (Ruconest)
     - icatibant SQ (Firazyr)

   - **NF:** None
   - A new SQ-administered product, plasma-derived human C1 esterase inhibitor SQ (Haegarda) was recently approved for HAE prophylaxis. Haegarda will remain in pending NF status until the November DoD P&T Committee review.
   - Note that BCF selection for the Corticosteroids – Immune Modulator Class include prednisone.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for the HAE prophylaxis product Cinryze, requiring a trial of Danazol in new users. The PA will also apply to Haegarda upon market launch. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—QLs for the HAE products were recommended in August 2016. The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) maintaining the current QLs for Berinert, Ruconest, Cinryze, and icatibant (Firazyr), and also recommended QLs for Haegarda upon market launch. See Appendix D for the QLs.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) an effective date of the first Wednesday after a 30-day implementation period. Based on the P&T Committee's recommendation, the effective date is November 22, 2017.

C. Antiretroviral Agents: Human Immunodeficiency Virus (HIV)

The antiretroviral agents for HIV include 27 unique chemical entities that are combined into over 42 medications. The class was further categorized based on mechanism of action of the individual active ingredients into the integrase strand transfer inhibitors (INSTIs), non-nucleoside reverse transcriptase inhibitor (NNRTIs), nucleoside/nucleotide reverse transcriptase inhibitor (NRTIs), and combination products.

Only a few of the older HIV agents are available in generic formulations. Therefore, the clinical effectiveness review focused on the place in therapy of the new branded entrants to the market.

Relative Clinical Effectiveness Analysis and Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- The newer antiretroviral regimens are associated with fewer serious and intolerable adverse effects than regimens used in the past. First-line (recommended) antiretroviral agents are generally safe and well tolerated in comparison to the other products.
- In treatment-naïve patients, the optimal therapy for HIV should include at least three different drugs, from two or more different drug classes, ideally administered once daily. Current guidelines recommend a regimen containing two NRTIs plus one protease inhibitor or one INSTI.
- First line single-tablet regimens include Triumeq, Stribild, and Genvoya.
- Emtricitabine/tenofovir disoproxil fumarate (Truvada) is the only product FDA approved for HIV pre-exposure prophylaxis (PrEP) based on the iPrEX and PartnersPrEP studies enrolling a population of men who have sex with men, high-risk individuals, or serodiscordant couples
- A systematic review from 11 placebo-controlled trials enrolling 9,000 patients comparing Truvada versus placebo reported that treatment resulted in a 51% reduction in the risk of HIV infection (risk ratio = 0.49, 95% CI: 0.28–0.85, P = 0.001). In terms of safety, Truvada is comparable to placebo.

- Effectiveness of Truvada for PreEP is dependent on adherence. PrEP therapy with Truvada is more effective in patients with high rates of medication adherence, and is essentially not effective in patients who have low adherence rates.
- The HIV antiretroviral agents have a low degree of therapeutic interchangeability; treatment choice must be tailored to the individual patient by considering drug characteristics and risk of resistance.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that of the top three most cost-effective treatment regimens, Triumeq was the most cost effective, followed by Genvoya, and Stribild.
- BIA results showed that designating all the HIV antiretroviral agents as formulary on the UF had a lower budget impact on MHS costs than the current baseline.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following, listed alphabetically by trade name, with first-line or recommended products bolded:

    - **UF**:
        - Aptivus (tipranavir)
        - Atripla (efavirenz/emtricitabine/tenofovir disoproxil fumarate)
        - Combivir (lamivudine/zidovudine)
        - **Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)**
        - Crixivan (indinavir)
        - **Descovy (emtricitabine/tenofovir alafenamide)**
        - Edurant (rilpivirine)
        - Emtriva (emtricitabine)
        - Epivir (lamivudine)
        - Epzicom (abacavir/lamivudine)
        - Evotaz (atazanavir/cobicistat)
        - Fuzeon (enfuviritide)
        - **Genvoya (cobicistat/elvitegravir/emtricitabine/tenofovir alafenamide)**
        - Intelence (etravirine)
        - Invirase (saquinavir)
        - Isentress (raltegravir)
        - **Isentress HD (raltegravir extended-release)**
        - Lexiva (fosamprenavir)
        - Kaletra (lopinavir/ritonavir)
        - **Norvir (ritonavir)**
        - **Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)**
        - Prezcobix (darunavir/cobicistat)
        - **Prezista (darunavir)**
        - Rescriptor (delavirdine)

- Retrovir (zidovudine)
- Reyataz (atazanavir)
- **Selzentry (maraviroc injection and oral solution)**
- **Stribild (cobicistat/elvitegravir/emtricitabine/tenofovir disoproxil fumarate)**
- Sustiva (efavirenz)
- **Tivicay (dolutegravir)**
- **Triumeq (abacavir/dolutegravir/lamivudine)**
- Trizivir (abacavir/lamivudine/zidovudine)
- **Truvada (emtricitabine/tenofovir disoproxil fumarate)**
- Tybost (cobicistat)
- Videx EC (didanosine delayed-release)
- Videx Pediatric (didanosine)
- Viracept (nelfinavir)
- Viramune (nevirapine)
- Viramune XR (nevirapine ER)
- Viread (tenofovir disoproxil fumarate)
- Zerit (stavudine)
- Ziagen (abacavir)

- **NF**: None

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) that designating a BCF HIV antiretroviral agent is clinically inappropriate. Reasons against selecting a BCF product include limiting treatment choices in a disease where resistance is a concern, rapidly changing treatment guidelines, patient comorbidities, individual drug-drug interaction profiles, transmitted resistance, and the likelihood of improved antiretroviral regimens becoming available in the U.S. market.

3. ***COMMITTEE ACTION: UF IMPLEMENTATION PERIOD—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) an effective date upon signing of the minutes in all points of service (POS).

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) 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 August 2017 P&T Committee meeting, a brief summary of their clinical attributes, their formulary recommendations, and see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) the following:

- **UF**:
    - brigatinib (Alunbrig) – Oral Oncology Agents for Lung Cancer
    - methotrexate (Xatmep) oral solution – Antirheumatic Drugs
    - midostaurin (Rydapt) – Oral Oncology Agents for Acute Myeloid Leukemia (AML)
    - niraparib (Zejula) – Oral Oncology Agents for Ovarian Cancer
    - prasterone (Intrarosa) vaginal insert – Vaginal Lubricants
    - ribociclib/letrozole (Kisqali Femara Co-Pack) – Oral Oncologic Agents for Breast Cancer

- **NF:**
    - abaloparatide (Tymlos) injection – Osteoporosis Agents
    - brodalumab (Siliq) injection – Targeted Immunomodulatory Biologics (TIBs)
    - dronabinol (Syndros) oral solution – Antiemetic and Antivertigo Agents
    - fluticasone/salmeterol (AirDuo RespiClick) oral inhaler – Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)
    - mixed amphetamine salts ER (Mydayis) – Attention Deficit Hyperactivity Disorder (ADHD) Drugs
    - morphine sulfate ER (Morphabond XR) – Narcotic Analgesics
    - safinamide (Xadago) – Parkinson's Disease Drugs
    - sarilumab (Kevzara) injection – TIBs
    - valbenazine (Ingrezza) – Neuromuscular Miscellaneous Agents

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) MN criteria for abaloparatide (Tymlos), brodalumab (Siliq), dronabinol oral solution (Syndros), fluticasone/salmeterol (AirDuo RespiClick), mixed amphetamine salts ER (Mydayis), morphine sulfate ER (Morphabond XR), safinamide (Xadago), sarilumab (Kevzara), and valbenazine (Ingrezza). See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) the following:

- Applying the same manual PA criteria for sarilumab (Kevzara) and brodalumab (Siliq) in new and current users, as is currently in place for the

other non step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for brodalumab, a trial of secukinumab (Cosentyx) is required if the patient cannot be treated with Humira. See Appendix C for the full criteria.

- Applying PA criteria to new users of midostaurin (Rydapt), ribociclib/letrozole (Kisqali Femara Co-Pack), prasterone vaginal insert (Intrarosa), safinamide (Xadago), and valbenazine (Ingrezza).

- Applying PA criteria to new and current users of dronabinol oral solution (Syndros), fluticasone/salmeterol (AirDuo RespiClick), methotrexate (Xatmep) oral solution, and mixed amphetamine salts ER (Mydayis). See Appendix C for the full criteria.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent day 1; and 13 for, 0 opposed, 1 abstained, 1 absent day 2) an effective date upon the first Wednesday after the signing of the minutes in all POS, on October 25, 2017.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. **New Manual PA Criteria**

a) **TIBs:—Guselkumab (Tremfya)**

The TIBs were reviewed by the P&T Committee in August 2014 and automated PA (step therapy) and manual PA criteria were recommended for the class. Adalimumab (Humira) was selected as the UF step-preferred agent. Guselkumab (Tremfya) is the fifth TIB approved for treating moderate to severe plaque psoriasis; it will be reviewed for formulary status as a newly-approved drug at an upcoming meeting.

(1) ***COMMITTEE ACTION: GUSELKUMAB (TREMFYA) AUTOMATED AND MANUAL PA CRITERIA***—The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) automated (step therapy) and manual PA criteria for Tremfya, in new and current users, to require a trial of adalimumab (Humira) first, consistent with the existing step therapy criteria for the TIBs Drug Class. See Appendix C for the full criteria.

b) **GI-2 Agents for Opioid-Induced Constipation (OIC)—Naloxegol (Movantik) and Methylnaltrexone (Relistor) Manual PA Criteria**

The GI-2 drugs were previously reviewed for UF status in November 2015, and the chloride channel activator lubiprostone (Amitiza) was selected for UF status. Naloxegol (Movantik) and methylnaltrexone (Relistor) are peripherally-acting mu opioid receptor antagonists (PAMORAs) approved for OIC. OIC treatment

guidelines list lifestyle modifications and laxatives as first line treatment, with PAMORAs and chloride channel activators recommended as second-line agents.

(1) ***COMMITTEE ACTION: NALOXEGOL (MOVANTIK) AND METHYLNALTREXONE (RELISTOR) MANUAL PA CRITERIA*** The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for Movantik and Relistor in all new and current users, requiring a trial of Amitiza first. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria and Step Therapy**—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. Updated manual PA will apply to new users.

   a) **Acne Agents—Topical Acne and Rosacea Agents: Dapsone Gel 5% and 7.5% (Aczone)**—Aczone was reviewed in August 2016 with step therapy and manual PA criteria recommended. Current clinical practice guidelines for acne specify women over the age of 18 as the group who gain the most benefit from Aczone. However, the Aczone package insert states the drug is approved for patients 13 years of age and older. The manual PA criteria were updated to reflect the labeled indication. Note that no changes are recommended for the existing step therapy criteria.

   b) **TIBs: Tocilizumab (Actemra)**—PA criteria were updated for tocilizumab (Actemra) to allow for the new indication for giant cell arteritis.

   c) **Ophthalmic Immunomodulatory Agents: Lifitegrast (Xiidra)**—Xiidra was reviewed as a new drug in November 2016 with manual PA criteria recommended. Criteria were updated to have an expiration date of one year, similar to what is in place for cyclosporine (Restasis).

   d) **Corticosteroids – Immune Modulators: Crisaborole (Eucrisa)**—Eucrisa was reviewed for formulary status in May 2017. The manual PA criteria were updated to allow for prescribing by allergists or immunologists, in addition to dermatologists.

   e) **Proton Pump Inhibitors (PPIs): Esomeprazole Delayed Release Packets for Suspension (Nexium Packets)**—Esomeprazole (Nexium) was designated NF and non step-preferred at an interim meeting in March 2017; a trial of at least three formulary step-preferred products is required prior to use of Nexium. Nexium delayed release packets for suspension are approved for patients as young as one month of age, and are also approved for use in patients with percutaneous endoscopic gastrostomy (PEG) tubes. The Nexium PA criteria were revised to allow use of the delayed release packets for suspension in patients younger than five years and in patients with PEG tubes.

f) **Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors Step Therapy and Manual PA Criteria**—Existing PA criteria for the SGLT2 inhibitors require a trial of metformin and at least one drug from two additional different oral non-insulin diabetes drug subclasses. The P&T Committee recommended simplifying the step therapy and manual PA requirements for the SGLT2 inhibitors. All new users of SGLT2 inhibitors are required to try only metformin unless contraindications exist. Empagliflozin remains the preferred agent within the SGLT2 inhibitor class.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND STEP THERAPY***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for Aczone, Actemra, Xiidra, Eucrisa, Nexium delayed release packets for suspension, and the step therapy and manual PA changes for the SGLT2 inhibitors.

B. Quantity Limits (QLs)

1. **General QLs—**QLs were reviewed for eight drugs: the TIBs brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), and ustekinumab vials (Stelara); brigatinib (Alunbrig) for lung cancer, ribociclib-letrozole (Kisqali-Femara) for breast cancer, midostaurin (Rydapt) for leukemia, and fluticasone/salmeterol (AirDuo RespiClick) for asthma.

a) ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) QLs for Siliq, Kevzara, Tremfya, Stelara, Alunbrig, Kisqali-Femara, Rydapt, AirDuo RespiClick. See Appendix D for the QLs.

2. **Defaults QLs for the TIBs and Oncology Drugs**—QLs already exist for the TIBs and oncologic drugs classes. Several new products are in the pipeline, making maintenance of individual QLs time intensive. Default QLs are recommended due to concerns of adherence and discontinuation or dosage reduction in these costly agents.

a) ***COMMITTEE ACTION: TIBS AND ONCOLOGIC AGENTS DEFAULT QLs—***The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) default QLs for the TIBs and oncologic agents of up to a 30-day supply in the Retail Network and of up to a 60-day supply in the MTFs/Mail Order. Any new TIB approved by the FDA that is intended for self-injection and any new oral oncology drug approved by the FDA will be subject to the default QLs.

C. PA and QLs Implementation Periods

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

- 13 for, 0 opposed, 1 abstained, 1 absent—The new step therapy and manual PA for Tremfya become effective on the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 17, 2018.
- 14 for, 0 opposed, 1 abstained, 0 absent—The new manual PAs for Movantik and Relistor become effective on the first Wednesday after a 90-day implementation period in all POS. Based on the P&T Committee's recommendation, the effective date is January 17, 2018.
- 14 for, 0 opposed, 1 abstained, 0 absent—Updates to the current PAs for dapsone 5% and 7.5% gel (Aczone), tocilizumab (Actemra), lifitegrast (Xiidra), crisaborole (Eucrisa), esomeprazole delayed release packets for suspension (Nexium Packets) and the step therapy and manual PA for the SGLT2 inhibitors become effective upon signing of the minutes in all POS.
- 13 for, 0 opposed, 1 abstained, 1 absent—The QLs for Siliq, Kevzara, Tremfya, Stelara vials, Alunbrig, Kisqali-Femara, Rydapt, AirDuo RespiClick become effective upon signing of the minutes.
- 13 for, 0 opposed, 1 abstained, 1 absent—The default QLs for new TIBs and oncologic agents become effective upon signing of the minutes.

VII. LINE EXTENSIONS

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

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION***—The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) clarifying the formulary status of the following two products to reflect the current formulary status, step therapy/PA criteria, and QLs for the parent compound. Implementation will occur upon signing of the minutes.

- Pulmonary-1 Agents: Pulmonary Miscellaneous drugs for Idiopathic Pulmonary Fibrosis—pirfenidone 801mg tablets (Esbriet) as UF, step-preferred, with the same PA, and 30-day supply QLs as Esbriet 267 mg.

- Endocrine Agents Miscellaneous: Iron Chelators—deferasirox sprinkles (Jadenu Sprinkles) as UF, similar to Jadenu tablets.

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

The P&T Committee reviewed one drug from a pharmaceutical manufacturer that was not included on a DoD Retail Refund Pricing Agreement; this drug was not in compliance with FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703,

it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail POS and medical necessity at MTFs. These NF drugs will remain available in the mail order POS without pre-authorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following product be designated NF on the UF:

- Canton Labs: naproxen sodium (Naprosyn) 500 tablet

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) the following pre-authorization criteria for Naprosyn:

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

These pre-authorization criteria do not apply to any other POS other than retail network pharmacies.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Naprosyn; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is January 17, 2018.

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 NF during the August 2017 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the August 2017 meeting, including the newly-approved drugs affected by the EMMPI, will be effective upon the first Wednesday after the signing of the minutes, on October 25, 2017.

A. Newly-Approved Drugs per 32 CFR 199.21(g)(5)

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

The P&T Committee recommended (13 for, 0 opposed, 1 abstained 1 absent):

a) **Do Not Add:** Prasterone (Intrarosa) is associated with low persistence rates; addition of oral oncology agents such as midostaurin (Rydapt),

niraparib (Zejula), ribociclib/letrozole (Kisqali-Femara), methotrexate (Xatmep) oral solution, and brigatinib (Alunbrig) to the EMMPI program should be considered at a future date, pending more experience with availability of these agents at mail order.

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

   The P&T Committee recommended (13 for, 0 opposed, 1 abstained 1 absent):

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: sarilumab (Kevzara), abaloparatide (Tymlos), safinamide (Xadago), and fluticasone/salmeterol (AirDuo RespiClick).

   b) **Do Not Add:** The previously established exception from the mail order requirement for C-II controlled substances applies to morphine sulfate ER tablets (Morphabond XR), mixed amphetamine salts ER (Mydayis), and dronabinol oral solution (Syndros). The following agents may not be feasible to provide through mail order and should be excepted pending further information: brodalumab (Siliq) and valbenazine (Ingrezza).

3. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR PRASTERONE (INTRAROSA)***—The P&T Committee recommended (13 for, 0 opposed, 1 abstained, 1 absent) excluding prasterone (Intrarosa) from the Auto-Refill program administered by Express Scripts, Inc, at TRICARE Mail Order Pharmacy, to be implemented upon signing of the minutes.

X. PRENATAL VITAMINS AND OTHER PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK

The P&T Committee discussed a list containing 694 National Drug Codes (NDCs) that the First DataBank drug database will transition from designation as prescription drugs to non–prescription items in January 2018. The affected agents are primarily prenatal vitamins containing folic acid but also include various urinary pH modifiers and prescription fluoride or zinc products. The action resulted from an FDA guidance regarding medical foods in September 2016.

The P&T Committee recommended temporarily continuing coverage for the affected drugs under the TRICARE pharmacy benefit, to allow adequate time for a full evaluation and to dovetail with current efforts to standardize non-prescription items supplied by MTFs (both across MTFs and across MHS points of service).

The issue of prenatal vitamins was specifically considered by the Committee. Prenatal vitamins are a low-cost intervention known to improve outcomes by preventing neural tube defects and providing adequate iron stores to prevent anemia and decrease nausea and vomiting during pregnancy. U.S. Preventive Services Task Force (USPSTF) guidelines recommend that all women who are planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg of folic acid (Grade A recommendation). Therefore, continued coverage of prenatal

vitamins is highly desirable in order to ensure uninterrupted access to essential care. The P&T Committee further noted that provision of prenatal vitamins as part of the TRICARE pharmacy benefit is more important for the MHS than civilian health plans, given worldwide assignment of female service members and beneficiaries to countries with variable availability of food products fortified with folic acid.

The P&T Committee also recommended standardizing the availability of prenatal vitamins across the MHS points of service (retail, mail order, and MTFs). The highest volume, most cost effective options that would provide a variety of formulations to meet the clinical needs of beneficiaries were identified, with the selected products comprising 91% of the dispensed prescriptions.

A. ***COMMITTEE ACTION: PRENATAL VITAMINS AND OTHER PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK—***The P&T Committee recommended (14 for, 0 opposed, 1 abstained, 0 absent) the following, effective upon signing of the minutes:

1. **Classes other than the Prenatal Vitamins**: Temporarily continuing coverage for products on the list of 694 NDCs losing prescription status in classes other than prenatal vitamins, to allow time for full evaluation and review for standardization.

2. **Prenatal Vitamins:** Adding the following 8 products (by brand name) to the over-the-counter (OTC) program and the MTF OTC test list: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi + DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA to standardize availability across the MHS. (Note: Some of these brand names may be used by multiple manufacturers; the intent is to select the lowest cost, highest value products that provide the same formulations.)

3. Evaluating statutory and/or regulatory authorities to address continued coverage of selected vitamins and other products when considered to be clinically and cost effective.

XI. NDAA 2017, SECTION 743: DRUG ACQUISITION COST PARITY IN THE TRICARE PHARMACY BENEFITS PROGRAM

The Committee reviewed Section 743 of NDAA 2017, results of DHA discussions with chain drug store and pharmaceutical manufacturer representatives, and historical data on cost parity in bidding. Additionally, the Committee invited manufacturers to offer cost parity bids for the August 2017 P&T Committee meeting.

Currently, manufacturers may voluntarily offer cost parity. Overall, historical trends and discussions with representatives suggest manufacturers will not pursue parity pricing. Similarly, despite encouragement to consider cost parity for the current meeting, cost parity

pricing was not offered for any bids. Copayments are currently highest at the retail network. Only non-Medicare patient prescriptions are eligible for the pilot. Administrative and contracting complexity will increase with the pilot.

A. ***COMMITTEE ACTION*—**The P&T Committee recommended against (15 for, 0 opposed, 0 abstained, 0 absent) pursuing the price parity pilot.

XII. ITEMS FOR INFORMATION

A. PROTON PUMP INHIBITORS

The Committee was briefed on utilization of PPIs, following the recommendation from the March 2017 Interim Meeting to designate esomeprazole as NF and non step-preferred. Comparable to 2007 brand switch from Aciphex to Nexium, the transition has been rapid at both the MTFs and purchased care. The utilization of cost effective agents has been broad with the assistance of appropriate prior authorization and medical necessity procedures. As expected, a small percentage of patient remain on the previously step-preferred brand product.

XIII. ADJOURNMENT

The meeting adjourned at 1440 hours on August 10, 2017. The next meeting will be in November 2017.

Appendix A—Attendance: August 2017 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

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

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

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

Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☐ concurs with all recommendations.

☒ concurs with the recommendations, with the following modifications:

Prenatal vitamins and other products losing OTC status in First DataBank: Note that following the August 2017 P&T Committee meeting, the POD was notified of First DataBank's plans to delay the January 1, 2018 implementation. As a result, implementation of the above recommendations to add 8 products to the OTC program are delayed pending further clarification. They will be continued to be covered as prescription products.

☐ concurs with the recommendations, except for the following:

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

10 OCT 17
Date

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

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
LTC Michele Hudak, MSC for CAPT Edward Norton, MSC	Deputy, DHA Integrated Utilization Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
Lt Col John Oberlin, MC	Air Force, Physician
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
CDR Heather Hellwig, MSC for CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Mr. Joe Canzolino	Department of Veterans Affairs
Voting Members Absent	
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Nonvoting Members Present	
Mr. Randy Stone	Office of General Counsel, DHA
MAJ Norman Tuala via telephone	Defense Logistics Agency Troop Support
Dean Valibhai, PharmD, MBA via telephone	DHA Purchased Care Branch
Guests	
Dr. Barclay Butler (SES)	Defense Health Agency, J4 Component Acquisition Executive
LCDR Joseph Galka	Defense Logistics Agency Troop Support
Soo Kun Kim	Defense Logistics Agency Troop Support
Mr. Dwight Bonham	DHA Contract Operations Division
Mr. Keith Boulware	DHA Contract Operations Division
Ms. Teresa Lee	DHA Contract Operations Division
LTC Joseph Yancey	Defense Health Agency, J3 Operations
CAPT Ryan Schupbach	Indian Health Service
CDR Marisol Martinez	Centers for Disease Control and Prevention

Appendix A—Attendance (continued)

Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
David Folmar, PharmD, BCPS	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
LCDR Christina Andrade	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
CPT Zachary Leftwich, MSC	DHA Formulary Management Branch
Ms. Deborah Garcia	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS, via telephone	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
CDR Eric Parsons, MSC	DHA Purchased Care Branch
David Meade, PharmD via telephone	DHA Integrated Utilization Branch
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via telephone	DHA Integrated Utilization Branch
Maj Robert Kennedy, BSC	San Antonio Military Medical Center
Maj Gregory Palmrose, BSC	University of Texas PhD Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• insulin glargine 100 U/mL (Basaglar) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus)
• insulin degludec (Tresiba) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus)
• insulin detemir (Levemir Pen) **Basal Insulins**	• Patient has been adherent to insulin glargine (Lantus) and has failed to achieve glycemic control • No formulary alternative: The patient is pregnant and is not able to use insulin glargine (Lantus). **Formulary Alternatives:** insulin glargine (Lantus) **Note that Medical Necessity only applies to detemir pen; detemir vials remain formulary**
• abaloparatide (Tymlos) **Osteoporosis Agents**	• Use of formulary agents has resulted in therapeutic failure **Formulary Alternatives:** teriparatide (Forteo), bisphosphonates
• brodalumab (Siliq) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira) and secukinumab (Cosentyx) are contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) and secukinumab (Cosentyx) • Adalimumab (Humira) and secukinumab (Cosentyx) have resulted in therapeutic failure **Formulary Alternatives:** adalimumab (Humira), secukinumab (Cosentyx), ustekinumab (Stelara), and apremilast (Otezla)
• sarilumab (Kevzara) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira) is contraindicated • Patient has experienced significant or likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) and methotrexate have resulted in therapeutic failure • No alternative formulary agent: The patient has symptomatic congestive heart failure. **Formulary Alternative:** adalimumab (Humira)

Drug / Drug Class	Medical Necessity Criteria
• dronabinol oral solution (Syndros) **Antiemetic & Antivertigo Agents**	• No alternative formulary agent: patient has failed formulary antiemetics or has weight loss due to AIDS meds, and has difficulty swallowing dronabinol capsules **Formulary Alternatives:** dronabinol capsules (Marinol, generics), ondansetron (Zofran, generics), aprepitant (Emend), benzodiazepines, metoclopramide, promethazine, prochlorperazine, or corticosteroids, dexamethasone, or megestrol
• fluticasone/salmeterol (AirDuo RespiClick) **Pulmonary-1s: Inhaled Corticosteroids / Long-Acting Beta Agonists (ICS/LABAs)**	• No alternative formulary agent. The patient requires salmeterol as the LABA component and requires the lower dose found in AirDuo compared to Advair OR • The patient requires fluticasone/salmeterol and cannot manipulate the Diskus or hydrofluoroalkane metered-dose inhaler (HFA MDI) device **Formulary Alternatives:** fluticasone/salmeterol (Advair Diskus, Advair HFA)
• mixed amphetamine salts ER (Mydayis) **Attention Deficit Hyperactivity Disorder (ADHD) Drugs**	• Use of generic Adderall XR and Concerta have resulted in therapeutic failure **Formulary Alternatives:** mixed amphetamine salts ER (Adderall XR, generics), extended-release methylphenidate (Concerta, generics)
• morphine sulfate ER (Morphabond XR) **Narcotic Analgesics**	• Patient has experienced therapeutic failure from at least two formulary long-acting narcotic analgesics. **Formulary Alternatives:** oxycodone controlled release (Oxycontin, generic), and other long acting narcotic analgesics, including fentanyl transdermal system (Duragesic, generics), morphine sulfate sustained release (MS Contin, generics)
• safinamide (Xadago) **Parkinson's Disease Drugs**	• Patient has experienced significant adverse effects from a formulary MAO-B inhibitor (selegiline or rasagiline) that are not expected to occur with safinamide • Use of formulary agent resulted in therapeutic failure **Formulary Alternatives:** selegiline, rasagiline
• valbenazine (Ingrezza) **Neuromuscular Miscellaneous Agents**	• Use of formulary agent has resulted in therapeutic failure **Formulary Alternatives:** tetrabenazine (Xenazine), deutetrabenazine (Austedo)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• insulin degludec (Tresiba) **Basal Insulins**	**Changes from August 2017 meeting are in bold.** Manual PA criteria apply to all new users of Tresiba. Manual PA criteria—Tresiba is approved if all criteria are met: 1. **Patient is age ≥ 1** AND 2. Patient must have tried and failed or is intolerant to insulin glargine (Lantus) • PA does not expire • Non-FDA approved uses are not approved.
• insulin detemir pens and vials (Levemir) **Basal Insulins**	Manual PA criteria apply to all new users of Levemir pens and vials. Manual PA criteria—Levemir pen or vial is approved if all criteria are met: 1. Patient must have tried and failed insulin glargine (Lantus) Or 2. Patient is pregnant and cannot use insulin glargine (Lantus) • PA does not expire • Non-FDA approved uses are not approved.
• insulin glargine 100 U/mL (Basaglar) **Basal Insulins**	Manual PA criteria apply to all new users of Basaglar. Manual PA criteria—Basaglar is approved if the following criteria is met: 1. Patient must have tried and failed insulin glargine (Lantus). • PA does not expire • Non-FDA approved uses are not approved.
• insulin glargine 300 U/mL (Toujeo) **Basal Insulins**	**Note – No changes from the previous PA from November 2015 were recommended at the August 2017 meeting.** Manual PA criteria apply to all new users of Toujeo. Manual PA criteria—Toujeo is approved if: • The patient is at least 18 years of age AND • The patient has diabetes and is using a minimum of 100 units of insulin glargine (Lantus) per day AND • The patient requires a dosage increase with Lantus and has experienced a clinically significant, severe hypoglycemia episode, despite splitting the Lantus dose AND • The patient has been counseled regarding the risk of dosing errors. • Note that the following are not acceptable reasons for Toujeo: o Non-adherence to previous insulin treatment o Patient or prescriber preference for the use of Toujeo o Patient or prescriber preference for a smaller injection volume Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• plasma-derived human C1 esterase inhibitor IV (Cinryze) • plasma-derived human C1 esterase inhibitor SQ (Haegarda) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	Manual PA criteria apply to all new users of Cinryze and Haegarda. Manual PA criteria—Cinryze or Haegarda is approved if: • The patient is ≥13 years old (Cinryze) or ≥12 years old (Haegarda) **AND** • The patient must be diagnosed with hereditary angioedema (HAE) Type I, II, or III (HAE with normal C1-esterase inhibitor) **AND** • The drug is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist **AND** • The patient must experience ≥2 HAE attacks per month **AND** • The patient has tried and failed an attenuated androgen (danazol) **OR** o Patient has experienced or is expected to experience serious adverse effects from the use of an androgen (e.g., virilization of women, stroke, or myocardial infarction, venous thromboembolism) **OR** o Patient is female of childbearing age • Cinryze or Haegarda is not approved for any indication other than HAE. • PA does not expire.
• brodalumab (Siliq) **Targeted Immunomodulatory Biologics (TIBs)**	Step Therapy and Manual PA Criteria apply to all new and current users of brodalumab (Siliq). Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) and secukinumab (Cosentyx) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days AND Manual PA criteria: If automated criteria are not met, coverage is approved for Siliq if: • Contraindications exist to Humira and Cosentyx • Inadequate response to Humira and Cosentyx • Adverse reactions to Humira and Cosentyx not expected with Siliq. AND Coverage approved for patients > 18 years with: • Active moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy AND • The patient does NOT have suicidal ideation and behavior Coverage NOT provided for concomitant use with other TIBs, including but not limited to abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), tocilizumab (Actemra), rituximab (Rituxan), ustekinumab (Stelara), apremilast (Otezla), secukinumab (Cosentyx), ixekizumab (Taltz) or infliximab (Remicade) Off-label uses are NOT approved. Prior Authorization expires in 6 months Renewal PA Criteria: After 6 months, PA must be resubmitted. Continued use of Siliq will be allowed if the patient has responded to therapy and has not exhibited suicidal ideation and behavior.

Drug / Drug Class	Prior Authorization Criteria
• sarilumab (Kevzara) **Targeted Immunomodulatory Biologics (TIBs)**	Step therapy and Manual PA Criteria apply to all new and current users of sarilumab (Kevza Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Kevzara if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non step-preferred TIB • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF AND Coverage approved for patients > 18 years with: • Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs) Coverage is NOT provided for concomitant use with other TIBs, including but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), rituximab (Rituxan), secukinumab (Cosentyx), or ixekizumab (Taltz). Off-label uses are not approved, including uveitis, polyarticular and systemic juvenile idiopathic arthritis (JIA) or ankylosing spondylitis PA does not expire.
• guselkumab (Tremfya) **Targeted Immunomodulatory Biologics (TIBs)**	Step therapy and Manual PA Criteria apply to all new and current users of guselkumab (Tremfya). Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Tremfya if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-tumor necrosis factor [TNF] or non-TNF) • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic congestive heart failure (CHF) • Adverse reactions to Humira not expected with requested non step-preferred TIB AND Coverage approved for patients ≥ 18 years with: • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy Prior Authorization does not expire. Non-FDA approved uses are not approved. Coverage is NOT provided for concomitant use with other TIBs including but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), rituximab (Rituxan), secukinumab (Cosentyx), or ixekizumab (Taltz).

Drug / Drug Class	Prior Authorization Criteria
• midostaurin (Rydapt) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Rydapt. Manual PA criteria—Rydapt is approved if: • Patient is ≥ 18 AND • Rydapt is being prescribed by or in consultation with a hematologist/oncologist AND • Patient uses Rydapt in combination with standard chemotherapy protocols AND • Patient has a diagnosis of Acute Myelogenous Leukemia (AML) and FLT3 mutation as determined by FDA-approved test OR • Patient has a diagnosis of advanced systemic mastocytosis (aggressive systemic mastocytosis; systemic mastocytosis associated with hematologic neoplasm) or mast cell leukemia Off-label uses are not approved. PA expires in 1 year. Renewal Manual PA criteria: Rydapt is approved indefinitely for continuation of therapy if patient has documented clinical and/or symptom improvement.
• ribociclib-letrozole (Kisqali Femara Co-Pack) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Kisqali-Femara. Manual PA criteria—Kisqali-Femara is approved if: • Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND • Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer Off-label uses are not approved. PA does not expire.
• dronabinol (Syndros) **Antiemetic & Antivertigo Agents**	Manual PA criteria apply to all new and current users of Syndros. Manual PA criteria—Syndros is approved if all criteria are met: • Patient is ≥18 years old AND • Patient cannot take dronabinol capsule due to swallowing difficulties AND • Patient has chemotherapy-induced nausea and vomiting that has not responded to therapy with other antiemetics, including 5HT3 antagonists (ondansetron, granisetron), substance P/neurokinin (NK1) receptor antagonists (aprepitant), benzodiazepine, metoclopramide, phenothiazines (promethazine or prochlorperazine), or dexamethasone OR • Patient has weight loss due to AIDS and has not responded to steroids or megestrol Off-label uses are NOT approved, including use as an opioid-sparing agent for patient receiving opioids PA does not expire.
• fluticasone/salmeterol (AirDuo RespiClick) **Pulmonary ICS/LABAs**	PA criteria apply to all new and current users of AirDuo RespiClick who are 12 years of age or older. Note that AirDuo will not be part of the current automated step therapy for the ICS/LABA oral inhalers; separate manual PA will be required. Manual PA criteria—AirDuo RespiClick is approved if: • Patient has a diagnosis of asthma AND • Patient is older than 12 years of age AND • Patient requires salmeterol as the LABA component and requires the lower dose found in AirDuo versus Advair Diskus or HFA OR • Patient requires fluticasone/salmeterol and cannot manipulate the Advair Diskus or Advair HFA metered dose inhaler Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• methotrexate (Xatmep) oral solution **Antirheumatic Drugs**	PA criteria apply to all new and current users of Xatmep. Automated PA criteria • Xatmep will be approved for patients 12 years of age and younger Manual PA criteria—Manual PA criteria apply if the patient is older than 12 years of age. Xatmep is approved if: • The patient must have a diagnosis of acute lymphoblastic leukemia (ALL) or active polyarticular juvenile idiopathic arthritis (pJIA); AND • The patient has a history of difficulty swallowing tablets or has a medical condition that is characterized by difficulty swallowing or inability to swallow Off-label uses are not approved. PA does not expire.
• mixed amphetamine salts ER (Mydayis) **ADHD Drugs**	Manual PA criteria apply to all new and current users of Mydayis. Manual PA criteria—Mydayis is approved if all criteria are met: • Patient is 13 years of age or older AND • Patient has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND • Patient has tried and failed generic Adderall XR AND • Patient has tried and failed generic Concerta Off-label uses are NOT approved. PA does not expire.
• prasterone (Intrarosa) **Vaginal Lubricants**	Manual PA criteria apply to all new users of Intrarosa. Manual PA criteria—Intrarosa coverage approved for 1 year if all criteria are met: 1. Patient is a post-menopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy. 2. Patient has tried and failed a low dose vaginal estrogen preparation (e.g., Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem). 3. Patient does not have any of the following: i. Undiagnosed abnormal genital bleeding ii. Pregnant or breastfeeding iii. History of breast cancer or currently have breast cancer 4. Use of Intrarosa will be for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be reevaluated periodically as clinically appropriate to determine if treatment is still necessary. Off-label uses are not approved. PA expires in 1 year. PA Renewal criteria: PA is approved indefinitely if the patient has had improvement in the severity of dyspareunia symptoms.
• safinamide (Xadago) **Parkinson's Disease Drugs**	Manual PA criteria apply to all new users of Xadago. Manual PA Criteria: Coverage approved if all criteria are met: 1. Patient is ≥ 18 years old AND 2. Patient has a diagnosis of Parkinson's disease AND 3. Patient has tried and failed rasagiline or selegiline AND 4. Xadago is used as an adjunct to levodopa/carbidopa or a dopamine agonist. Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• valbenazine (Ingrezza) **Neuromuscular Miscellaneous Agents**	Manual PA criteria apply to all new users of Ingrezza. Manual PA Criteria: Coverage approved if all criteria are met: 1. Age > 18 years 2. Prescribed by or in consultation with a neurologist or psychiatrist 3. Patient has moderate to severe tardive dyskinesia along with schizophrenia, schizoaffective disorder, or a mood disorder 4. Patient does not have congenital long QT syndrome or arrhythmias associated with QT prolongation 5. Patient has had an adequate trial and has failed or has a contraindication to tetrabenazine or deutetrabenazine 6. Provider has considered use of clonazepam and ginkgo biloba 7. Patient is not taking any of the following: • MAOI inhibitor • Another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine) • CYP3A4 inducers Off-label uses are NOT approved. PA does not expire.
• methylnaltrexone (Relistor) • naloxegol (Movantik) **Gastrointestinal-2 Agents for Opioid-Induced Constipation**	Manual PA criteria apply to all new and current users of Movantik and Relistor. Manual PA criteria: Coverage will be approved if: • The patient is ≥ 18 years with a diagnosis of opioid-induced constipation (OIC); AND • The patient is concurrently taking an opioid agonist and is not receiving other opioid antagonists; AND • The patient has failed or is unable to tolerate two or more of the following: o At least one stimulant laxative (e.g., sennosides or bisacodyl) o At least one osmotic laxative (e.g., MiraLAX, lactulose, or magnesium citrate); AND • The patient has failed therapy with lubiprostone (Amitiza); AND • The patient does not have a known or suspected GI obstruction or is not at increased risk of recurrent obstruction); AND • The patient is not currently taking a drug metabolized by CYP3A4 (for Movantik) Non-FDA approved uses are not approved. Prior authorization does not expire.
• dapsone 5% gel (Aczone) • dapsone 7.5% gel (Aczone) **Topical Acne and Rosacea Agents**	**Changes from August 2017 meeting are in bold and strikethrough. See the August 2016 meeting minutes for the complete automated PA criteria implemented on February 8, 2017.** Manual PA Criteria: If automated PA criteria are not met, Aczone will be approved if: • The patient has a diagnosis of acne vulgaris, AND o Patient is ~~**an adult female**~~ **≥13 years** with a diagnosis of inflammatory acne, AND o The patient has tried and failed at least 3 step-preferred topical generic acne products, including combination therapy with clindamycin and benzoyl peroxide. PA expires in 365 days.

Drug / Drug Class	Prior Authorization Criteria
• tocilizumab (Actemra) **Targeted Immunomodulatory Biologics – Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Changes from August 2017 meeting are in bold. See August 2014 meeting minutes for the complete automated PA criteria implemented on February 18, 2014.** Manual PA criteria: If automated criteria are not met, coverage is approved for Actemra if: • Contraindications exist to Humira • Inadequate response to Humira (need for different anti-TNF or non-TNF) • Adverse reactions to Humira not expected with requested non step-preferred TIB • There is no formulary alternative: patient requires a non-TNF TIB for symptomatic CHF • Patient has been stable on an IV TIB with continuous use in last 3 months and needs to transition to the SQ formulation of Actemra AND Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs) • Subcutaneous Actemra is not approved for use in systemic or pJIA • **Adult patients with giant cell arteritis** Coverage is NOT provided for concomitant use other TIBs.
• lifitegrast ophthalmic solution (Xiidra) **Ophthalmic Anti-Inflammatory / Immunomodulatory Agents**	**Changes from August 2017 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of lifitegrast ophthalmic solution. Manual PA criteria: Coverage will be approved if: 1. The patient is age ≥ 18 AND 2. Has documented diagnosis of moderate to severe inflammatory dry eye disease AND 3. Drug is prescribed by an ophthalmologist or optometrist AND 4. Patient has failed to respond to an adequate trial of artificial tears • Combination use of Xiidra and Restasis not allowed Off-label uses are NOT approved **~~PA does not expire~~ PA expires in one year.** **Renewal PA Criteria: After one year, PA must be resubmitted. Coverage approved indefinitely if:** • **Patient must have documented improvement in signs of dry eye disease (DED) as measured by at least one of the following:** o **Decrease in corneal fluorescein staining score OR** o **Increase in number of mm per 5 minutes using Schirmer's tear test in comparison to original scores AND** • **Patient has documented improvement in ocular discomfort AND** • **Patient is not using Xiidra and Restasis as combination therapy.**
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	**Changes from August 2017 meeting are in bold.** Manual PA criteria apply to all new and current users of Eucrisa. Manual PA Criteria: coverage will be approved if: • Patient has mild to moderate atopic dermatitis AND • Prescribed by a dermatologist, **allergist or immunologist** AND • Patient has a contraindication to, intolerability to, or failed treatment with at least one high potency / class 1 topical corticosteroid. Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• esomeprazole delayed release packets for suspension (Nexium) **Proton Pump Inhibitors (PPIs)**	**Changes from August 2017 meeting are in bold. See the February 2017 Interim Meeting minutes for complete automated PA criteria implemented on June 28, 2017.** PA criteria apply to all new and current users of esomeprazole (Nexium). Manual PA criteria: A trial of omeprazole (Prilosec, generics), pantoprazole tablets (Protonix, generics), and rabeprazole (Aciphex, generics) is NOT required if: • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole tablets (Aciphex, generics), and the patient had an inadequate response. • The patient has tried omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics), and the patient was unable to tolerate them due to adverse effects. • Treatment with omeprazole, pantoprazole tablets, and rabeprazole (Aciphex, generics) is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency). OR • **For esomeprazole delayed release packets for suspension only:** o **The patient is younger than 5 years of age. OR** o **The patient requires a percutaneous endoscopic gastrostomy (PEG) tube.**
• canagliflozin (Invokana) • canagliflozin/ metformin (Invokamet) • dapagliflozin (Farxiga) • dapagliflozin/ metformin ER (Xigduo XR) **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	**Changes from August 2017 meeting are in strikethrough.** All new users of an SGLT2 inhibitor are required to try metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ before receiving an SGLT2 inhibitor. Patients currently taking an SGLT2 inhibitor must have had a trial of metformin ~~or a sulfonylurea (SU) and a DPP-4 inhibitor~~ first. Additionally, empagliflozin-containing products (Jardiance, Glyxambi) are the preferred agents in the SGLT2 inhibitors subclass. New and current users of canagliflozin or dapagliflozin must try an empagliflozin product first. Automated PA criteria • The patient has filled a prescription for metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. OR • The patient has received a prescription for a preferred SGLT2 inhibitor (Jardiance, Glyxambi) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. AND Manual PA criteria—If automated PA criteria are not met, Jardiance or Glyxambi is approved (e.g., a trial of metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~ ~~are~~ is NOT required) if: • The patient has had an inadequate response to metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~; or • The patient has experienced a significant adverse effect from metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~; or • The patient has a contraindication to metformin ~~and at least one drug from 2 additional different oral non-insulin diabetes drug classes~~. AND The patient has experienced significant adverse events from an empagliflozin-containing product (Jardiance or Glyxambi) that are not expected to occur with Invokana, Invokamet, Farxiga, or Xigduo XR.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• plasma-derived human C1 esterase inhibitor SQ (Haegarda) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	▪ MTF/Mail: 60 vials/90 days Retail: 20 vials/30 days
• plasma-derived human C1 esterase inhibitor IV (Cinryze) • plasma-derived human C1 esterase inhibitor IV (Berinert) • recombinant C1 esterase inhibitor IV (Ruconest) • Icatibant SQ (Firazyr) **Corticosteroids – Immune Modulators – Hereditary Angioedema (HAE) Subclass**	▪ Note no changes from the QLs from August 2016 ▪ Retail (30 days) / MTF/ Mail Order (90 days) o Cinryze: Retail: 20 vials; MTF and Mail: 60 vials o Berinert: Retail: 30 vials; MTF and Mail: 90 vials o Ruconest: Retail: 60 vials; MTF and Mail: 180 vials o Firazyr: Retail: 4 syringes; MTF and Mail: 12 syringes
• brodalumab (Siliq) • guselkumab (Tremfya) • sarilumab (Kevzara) • ustekinumab (Stelara) vial formulation **Targeted Immunomodulatory Biologics (TIBs)**	▪ Retail Network: 28-day supply ▪ Mail/MTF: 56-day supply
• ribociclib-letrozole (Kisqali-Femara) **Oral Oncologic Drugs**	▪ Retail Network: 28-day supply ▪ MTF/Mail: 56-day supply
• midostaurin (Rydapt) **Oral Oncologic Drugs**	▪ Retail Network: 28-day supply MTF/Mail: 56-day supply
• brigatinib (Alunbrig) **Oral Oncologic Drugs**	▪ Retail Network: 30-day supply Mail/MTF: 60-day supply
• fluticasone/salmeterol (AirDuo RespiClick) **Pulmonary-1 Agents: Long-Acting Beta Agonists/Inhaled Corticosteroids Combinations**	▪ Retail Network: 1 inhaler in 30 days MTF/Mail: 3 inhalers in 90 days
• fluticasone/azelastine (Dymista) **Nasal Allergy Drugs**	▪ Retail: 1 inhaler in 30 days ▪ MTF/Mail: 3 inhalers in 90 days

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

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
abaloparatide (Tymlos) injection	Osteoporosis agents	▪ teriparatide (Forteo)	Postmenopausal osteoporosis in women with a high risk for fracture	• 2nd available parathyroid hormone (PTH) analog indicated for the treatment of postmenopausal osteoporosis; not approved for use in men or for prevention of osteoporosis • Evaluated in one placebo controlled trial (18 mo) with teriparatide as an active comparative and an extension study (additional 6 mo); no head-to-head studies – Abaloparatide had a lower rate of new vertebral fractures at 18 mo (0.6%) compared to placebo (4.2%) – Bone density (BMD) improved at all sites • Indirect comparison showed rates of new vertebral fractures were lower than teriparatide and similar to rates of non- vertebral fractures – Absolute rate of new vertebral fractures of abaloparatide (3.6%) vs teriparatide (9.3%) – Absolute rate of non-vertebral fractures of abaloparatide (2%) compared to teriparatide (1.46%) • Similarities to teriparatide include common ADRs, once daily SQ administration, and BBW regarding osteosarcoma • No compelling advantage over existing formulary agents	• NF • Add to mail
brigatinib (Alunbrig)	Oral Oncologic Agents for Lung Cancer	▪ crizotinib (Xalkori) ▪ alectinib (Alecensa)	Advanced anaplastic lymphoma kinase positive (ALK+) non-small cell lung cancer (NSCLC) failing crizotinib	• ALK+ accounts for 2-7% of NSCLC • 3rd agent approved after progression with crizotinib, targeting advance disease • Effective in those who had brain metastases where this tumor often presents • Accelerated approval based on tumor size reduction, requires additional studies to verify • Phase II trial that led to approval based on objective response rates will also assess overall survival, progression free survival; and pending Phase III study comparing as 1st line therapy	• UF • Exempt from mail
brodalumab (Siliq) injection	Targeted Immuno-modulatory Biologics (TIBs)	▪ adalimumab (Humira) ▪ ustekinumab (Stelara) ▪ secukinumab (Cosentyx) ▪ etanercept (Enbrel) ▪ ixekizumab (Taltz)	Adults w/ moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy AND have failed other systemic therapies	• 3rd IL-17A receptor antagonist (like Cosentyx & Taltz) • Dosed 210 mg SQ on Weeks 0, 1, & 2, followed by 210 mg SQ every 2 weeks • Treatment beyond 16 wks in patients who have not achieved an adequate response (after 12-16 wks of treatment) is not likely to result in greater success • In two head-to-head trials, Siliq (IL-17A) was superior to Stelara (IL12/23) • All IL-17 antagonists increase risk of infections, latent tuberculosis reactivation, and should be avoided with live vaccines • BBW: Siliq is the only TIB with a black box warning for risk of suicidal ideations and behavior, requiring REMS program enrollment • Step therapy exists for the class; Humira preferred	• NF and Non Step-Preferred • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
dronabinol (Syndros) oral solution	Antiemetic & Antivertigo Agents	▪ dronabinol caps generic ▪ Marinol caps brand ▪ ondansetron ▪ aprepitant	• Adults only • Anorexia in AIDS pts • Chemo-induced nausea & vomiting	• New oral solution of the cannabinoid receptor antagonist dronabinol (Marinol), which is available as generic capsules • No clinical studies available; FDA approval was based on bioavailability testing to Marinol capsules • DEA Schedule: Syndros is C-II vs C-III for Marinol • Contains dehydrated alcohol; risk of disulfiram or metronidazole drug interactions; avoid use in pregnancy and preterm neonates. • Potential risk of dosing errors with supplied oral syringe which is not used for administration • Provides an alternative delivery system for patients who have failed conventional antiemetic therapy and who have difficulty swallowing dronabinol capsules • Overall has no advantages compared to UF antiemetics and dronabinol capsules	• NF • Exempt from mail
fluticasone/ salmeterol (AirDuo RespiClick) oral inhaler	Inhaled Corti-costeroids/ Long-Acting Beta Agonists (ICS/LABAs)	▪ fluticasone/ salmeterol (Advair Diskus & HFA) ▪ fluticasone/ vilanterol (Breo)	Treatment of asthma for patients age 12 and older	• Another option for treating asthma in patients older than 12 years • Same active ingredients as Advair but with different doses of fluticasone and salmeterol • No evidence of benefit over current therapy • Step Therapy applies in this class • Advair HFA and Diskus are the preferred agents	• NF and Non Step-Preferred • Add to mail list
methotrexate (Xatmep) oral solution	Antirheumatics	methotrexate	Acute lymphoblastic leukemia (ALL) as a component of combo chemo maintenance regimen in pediatric pts Active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of / inadequate response to first-line therapy including NSAIDs	• Initial US approval for methotrexate in 1953 • Convenient ready to use oral solution for pediatric indications, and for pts who are intolerant to currently available MTX options • Currently not FDA approved, ready to use oral formulation of MTX for use by pediatric patients, or those with difficulty swallowing or needle phobia	• UF • Exempt from mail
midostaurin (Rydapt)	Oral Oncologic Agents for Acute Myeloid Leukemia (AML)	No available pharmacy benefit comparator	AML in combo with chemotherapy; aggressive systemic mastocytosis, systemic mastocytosis w/associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)	• 1st oral tyrosine kinase approved in AML (FLT3+ with approved test) • Additionally approved for advanced systemic mastocytosis (SM) • Demonstrated increased overall survival benefit, reducing mortality • In advanced SM clinical response in 60% of pts reported • Current treatment options for AML are chemotherapies, medical benefit • No similar oral option	• UF • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
mixed amphetamine salts ER (Mydayis)	Attention Deficit Hyperactivity Disorder (ADHD) drugs	▪ Adderall XR, generics ▪ Adzenys XR ▪ Dyanavel ▪ Concerta, generics ▪ Aptensio XR ▪ Quillivant XR	Treatment of ADHD in patients 13 years and older	• Approved for patients ≥ 13 years of age • Effects can last up to 16 hrs; insomnia is the most common AE • BBW: CNS stimulants, including amphetamine extended-release oral formulations, have a high potential for abuse and dependence. • Multiple direct competitors available • Active ingredient in Mydayis is the same as Adderall XR • No compelling clinical advantages over existing formulary agents	• NF • Exempt from mail
morphine sulfate ER (Morphabond XR)	Narcotic Analgesics	▪ morphine ER (MS Contin) ▪ morphine ER (Arymo ER)	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment	• 3rd morphine abuse deterrent formulation (ADF) long-acting narcotic analgesic • 8th abuse deterrent opioid • Another option for treating chronic pain • ADFs have not been shown as better than non-ADFs in deterring inappropriate opioid use	• NF • Exempt from mail
niraparib (Zejula)	Oral Oncologic Agents for Ovarian Cancer	▪ olaparib (Lynparza) ▪ rucaparib (Rubraca)	Maintenance tx of adult pts with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy	• 3rd available PARP (Poly ADP-Ribose Polymerase) inhibitor for ovarian cancer • For maintenance therapy, in those who are platinum sensitive • Does not require multiple lines of therapy outside of platinum sensitive courses • Does not require co-diagnostic in the FDA label, unlike prior agents • Concerns regarding effect of this agent on subsequent chemotherapies that are inevitably required in this disease that has high rate of recurrence	• UF • Exempt from mail
prasterone (Intrarosa) vaginal insert	Vaginal Lubricants	▪ ospemifene (Osphena) ▪ conjugated estrogen cream (Premarin)	Treatment of moderate to severe dyspareunia due to menopause	• Prasterone is an inactive endogenous steroid precursor (dehydroepiandrosterone or DHEA); vaginal insert • ACOG Guidelines and Am Journal of Obstetrics and Gynecology – Vaginal symptoms are best treated with systemic or topical hormonal therapy, but topical methods are preferable due to fewer AEs – Give hormonal therapy in the lowest dose and for the shortest period possible to decrease risk of serious AEs • Prasterone dosed at 0.50% (6.5 mg) vaginally at bedtime for 12 weeks showed statistical significance in decreasing dyspareunia compared to placebo • Short-term AEs only for vaginal discharge were statistically significant compared to placebo • Long-term AEs in association with vaginal DHEA is uncertain and lacks safety data • Prasterone is the first topical (locally applied) inactive hormone approved for dyspareunia	• UF • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
ribociclib letrozole (Kisqali Femara Co-Pack)	Oral Oncologic Agents for Breast Cancer	▪ palbociclib (Ibrance) + aromatase inhibitor	Breast Cancer	• Kisqali reviewed in May 2017 as individual agent and made UF • This formulation adds letrozole, which has been available for 20 years • No changes to either agent, provides convenience packaging and allows for one pharmacy transaction • Agents are typically co-prescribed	• UF • Exempt from mail
safinamide (Xadago)	Parkinson's Disease Drugs	▪ rasagiline ▪ selegiline	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's Disease experiencing "off" episodes	• 2nd line adjunctive MAO-B treatment behind rasagiline • Must be used in conjunction with levodopa/carbidopa	• NF • Add to mail
sarilumab (Kevzara) injection	Targeted Immuno-modulatory Biologics (TIBs)	▪ adalimumab (Humira) ▪ tocilizumab (Actemra)	Adults with mild to moderate RA with inadequate response or intolerance to at least one DMARD	• 2nd IL-6 receptor antagonist for RA; same as Actemra • Can be used alone in cases involving intolerance to MTX or when treatment with MTX is inappropriate • Dose: 200 mg SQ every 2 weeks; 150 mg SQ every 2 weeks if decreased white count or platelets; or increased LFTs • One head-to-head trial vs Humira showed Kevzara had superior reduction of disease activity and improved RA signs and symptoms; but Humira was under-dosed • Under FDA review for uveitis, ankylosing spondylitis and juvenile idiopathic arthritis • No evidence Kevzara would have different efficacy or safety profile than Actemra • Step Therapy exists for the class; Humira is preferred	• NF and Non step-preferred • Add to mail list
valbenazine (Ingrezza)	Neuro-muscular Miscellaneous Agents	▪ clonazepam ▪ amantadine ▪ tetrabenazine (Xenazine)	Tardive dyskinesia	• 3rd FDA approved VMAT2 inhibitor and the first indicated for tardive dyskinesia (TD) • Administered orally once daily • Efficacy based on one 6-week placebo-controlled trial using the AIMS score to determine improvement in TD symptoms • Valbenazine reduced the AIMS score by 3.2 points from baseline compared to placebo (0.1) • No difference between valbenazine and placebo in clinician global impression change for TD symptoms • Study limitations: short trial duration and no head-to-head studies • Generally well tolerated; somnolence & QT prolongation were the major ADRs • Numerous drug interactions exist including interactions with MAOIs, CYP3A4 inducers and inhibitors, CYP2D6 inhibitors, and digoxin • Offers another treatment option for patients with TD	• NF • Exempt from mail

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

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
August 2017	**Basal Insulin Analogs** Maintain the following UF and NF drugs on the EMMPI list: ▪ insulin degludec (Tresiba) ▪ insulin detemir pen and vial (Levemir) ▪ insulin glargine pen and vial (Lantus) ▪ insulin glargine 300 U/mL (Toujeo) ▪ insulin glargine 100 U/mL (Basaglar) **Newly-Approved Drugs per 32 CFR 199.21(g)(5)** ▪ sarilumab (Kevzara) ▪ abaloparatide (Tymlos) ▪ safinamide (Xadago) ▪ fluticasone/salmeterol (AirDuo RespiClick)	**Newly-Approved Drugs per 32 CFR 199.21(g)(5)** C-II controlled substances exception applies ▪ morphine sulfate ER tablets (Morphabond XR) ▪ mixed amphetamine salts ER (Mydayis) ▪ dronabinol oral solution (Syndros) Addition of oral oncology agents to the EMMPI program should be considered at a future date ▪ midostaurin (Rydapt) ▪ niraparib (Zejula) ▪ ribociclib/letrozole (Kisqali-Femara) ▪ methotrexate (Xatmep) oral solution ▪ brigatinib (Alunbrig) Other ▪ prasterone (Intrarosa) due to low persistence rates ▪ brodalumab (Siliq) pending further information ▪ valbenazine (Ingrezza) pending further information

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2017	**Basal Insulin Analogs**	UF Class Review Previously reviewed Feb 2010	**BCF Step-Preferred** ▪ glargine pen and vial (Lantus)	**UF Non Step-Preferred** ▪ detemir vial (Levemir) ▪ glargine 300 U/mL (Toujeo)	**NF Non Step-Preferred** ▪ degludec (Tresiba) ▪ detemir pen (Levemir) ▪ glargine 100 U/mL (Basaglar)	Pending signing of the minutes / 30 days The effective date is Nov 22, 2017	▪ Manual PA criteria apply to all new users ▪ Manual PAs for Toujeo, Tresiba, Basaglar, and Levemir pen	▪ Must try Lantus first in all new users of Toujeo, Tresiba, Basaglar, and Levemir See Appendix C
Aug 2017	**Corticosteroids-Immune Modulators Drug Class - Hereditary Angioedema (HAE) Subclass**	UF Class review Class not previously reviewed	▪BCF: No HAE product selected ▪Corticosteroid - Immune Modulator Subclass BCF product includes prednisone	▪ plasma-derived human C1 esterase inhibitor IV (Cinryze) ▪ plasma-derived human C1 esterase inhibitor IV (Berinert) ▪ recombinant C1 esterase inhibitor IV (Ruconest) icatibant SQ (Firazyr)	None	Pending signing of the minutes / 30 days The effective date is Nov 22, 2017	Manual PA criteria apply to Cinryze and Haegarda	▪ New patients must try attenuated androgen (Danazol) prior to use of Cinryze or Haegarda. See Appendix C Haegarda approved in July 2017, but not yet reviewed
Aug 2017	**Antiretroviral Agents for HIV**	UF Class Review	▪None	▪ All HIV drugs marketed in the U.S. as of Aug 2017 were recommended for UF status, as listed on pages 8 to 9 of this document.	None	Pending signing of the minutes	-	-

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

Appendix H—Table of Abbreviations

A1c	hemoglobin A1c
ACE	angiotensin converting enzyme
ADHD	attention deficit hyperactivity disorder
ALK+	anaplastic lymphoma kinase positive gene
AML	acute myeloid leukemia
BCF	Basic Core Formulary
BIA	budget impact analysis
CFR	Code of Federal Regulations
CHF	congestive heart failure
CMA	cost minimization analysis
DHA	Defense Health Agency
DMARDs	disease modifying anti-rheumatic drugs
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GI	gastrointestinal
GLP1RA	glucagon-like peptide-1 receptor agonist
ICS/LABA	inhaled corticosteroid/long-acting beta agonist
IV	intravenous
HAE	hereditary angioedema
HFA/MDI	hydrofluoroalkane metered-dose inhaler
HIV	human immunodeficiency virus
INSTIs	integrase strand transfer inhibitors
IR	immediate release
JIA	juvenile idiopathic arthritis
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NDC	National Drug Code
NNRTIs	nucleoside reverse transcriptase inhibitor
NRTIs	nucleoside/nucleotide reverse transcriptase inhibitor
NPH	neutral protamine Hagedorn
NF	nonformulary
NSCLC	non-small cell lung cancer
OTC	over-the-counter
OIC	opioid-induced constipation
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAMORAs	peripherally-acting mu opioid receptor antagonists
PARP	poly-ADP ribose polymerase-1 enzyme
PEG	percutaneous endoscopic gastrostomy

pJIA	polyarticular juvenile idiopathic arthritis
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPI	proton pump inhibitor
PrEP	pre-exposure prophylaxis
PTH	parathyroid hormone
QLs	quantity limits
SGLT2	sodium glucose co-transporter 2
SQ	subcutaneous
TD	tardive dyskinesia
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
UF	Uniform Formulary
USPSTF	U.S. Preventive Services Task Force
VA	U.S. Department of Veterans Affairs
XR	extended release