DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2017

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 10 and 11, 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 February 2017 Minutes—**RADM Colin Chinn, MC, USN, Acting Deputy Director, DHA, approved the minutes from the March 7, 2017, DoD P&T Committee interim meeting for the proton pump inhibitors on March 31, 2017, and approved the minutes from the February 2017 DoD P&T Committee meeting on May 4, 2017.

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

    a) **Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) Implementation Date—**The implementation date for all EMMPI recommendations from the February 2017 meeting, including the newly-approved drugs affected by the EMMPI, will occur upon signing of the minutes.

    b) **Nexium Branded Products—**Nexium branded and generic products are non-formulary and therefore generally not available in Military Treatment Facilities (MTFs) or in the Retail Network point of service (POS). They are available in the mail order program and at the MTFs through the non-formulary special approval process for eligible beneficiaries.

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

A. Pulmonary-1 Drug Class: Pulmonary Miscellaneous Subclass—Idiopathic Pulmonary Fibrosis (IPF) Drugs

Background—The IPF drugs have not been previously reviewed for UF status. Manual prior authorization (PA) requirements have been in place since February 2016 for both nintedanib (Ofev) and pirfenidone (Esbriet).

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- IPF is difficult to diagnose and has limited therapeutic options. Nintedanib (Ofev) and pirfenidone (Esbriet) are the first therapeutic advances for the disease, and have different mechanisms of action. How nintedanib and pirfenidone slow the decline of lung function in IPF is not fully understood.
- There are no studies directly comparing nintedanib and pirfenidone. These two drugs may delay disease progression; however, the most appropriate subset of IPF patients who will respond to therapy and who will tolerate the adverse effects is difficult to predict.
- While neither agent is curative, FDA approval was based on studies showing nintedanib and pirfenidone may reduce the rate of inexorable decline in lung function that is the hallmark of IPF.
- Available meta-analyses suggest that nintedanib and pirfenidone favorably affect endpoints of lung function including forced vital capacity over 52 weeks. Overall, the available evidence suggests these two drugs have similar efficacy when compared to placebo.
- The most commonly reported adverse events for nintedanib and pirfenidone include gastrointestinal (GI) effects. Pirfenidone uniquely can cause rash/photosensitivity, while nintedanib is rated as pregnancy Category D. Pirfenidone should not be used in patients with renal dysfunction, and is associated with a different drug interaction profile than nintedanib.
- Both products are associated with significant discontinuation rates, and may require dosage reductions or temporary stoppage due to adverse effects.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that pirfenidone (Esbriet) was the most cost-effective IPF agent, followed by nintedanib (Ofev).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating pirfenidone (Esbriet) as formulary and step-preferred, with nintedanib (Ofev) as formulary

and non step-preferred, demonstrated the largest estimated cost avoidance for the Military Health System (MHS).

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

    - **UF and Step-Preferred:** pirfenidone (Esbriet)
    - **UF and Non Step-Preferred:** nintedanib (Ofev)
    - **NF:** no products

    Note that as part of this recommendation, all new users of an IPF agent are required to try Esbriet first. Additionally, no IPF products were recommended for BCF addition. For the Pulmonary-1 Drug Class, there are several BCF drugs, including fluticasone (Flovent), salmeterol (Serevent), and fluticasone/salmeterol (Advair).

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updating the current manual PA criteria to require a trial of pirfenidone (Esbriet) in new users, prior to use of nintedanib (Ofev). The step therapy requirement for a trial of Esbriet in new users is included in the manual PA criteria. No changes were recommended to the current manual PA for Esbriet. Coverage for the IPF agents requires a confirmed IPF diagnosis, management by a pulmonologist, and non-smoking status. PA will expire after one year of therapy, with renewal criteria requiring a significant slowing of the annual rate of decline of forced vital capacity (FVC). See Appendix C for full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***QLs currently apply to Esbriet and Ofev. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the current quantity limit of a 30-day supply for both IPF agents, at all three points of service, consistent with current manufacturer packaging.

4. ***COMMITTEE ACTION: EMMPI REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding the IPF drugs to the EMMPI list upon signing of the minutes. See Appendix F.

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday after a 30-day implementation. Based on the P&T Committee's recommendation, the effective date is August 30th, 2017.

B. Ophthalmic-1s: Dual Acting Antihistamines/Mast Cell Stabilizers

Background—The Ophthalmic-1 Dual Acting Antihistamine and Mast Cell Stabilizer (AH/MCS) Drug Class was previously reviewed for UF status in August 2010. Ketotifen (Zaditor, generic) is available over-the-counter (OTC) and was not included in the review.

Three products containing the active ingredient olopatadine are available. Olopatadine 0.1% (Patanol) is administered twice daily, is available as a generic formulation, and is the current BCF selection for the class. Olopatadine 0.2% (Pataday) has been marketed since 2004 and is administered once daily; generic formulations are expected later this year. Olopatadine 0.7% (Pazeo) entered the market in 2015 and is administered once daily; it was designated NF at the February 2016 meeting.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 1 opposed, 0 abstained, 0 absent) the following for the ophthalmic AH/MCS:

- The ophthalmic AH/MCS are the standard of care for treating the signs and symptoms of allergic conjunctivitis. Allergic conjunctivitis is a highly seasonal condition, and MHS utilization for the class reflects this variability.
- Clinical practice guidelines from the American Academy of Ophthalmology and the American Optometric Association recommend the AH/MCS as first-line therapy for acute and chronic allergic conjunctivitis. The guidelines do not prefer one product over another.
- A 2015 Cochrane review and 2016 meta-analysis concluded there is insufficient evidence to discern whether one AH/MCS is the more effective than another. Olopatadine may be more effective than OTC ketotifen, but less effective than alcaftadine; however, these differences among products may not be clinically relevant.
- In terms of efficacy and safety, head-to-head studies show olopatadine 0.1% (Patanol) is comparable to olopatadine 0.2% (Pataday). Olopatadine 0.7% (Pazeo) reduced ocular itching to a greater extent than olopatadine 0.2%; however, although these results were statistically significant 24 hours following administration (when the next daily dose is due), the result did not meet the threshold for clinical significance.
- With regard to safety and tolerability, the overall adverse event rate is low. All the products can cause burning, stinging, headaches, dry eye, blurred vision, and hyperemia. Bepotastine (Bepreve) may cause taste perversion in up to 25% of patients.
- There is no new data to change the conclusion from the previous review that the AH/MCS are highly therapeutically interchangeable.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic azelastine (Optivar) was the most cost-effective AH/MCS, followed by generic epinastine (Elestat), brand olopatadine 0.7% (Pazeo), generic olopatadine 0.1% (Patanol), brand olopatadine 0.1% (Patanol),

brand emedastine (Emadine), brand bepotastine (Bepreve), brand alcaftadine (Lastacaft), and brand olopatadine 0.2% (Pataday).

- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating generic olopatadine 0.1% (Patanol), generic azelastine (Optivar), generic epinastine (Elestat), and brand olopatadine 0.7% (Pazeo) as UF, and brand emedastine (Emadine), brand bepotastine (Bepreve), brand alcaftadine (Lastacaft), and brand olopatadine 0.2% (Pataday) as NF, demonstrated the largest estimated cost avoidance for the MHS.

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

   - **UF:**
     - olopatadine 0.1% (generic Patanol)
     - olopatadine 0.7% (Pazeo)
     - azelastine 0.05% (generic Optivar)
     - epinastine 0.05% (generic Elestat)

   - **NF:**
     - olopatadine 0.2% (Pataday)
     - alcaftadine 0.25% (Lastacaft)
     - bepotastine 1.5% (Bepreve)
     - emedastine 0.05% (Emadine)

   Note that the drugs recommended for NF status are exempt from the "NF goes to Mail" requirement, due to the acute use exception. See Appendix F.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining olopatadine 0.1% (generic Patanol) on the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the dual acting AH/MCS. All new and current users of a NF product, olopatadine 0.2% (Pataday), Lastacaft, Bepreve, and Emadine require a trial of two formulary products within the past 90 days, unless the patient has experienced intolerable adverse events from the formulary products, or is pregnant. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for olopatadine 0.2% (Pataday), Lastacaft, Bepreve, and Emadine. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period and, 2) DHA send letters to beneficiaries who are affected by the UF decision. Based on the P&T Committee's recommendation, the effective date is November 1, 2017.

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly-approved drugs reviewed at the May 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 (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- **UF**:
    - deflazacort (Emflaza) – Corticosteroids – Immune Modulators – for Duchenne Muscular Dystrophy (DMD)
    - deutetrabenazine (Austedo) – Neurological Agents Miscellaneous for Huntington's Disease
    - dupilumab (Dupixent) – Corticosteroids – Immune Modulators – Immune Modulators Subclass for Atopic Dermatitis
    - ribociclib (Kisqali) – Oral Oncologic Agents for Breast Cancer
    - telotristat (Xermelo) – GI-2 Miscellaneous Agents for carcinoid syndrome diarrhea

- **NF:**
    - crisaborole (Eucrisa) – Corticosteroids – Immune Modulators – Immune Modulators Subclass for Atopic Dermatitis
    - insulin degludec/liraglutide (Xultophy) – Glucagon-Like Peptide-1 Receptor Agonist (GLP1RA)
    - morphine sulfate ER (Arymo ER) – Narcotic Analgesics and Combinations
    - oxymetazoline (Rhofade) – Acne Agents – Topical Acne and Rosacea Agents Subclass

- plecanatide (Trulance) – GI-2 Miscellaneous Agents for chronic idiopathic constipation

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for crisaborole (Eucrisa), plecanatide (Trulance), insulin degludec/liraglutide (Xultophy), morphine sulfate ER (Arymo ER), and oxymetazoline (Rhofade). See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- Applying the same manual PA criteria for insulin degludec/liraglutide (Xultophy) in new and current users, as is currently in place for insulin glargine/lixisenatide (Soliqua) and the other non step-preferred GLP1RAs. Patients must first try metformin or a sulfonylurea, and exenatide weekly injection (Bydureon) and albiglutide weekly injection (Tanzeum) prior to Xultophy. Additionally, for Xultophy, patients are required to be on basal insulin at a dosage of less than 50 units daily. See Appendix C for the full criteria.

- Applying the same step therapy and manual PA criteria for topical oxymetazoline (Rhofade) in new and current users as is currently in place for the non step-preferred topical rosacea products. Patients must first try one generic metronidazole step-preferred formulation and topical azelaic acid prior to Rhofade.

- Applying PA criteria to the following: new and current users of crisaborole (Eucrisa), dupilumab (Dupixent), deflazacort (Emflaza), plecanatide (Trulance), and telotristat (Xermelo); and in new users of deutetrabenazine (Austedo) and ribociclib (Kisqali). See Appendix C for the full criteria.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday after the signing of the minutes in all points of service (POS), including the new PAs for dupilumab (Dupixent), crisaborole (Eucrisa), deflazacort (Emflaza), plecanatide (Trulance), telotristat (Xermelo), liraglutide/insulin degludec (Xultophy), deutetrabenazine (Austedo), oxymetazoline (Rhofade), ribociclib (Kisqali).

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

a) **Non-Insulin Diabetes Drug: Biguanides—Metformin Extended Release (ER), Fortamet, and Glumetza Manual PA Criteria**

Fortamet and Glumetza are branded formulations of metformin ER (Glucophage XR), which were designated as NF at the November 2010 meeting, and maintained as NF in August 2016. Glumetza and Fortamet are available in 500 mg and 1000 mg tablets while generic metformin ER products are available in 500 mg and 750 mg tablets.

(1) ***COMMITTEE ACTION: FORTAMET AND GLUMETZA MANUAL PA CRITERIA***—Due to the significant cost differences between Fortamet and Glumetza and generic metformin ER, and the lack of clinically compelling benefits over generic metformin ER, the Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA in all new and current users of Glumetza and Fortamet. The patient will be required to try generic metformin ER first. Prior authorization will not expire. See Appendix C for the full criteria.

b) **Diuretics Carbonic Anhydrase Inhibitor: Dichlorphenamide (Keveyis) Manual PA Criteria**

Keveyis is an orphan drug approved for treating primary hyperkalemic or hypokalemic periodic paralysis, or related variants. The active ingredient dichlorphenamide was first marketed in 1958 under the brand name Daranide, but discontinued from the market. Keveyis was FDA-approved in August 2015, but just recently launched.

Acetazolamide (Diamox, generic) is commonly used off-label for this condition, but only one published retrospective trial is available. FDA approval for Keveyis was based on two clinical trials enrolling a total of 65 patients. The mechanism of action of Keveyis for treating periodic paralysis is unknown.

(1) ***COMMITTEE ACTION: DICHLORPHENAMIDE (KEVEYIS) MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) new manual PA criteria for Keveyis, requiring a diagnosis of hypo- or hyperkalemic periodic paralysis as outlined in the product labeling, and a trial of acetazolamide. Prior authorization will expire after two months. If the patient has responded to therapy, then Keveyis will be approved indefinitely. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria**—Updates to the manual PA criteria for several drugs was recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications, or FDA safety alerts, or availability of low cost generics for NF drugs in classes with step therapy. Updated manual PA will apply to new users.

    a) **Gastrointestinal-2 Miscellaneous Agents: Eluxadoline (Viberzi)**—Viberzi was reviewed in February 2016 with manual PA criteria recommended. An update to the manual PA criteria was recommended, based on a recent FDA safety alert. Patients who have had a cholecystectomy will be excluded from using Viberzi.

    b) **Anticonvulsant and Anti-Mania Drugs: Topiramate ER (Qudexy XR)** Qudexy XR was reviewed in May 2016 with manual PA criteria recommended. Criteria were updated to add the additional indication for migraine prophylaxis.

    c) **Non-Opioid Pain Syndromes: Pregabalin (Lyrica)**—Lyrica was reviewed in November 2011 with step therapy and manual PA criteria recommended. A trial of gabapentin is required prior to use of Lyrica, except in patients with seizure disorders. The manual PA criteria were updated to require a trial of duloxetine in addition to gabapentin for disorders not related to seizures or post-herpetic neuralgia.

    d) **Hepatitis C Virus Direct-Acting Antivirals: Ledipasvir/Sofosbuvir (Harvoni) and Sofosbuvir (Sovaldi)**—The direct-acting antivirals were most recently reviewed for formulary status in February 2017. The manual PA criteria were updated to reflect FDA approval in children 12 years of age and older.

    e) **Nasal Allergy Drugs: Fluticasone/Azelastine (Dymista)**—Dymista was reviewed in May 2014, with step therapy and manual PA criteria recommended. Currently, a trial of one step-preferred formulary nasal allergy drug (nasal formulations of generic fluticasone, flunisolide, azelastine, or ipratropium) is required prior to use of Dymista. Since the May 2014 class review, several nasal allergy drugs are now available in generic formulations, or OTC. Criteria were updated to include a trial of at least two formulary step-preferred drugs prior to use of Dymista.

    f) **Sedative Hypnotics: Newer Sedative Hypnotics—Eszopiclone (Lunesta) and Zolpidem ER (Ambien CR) Step Therapy**—Lunesta and Ambien CR were reviewed in May 2012 with the newer sedative hypnotics drug class, and both drugs are designated as UF and non step-preferred. Step therapy for the class requires a trial of a step-preferred drug (zolpidem IR or zaleplon) prior to use of non step-preferred agents. Cost-effective generic formulations of Lunesta and Ambien CR are now available.

    The step therapy criteria and manual criteria for the newer sedative hypnotics were updated to remove step therapy for eszopiclone and zolpidem ER.

Eszopiclone and zolpidem ER will be step-preferred agents in addition to zolpidem IR and zaleplon. Step therapy remains for non step-preferred agents including Rozerem, Intermezzo, Edluar, Silenor, and Zolpimist. Belsomra and Hetlioz have additional manual PA criteria. See Appendix C for the updated manual PA criteria for the class.

g) **Overactive Bladder (OAB) Drugs: Mirabegron (Myrbetriq)**—The OAB drugs were most recently reviewed for formulary status in November 2012, with step therapy requiring a 12-week trial of one cost-effective generic formulation of tolterodine ER, oxybutynin ER, or trospium IR prior to use of the non step-preferred drugs. Mirabegron was reviewed as a new drug at the May 2014 meeting, and was designated as UF and non step-preferred. Since the previous P&T Committee review, several cost-effective generic formulations of other OAB drugs have entered the market.

Overactive bladder is characterized by a high placebo response rate, and benefits are seen with behavioral therapies. There do not appear to be clinically relevant differences in efficacy between mirabegron and the antimuscarinic OAB drugs, based on meta-analyses and clinical practice guidelines.

The manual PA criteria for mirabegron were updated to recommend a trial of two formulary step-preferred products first. The criteria will continue to allow patients who are at significant risk for central nervous system effects from antimuscarinic drugs to receive mirabegron. The criteria were also updated to reflect package insert cautions regarding use in patients with compromised renal function. Additionally, a trial of behavioral interventions (including pelvic floor muscle training in women and bladder training) is recommended, based on the clinical practice guidelines.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND STEP THERAPY***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Viberzi, Qudexy XR, Lyrica, Harvoni, Sovaldi, Dymista, and the step therapy changes to eszopiclone and zolpidem ER.

(2) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA***
The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) updates to the manual PA criteria for Myrbetriq, as outlined above. See Appendix C for the full criteria.

(3) ***COMMITTEE ACTION: MIRABEGRON (MYRBETRIQ) EMMPI REQUIREMENTS***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) adding mirabegron to the EMMPI list, upon signing of the minutes, consistent with the other drugs in the overactive bladder class that are in the program.

B. Quantity Limits (QLs)

1. QLs were reviewed for seven drugs: ribociclib (Kisqali) for breast cancer, niraparib (Zejula) for ovarian cancer, panobinostat (Farydak) for multiple myeloma, azelastine/ fluticasone (Dymista) for seasonal allergic rhinitis, and crisaborole (Eucrisa) and dupilumab (Dupixent) for atopic dermatitis.

    a) ***COMMITTEE ACTIONS: QLs—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) QLs for Kisqali, Zejula, Farydak, Dymista, Eucrisa, and Dupixent. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

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

    - 16 for, 0 opposed, 0 abstained, 0 absent—The new manual PAs for extended-release metformin (Fortamet, Glumetza, generics), and dichlorphenamide (Keveyis) 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 November 1, 2017.
    - 16 for, 0 opposed, 0 abstained, 0 absent—Updates to the current PAs for eluxadoline (Viberzi), topiramate ER (Qudexy XR), pregabalin (Lyrica), ledipasvir/sofosbuvir (Harvoni), sofosbuvir (Sovaldi), and fluticasone/azelastine (Dymista), and the step therapy changes for eszopiclone and zolpidem ER become effective upon signing of the minutes in all POS.
    - 12 for, 0 opposed, 0 abstained, 4 absent—Updates to the current PA for mirabegron (Myrbetriq) become effective upon signing of the minutes in all POS.
    - 16 for, 0 opposed, 0 abstained, 0 absent—The QLs for Kisqali, Zejula, Farydak, Dymista, Eucrisa, and Dupixent become effective upon signing of the minutes.

VII. LINE EXTENSIONS

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

A. *COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION*—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 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.

- Attention Deficit Hyperactivity Disorder Drugs—Lisdexamfetamine chewable tablet (Vyvanse chewable) as NF with the same MN criteria as Vyvanse.

- Non-Insulin Diabetes Drugs: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors—Metformin extended-release (XR)/empagliflozin (Synjardy XR) as formulary and step-preferred with the same automated PA criteria as Synjardy.
- These recommendations will become effective upon signing of the minutes.

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 (11 for, 0 opposed, 0 abstained, 5 absent) the following product be designated NF on the UF:

- CSL Behring LLC: antihemophilic factor, recombinant single chain (Afstyla) 500 units, 1000 units, 2000 units, and 3000 units injection

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) the following pre-authorization criteria for Afstyla:

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

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

Should the mail order requirement impact availability of a drug, the P&T Committee will allow an exception to the Section 703 rule. The following drug will not be available in the Mail Order:

- Afstyla (antihemophilic factor, recombinant single chain), 500 units, 1000 units, 2000 units, and 3000 units subcutaneous injection is only available in the Retail Network.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for Afstyla; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is November 1, 2017.

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

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

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

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

The P&T Committee recommended (16 for, 0 opposed, 0 abstained 0 absent):

1. **Add:** Dupilumab (Dupixent) is suitable for mail and should be added to the EMMPI program.
2. **Do Not Add:** Deflazacort (Emflaza), telotristat (Xermelo), and deutetrabenazine (Austedo) are not feasible for mail order dispensing due to limited distribution requirements; addition of oral breast cancer agents such as ribociclib (Kisqali) to the EMMPI program should be considered at a future date.

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

The P&T Committee recommended (16 for, 0 opposed, 0 abstained 0 absent):

1. **Add:** Liraglutide/insulin degludec (Xultophy) and oxymetazoline (Rhofade) fall into classes that are already defined as automatic additions to the EMMPI program; the P&T Committee found no reason to exempt crisaborole (Eucrisa) or plecanatide (Trulance) from the mail order requirement.
2. **Do Not Add:** The previously established exception from the mail order requirement for C-II controlled substances applies to morphine sulfate ER tablets (Arymo ER).

X. RE-EVALUATION OF NF GENERICS

The P&T Committee reviewed the current utilization, formulary status, generic availability, comparative clinical effectiveness, and relative cost effectiveness, including the weighted average cost per unit, for all generically available NF agents in three previously reviewed UF drug classes: the second generation antihistamines, the antidepressants, and the testosterone replacement therapies.

Clinical Effectiveness Conclusion and Cost-Effectiveness Conclusion—The P&T Committee concluded that for all three drug classes, there was no new pertinent efficacy or safety information to change the clinical effectiveness conclusions from when the classes were originally reviewed for UF placement. Specific comments, including the results of comparative cost reviews, are below:

- *Second Generation Antihistamines: Levocetirizine (Xyzal) and Desloratadine (Clarinex)*—Levocetirizine and desloratadine continue to offer no significant, therapeutically meaningful advantages over other similar agents on the UF. While unit costs for generic versions of levocetirizine and desloratadine have dropped considerably, they remain substantially more costly than OTC loratadine and OTC cetirizine, without offering any additional advantage. In addition, the impact of the recent approval of the OTC version of levocetirizine (Xyzal Allergy 24HR) is yet unknown.

- *Selective Serotonin Reuptake Inhibitors (SSRIs): Fluoxetine 90 mg Delayed Release (Prozac Weekly) and Products for Premenstrual Dysphoric Disorder (PMDD) (Sarafem)*—Neither the special packaging for PMDD (Sarafem) nor a higher dosing strength for weekly administration (Prozac Weekly) offer significant clinical advantages compared to generic Prozac. Brand Sarafem capsules have been withdrawn, and are now available only as tablets; there appears to be at least one A-rated generic equivalent to Sarafem tablets. Both brand and generic Sarafem tablets, as well as brand and generic versions of Prozac Weekly, remain substantially more costly than generic fluoxetine capsules, which are available from multiple generic manufacturers at very low cost. Specific A-ratings for the generic fluoxetine capsules (i.e., to the discontinued Sarafem product vs. Prozac) are difficult to track operationally, but the vast majority of utilization across all POS is for the lowest cost generic fluoxetine capsules.

- *Testosterone Replacement Therapy (TRT):* This class was last reviewed in August of 2012, and the P&T Committee agreed there are no clinically relevant differences in efficacy or safety among available products, since they all contain testosterone. Fortesta (testosterone gel) was designated as UF and the sole step-preferred product. Androgel 1% and 1.62% gel were designated as NF and non step-preferred. As of May 2017, a number of the TRT products have become generically available, including Fortesta, Testim, Androgel 1% gel, and Androgel 1.62% gel. However, only generic Androgel 1% is now comparable to Fortesta in terms of weighted average cost across points of service and less costly than Fortesta at MTFs.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended the following, effective upon signing of the minutes:

1. The following products will remain NF, with both brand and generics subjected to mail order requirements:

    - (14 for, 1 opposed, 1 abstained, 0 absent)—*Second Generation Antihistamines:* levocetirizine (Xyzal, generics) and desloratadine (Clarinex, generics)
    - (16 for, 0 opposed, 0 abstained, 0 absent)—*Selective Serotonin Reuptake Inhibitors:* fluoxetine delayed release 90 mg (Prozac Weekly); Sarafem tablets and generic equivalents

2. The following will be returned to UF status and is no longer subject to the mail order requirement (since no brand agent currently exists):

    - (16 for, 0 opposed, 0 abstained, 0 absent)—*Selective Serotonin Reuptake Inhibitors:* all fluoxetine capsules currently designated as NF

3. The following agent will be returned to UF status and designated as step-preferred, with appropriate changes made to PA criteria to require an unsuccessful trial, contraindication, or intolerance to either Fortesta or generic Androgel 1% before receiving a non-preferred product. The brand product, but not the generic, remains on the EMMPI list.

    - (16 for, 0 opposed, 0 abstained, 0 absent)—*Testosterone Replacement Therapy:* Generic Androgel 1% gel

XI. UF SUB-WORKING GROUP UPDATE: ALIGNING OTC FORMULARIES

The P&T Committee was briefed on a plan by the UF Sub-Working Group, comprised of representatives from all the Services, regarding OTC drug dispensing at the MTFs. Currently, individual MTFs dispense a wide variety of OTC medications as determined by the local MTF. A transition to a more uniform list of OTC products available across MTFs, and ultimately across the pharmacy benefit is recommended. A phased approach to standardize OTC use across the MTFs is recommended. The Committee reviewed an initial OTC test list (based on historic usage across the system) to assess technical and other aspects of MTF coverage of OTC products under MHS Genesis. Phase one includes technical testing, phase two standardization of the MTFs and phase three standardization of all three points of service.

A. ***COMMITTEE ACTION*****—**The P&T Committee agreed (16 for, 0 opposed, 0 abstained, 0 absent) with the initial testing list of OTC products and the phased approach to standardization.

XII. 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. Since May 2005, several new regulatory authorities have expanded the responsibilities of the P&T Committee, resulting in increasing complexity of the TRICARE pharmacy benefit, and the need for quick determination of issues.

The Committee reviewed an updated list of previously approved functions/actions since 2005 to manage the benefit. 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 updated list of functions is found in Appendix G.

XIII. ITEMS FOR INFORMATION

A. DEPLOYMENT DISPENSING

The Committee was briefed on the role of the DHA Pharmacy Operations Division in deployment dispensing. The Committee evaluated medications dispensed prior to deployment, as well as in-theater, and discussed the limitations of the data presented.

B. VETERANS AFFAIRS (VA) CONTINUITY OF CARE DRUG 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 FY16 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.

XIV. ADJOURNMENT

The meeting adjourned at 1230 hours on May 11, 2017. The next meeting will be in August 2017.

Appendix A—Attendance: May 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) (formerly known as Innovator Drugs)

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

Appendix G—Pharmacy and Therapeutics 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:

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

7/27/17
Date

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

John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT Edward Norton, MSC	Acting Chief of DHA Pharmacy Operations Division
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
Col William Hannah, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
CDR Austin Parker, MC	Navy, Internal Medicine Physician
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
CAPT Shaun Carstairs, MC	Navy, Physician at Large
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
MAJ John Poulin, MC	Army, Physician at Large
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Lt Col Rodney Jorstad, BSC	Air Force, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Doreen Lounsbery, COL (Ret.), MC, USA	TRICARE Regional Office-South, Medical Director
Voting Members Absent	
Maj Larissa Weir, MC	Air Force, OB/GYN Physician
Ms. Jennifer Zacher for Mr. Joe Canzolino	Department of Veterans Affairs
Nonvoting Members Present	
Ms. Leigh Bradley (SES)	General Counsel, DHA
LCDR Ebenezer Aniagyei via telephone	Defense Logistics Agency Troop Support
Dean Valibhai, PharmD, MBA, via telephone	DHA Purchased Care Branch
Guests	
COL Alfonso S. Alarcon, MD	Director, TRICARE Area Office Latin America & Canada
Mr. Jason Wray	Defense Logistics Agency Troop Support
Capt Kevin Bourne	Defense Logistics Agency Troop Support
Mr. Dwight Bonham	DHA Contract Operations Division
Mr. Bruce Mitterer	DHA Contract Operations Division
Mr. Evan Zaslow	DHA Contract Operations Division
Mr. James Berns	DHA Contract Operations Division

Appendix A—Attendance (continued)

Guests	
CAPT Matt Baker	Indian Health Service
Scott Holuby, PharmD, BCPS	Brooke Army Medical Center
Maj Shaoping Sumner	Air Force Pharmacy Resident
Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, DHA Formulary Management Branch
CAPT Walter Downs, MC	DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
LCDR Christina Andrade	DHA Formulary Management Branch
Ms. Deborah Garcia via telephone	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Maj Ellen Roska, BSC	DHA Integrated Utilization Branch
Robert Conrad, PharmD via telephone	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS, via telephone	DHA Purchased Care Branch
Brian Beck, PharmD, BCPS	DHA Purchased Care Branch
David Meade, PharmD via telephone	DHA Integrated Utilization Branch
Ingrid Svihla, PharmD via telephone	DHA Integrated Utilization Branch

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• alcaftadine (Lastacaft) • bepotastine (Bepreve) • emedastine (Emadine) • olopatadine 0.2% (Pataday) **Ophthalmic-1s: AH/MCS**	• Use of all formulary agents has resulted in therapeutic failure • No alternative formulary agent. Applies for Lastacaft and Emadine when the patient is pregnant and requires a Pregnancy Category B medication. **Formulary Alternatives:** azelastine, epinastine, olopatadine 0.1%, and olopatadine 0.7% (Pazeo)
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	• Use of formulary agents are contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agent has resulted in therapeutic failure **Formulary Alternatives:** high potency (Class 1) topical corticosteroids (various)
• liraglutide/insulin degludec (Xultophy) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Use of formulary agents (both GLP1RAs Bydureon and Tanzeum AND insulin glargine) has resulted in therapeutic failure **Formulary Alternatives:** exenatide once weekly (Bydureon), albiglutide (Tanzeum), and insulin glargine (Lantus)
• morphine sulfate ER (Arymo ER) **Narcotic Analgesics: Long-Acting High Potency Narcotic Analgesics**	• Patient has had therapeutic failure of 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)
• oxymetazoline (Rhofade) **Topical Acne and Rosacea Agents: Miscellaneous Topical Agents**	• Use of metronidazole and azelaic acid are contraindicated • Patient has tried and failed metronidazole and azelaic acid • Patient has experienced significant adverse effects from metronidazole and azelaic acid **Formulary Alternatives:** metronidazole (metronidazole (1% gel; 0.75% lotion, and 0.75% cream) and azelaic acid 15%
• plecanatide (Trulance) **GI-2 Miscellaneous Drugs**	• Use of linaclotide resulted in therapeutic failure **Formulary Alternative:** linaclotide (Linzess)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• nintedanib (Ofev) **Pulmonary 1-s: Pulmonary Miscellaneous Subclass**	**Changes from the May 2017 meeting are in BOLD** **All new users of nintedanib (Ofev) are required to try pirfenidone (Esbriet) first.** Manual PA criteria: **Pirfenidone (Esbriet) is the preferred IPF agent; coverage is approved for nintedanib (Ofev) if the following:** • **The patient has had a trial of pirfenidone (Esbriet) and either:** o **Failed therapy with Esbriet due to progression of IPF, e.g. improvement or effectiveness of therapy is defined by a less than 10% decline in percent predicted forced vital capacity (FVC) OR** o **Experienced intolerable adverse effects (e.g., rash, photosensitivity; GI AEs) OR** • **The patient has clinical factors where Esbriet is not appropriate** o **The patient is taking a drug which will interact with Esbriet that does not interact with Ofev [moderate to strong CYP inhibitors – CYP 450-1A2 (e.g., fluvoxamine)] OR** o **The patient has end stage renal disease (ESRD) on dialysis** AND Coverage approved for patients with the following: • The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND • The patient is being actively managed by a pulmonologist, AND • The patient is not currently receiving pirfenidone (Esbriet) with nintedanib (Ofev) concomitantly. Dual therapy is not allowed (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa). PA expires after 1 year. • PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Ofev will be approved if there has been a significant reduction in the annual rate of decline of FVC. • Renewal PA criteria is limited to one year.
• pirfenidone (Esbriet) **Pulmonary 1-s: Pulmonary Miscellaneous Subclass**	**Changes from the May 2017 meeting are in BOLD** Manual PA criteria will **continue to** apply to all new users of pirfenidone (Esbriet) Manual PA Criteria: Coverage approved for patients: • The patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis, AND • The patient is being actively managed by a pulmonologist, AND • The patient is not currently receiving pirfenidone (Esbriet) with nintedanib (Ofev) concomitantly. Dual therapy is not allowed (i.e., if the patient is treated with Ofev, Esbriet cannot also be used during treatment, and vice-versa). PA expires after one year. • PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Esbriet will be approved if there has been a significant reduction in the annual rate of decline of FVC. • Renewal PA criteria is limited to one year.

Drug / Drug Class	Prior Authorization Criteria
• alcaftadine (Lastacaft) alcaftadine (Lastacaft) • bepotastine (Bepreve) • emedastine (Emadine) • olopatadine 0.1% (Pataday) **Ophthalmic 1-s: AH/MCS**	Manual PA criteria apply to all new and current users of Lastacaft, Bepreve, Emadine, and olopatadine 0.2% (Pataday). • The patient has ocular symptoms of allergic conjunctivitis AND o The patient has tried and failed two formulary alternatives (olopatadine 0.1%, olopatadine 0.7% (Pazeo), azelastine, or epinastine) in the last 90 days, OR o Use of two formulary alternatives (olopatadine, azelastine, or epinastine) has resulted in intolerable adverse effects, OR o The patient is pregnant (for Lastacaft and Emadine only) PA does not expire.
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	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 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.
• dupilumab (Dupixent) **Corticosteroids – Immune Modulators – Immune Modulators subclass**	Manual PA criteria apply to all new and current users of Dupixent. Manual PA Criteria: coverage will be approved for initial therapy for 6 months if: • Patient has moderate to severe or uncontrolled atopic dermatitis AND • Patient must be 18 years of age or older AND • Prescribed by a dermatologist AND • Patient has a contraindication to, intolerability to, or failed treatment with at least **ONE** high potency / class 1 topical corticosteroid AND • Patient has a contraindication, intolerability to, or failed treatment with at least **ONE** systemic immunosuppressant. PA expires after 6 months. Renewal PA Criteria: coverage will be approved indefinitely for continuation of therapy if: 1. 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) Off-label uses are NOT approved.
• deflazacort (Emflaza) **Corticosteroids – Immune Modulators**	Manual PA criteria apply to all new and current users of Emflaza. Manual PA Criteria: coverage will be approved indefinitely if all criteria are met: 1. Patient has a diagnosis of Duchenne Muscular Dystrophy AND 2. Prescribed by a neurologist AND 3. Patient is age 5 or older AND 4. Patient has tried prednisone for at least 6 months and has experienced at least one of the following adverse events: • Unmanageable weight gain OR • Patient has experienced severe behavioral adverse events s that requires a reduction in prednisone dose Off-label uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• plecanatide (Trulance) **GI-2 Miscellaneous Drugs**	Manual PA criteria apply to all new and current users of Trulance. Manual PA Criteria: Coverage approved if: 1. Patient is ≥ 18 years of age AND 2. Patient has clinically diagnosed chronic idiopathic constipation AND 3. Patient does not have gastrointestinal obstruction AND 4. Patient has failed or is intolerant to linaclotide (Linzess) AND 5. Dual therapy with another guanylate cyclase-C agonist is not allowed. Off-label uses are not approved. PA expires in one year. • PA criteria for renewal for new and current users: After one year, PA must be resubmitted. Continued use of Trulance will be approved if there has been improvement in constipation symptoms and NO dual therapy with another guanylate cyclase-C agonist. Renewal PA criteria is limited to one year.
• telotristat (Xermelo) **GI-2 Miscellaneous Drugs**	Manual PA criteria apply to all new and current users of Xermelo. Manual PA Criteria: Coverage approved for one year if all criteria are met: 1. Patient has diagnosis of carcinoid syndrome diarrhea. 2. Patient has had an inadequate treatment response to at least a 3-month trial of somatostatin analog therapy. 3. Telotristat must be used in combination with a somatostatin analog (i.e., octreotide or lanreotide). 4. Patient has ≥ 4 bowel movements daily. Off-label uses are NOT approved. PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Xermelo will be approved when a) used in combination with an somatostatin analog b) decrease from baseline in amount of average daily bowel movements, c) prescriber agrees to continue to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops, d) no severe constipation or abdominal pain develops. • Renewal PA criteria is limited to one year.
• liraglutide/insulin degludec (Xultophy) **Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	All new and current users of Xultophy are required to try metformin or a sulfonylurea (SU) before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin or a sulfonylurea first. Additionally, Bydureon and Tanzeum are the preferred agents in the GLP1RA Subclass. New and current users of Xultophy must try Bydureon and Tanzeum first. Manual PA Criteria: Coverage will be approved if the following criteria are met: • Xultophy is used as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus inadequately controlled on a basal insulin (< 50 units daily) • Patient has tried and failed therapy with metformin or sulfonylurea AND • The patient has had an inadequate response to Bydureon AND • The patient has had an inadequate response to Tanzeum. Prior Authorization does not expire. Off-label uses are not approved.

Drug / Drug Class	Prior Authorization Criteria
• deutetrabenazine (Austedo) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Austedo. Manual PA Criteria: Coverage approved for initial therapy for one year if all criteria are met: 1. Prescribed by or in consultation with a neurologist 2. Patient has a diagnosis of chorea associated with Huntington's Disease 3. Patient is not actively suicidal 4. Patient does not have depression, or is being adequately treated for depression 5. Patient does not have severe hepatic impairment 6. Patient is not taking any of the following: • MAOI inhibitor within the past 14 days • reserpine • tetrabenazine (Xenazine) or another VMAT-2 inhibitor 7. Patient has had an adequate trial of tetrabenazine for 12 weeks and had one of the following: • Experienced treatment failure • Experienced an adverse event that is not expected to occur with Austedo PA expires in one year. Manual PA Criteria (Renewal criteria: Coverage approved indefinitely for continuation of therapy if all criteria are met: 1. Patient has demonstrated improvement in chorea based on clinician assessment and is being monitored for depression and suicidal ideation Off-label uses are NOT approved (Tourette's, tardive dyskinesia, dystonia).
• oxymetazoline (Rhofade) **Topical Acne and Rosacea Agents: Miscellaneous Topical Agents**	All new and current users of Rhofade are required to try one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream). Automated PA Criteria: • The patient has filled a prescription for one generic topical step-preferred metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. Manual PA Criteria: If automated PA criteria are not met, Rhofade will be approved if: • Patient is at least 18 years of age and has the following diagnosis: o For **Rhofade**: patient has persistent facial erythema of rosacea **AND** o Patient has tried and failed one generic step-preferred formulary topical metronidazole product (1% gel, or 0.75% lotion or 0.75% cream) **AND** o Patient has tried and failed topical azelaic acid 15%. PA expires in one year. Off-label uses are not approved.
• ribociclib (Kisqali) **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Kisqali. Manual PA criteria: Kisqali is approved if: 1. Patient has advanced (metastatic) estrogen receptor-positive (ER+) disease; AND 2. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND 3. The patient is a postmenopausal woman and Kisqali will be used as first-line endocrine therapy in combination with an aromatase inhibitor. Off-label uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• topiramate ER (Qudexy XR) **Anticonvulsant and Anti-Mania**	**Changes from May 2017 meeting are in BOLD and strikethrough** Manual PA criteria apply to all new users of Qudexy XR: • Coverage approved for o Partial onset seizure and 1° generalized tonic-clonic seizures in patients ≥ 10 years o Lennox-Gastaut seizures in patients ≥ 6 years for Trokendi XR and age ≥ 2 years for Qudexy XR. o Adjunctive therapy for partial onset seizure or primary generalized tonic clonic seizure in patients 2 years of age or older (Qudexy XR) or 6 years and older (Trokendi XR). o **Migraine prophylaxis in adults (**Trokendi XR and **Qudexy XR)** • Coverage not approved for o Non-FDA approved indications, including ~~migraine headache and~~ weight loss • Patient is required to try topiramate first, unless the following has occurred: o Inadequate response not expected to occur with Trokendi XR or Qudexy XR. o Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Trokendi XR or Qudexy XR.
• metformin extended-release (Fortamet and Glumetza) **Non-Insulin Diabetes Drugs: Biguanides**	Manual PA criteria apply to all new and current users of Fortamet and Glumetza. The provider must explain why the patient cannot take two generic 500mg ER tablets separately (for patients taking requiring 1000 mg metformin ER). PA will be approved if patient is on a dose-alternating schedule (e.g., 500 mg alternating with 1000 mg every other day). PA does not expire. Off-label uses are not approved.
• dichlorphenamide (Keveyis) **Diuretics: Carbonic Anhydrase Inhibitors**	Manual PA criteria apply to all new and current users of Keveyis. Manual PA criteria: Keveyis is approved for 2 months for initial therapy if: **Hypo/Hyperkalemic Periodic Paralysis (HypoPP/HyperPP) and Related Variants.** Initial Therapy. Approve for 2 months if the patient meets the following criteria (i, ii, iii, iv, and v): i. Patient has a confirmed diagnosis of primary hypokalemic or hyperkalemic periodic paralysis by meeting at least ONE of the following (a, b, or c): a) Patient with HypoPP has had a serum potassium concentration of less than 3.5 mEq/L during a paralytic attack; OR for patient with HyperPP, patient has had an increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack; OR for patient with HyperPP, patient has had a serum potassium concentration during a paralytic attack of greater than 5.0 mEq/L; OR b) Patient has a family history of the condition; OR c) Patient has a genetically confirmed skeletal muscle calcium or sodium channel mutation; AND ii. Patient has had improvements in paralysis attack symptoms with potassium intake; AND iii. Patient has tried and failed oral acetazolamide therapy (e.g., Diamox tablets, Diamox Sequels extended-release capsules, generics); AND iv. According to the prescribing physician, acetazolamide therapy did not worsen the paralytic attack frequency or severity in the patient; AND v. Keveyis is prescribed by or in consultation with a neurologist or a physician who specializes in the care of patients with primary periodic paralysis (e.g., muscle

Drug / Drug Class	Prior Authorization Criteria
	disease specialist, or Physical Medicine and Rehabilitation [PMNR]). PA expires after two months. Renewal Manual PA criteria: Keveyis is approved indefinitely for continuation of therapy if: **Hypo/Hyperkalemic Periodic Paralysis (HypoPP/HyperPP) and Related Variants** • Patients Continuing Therapy. Approve indefinitely if the patient has responded to Keveyis (e.g., decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician. Off-label uses are not approved.
• eluxadoline (Viberzi) **GI-2 Miscellaneous Drugs**	**Changes from May 2017 meeting are in BOLD** Manual PA criteria apply to all new users of eluxadoline (Viberzi). Manual PA criteria: Coverage will be approved if: • Initial prescription written by or in consultation with a gastroenterologist; AND • The patient is ≥ 18 years; AND • Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink ≤ 3 alcoholic beverages per day; AND • Patient has no history of marijuana use or illicit drug use in the previous 6 months; AND • **Patient does not have a history of cholecystectomy. AND** • Patient does not have severe hepatic impairment (Child-Pugh C); AND • Patient has a documented diagnosis of irritable bowel syndrome with diarrhea (IBS-D); AND o The patient has had failure, intolerance, or contraindication to at least one antispasmodic agent; e.g., dicyclomine (Bentyl), Librax, hyoscyamine (Levsin), Donnatal, loperamide (Imodium) AND o The patient has had failure, intolerance, or contraindication to at least one tricyclic antidepressant (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline AND o The patient has failed a trial of rifaximin Non-FDA approved uses are not approved. Prior authorization does not expire.
• pregabalin (Lyrica) **Antidepressants and Non-Opioid Pain Syndrome Agents**	**Changes from May 2017 meeting are in BOLD and will apply to new users of Lyrica.** Manual PA Criteria: coverage will be approved if: • Indication: Seizure disorder **and post-herpetic neuralgia** o The patient has a contraindication to gabapentin that is not expected to occur with pregabalin (Lyrica) o The patient experienced adverse events with gabapentin that are not expected to occur with Lyrica o The patient previously responded to Lyrica and changing to gabapentin would incur unacceptable risk OR • **Indication: Non-seizure related disorder (diabetic peripheral neuropathy and fibromyalgia)** o The patient has tried and failed gabapentin therapy (trial of Gralise or Horizant does not qualify) **AND** o **Patient has tried and failed duloxetine** OR o The patient has a contraindication to gabapentin or **duloxetine** that is not expected to occur with pregabalin OR

Drug / Drug Class	Prior Authorization Criteria
	o The patient experienced adverse events with gabapentin or **duloxetine** that are not expected to occur with pregabalin OR o The patient previously responded to pregabalin and changing to gabapentin or **duloxetine** would incur unacceptable risk PA does not expire.
• ledipasvir / sofosbuvir (Harvoni) **Hepatitis C Virus: Direct Acting Antivirals (HCV DAA)**	**Changes from May 2017 meeting are in BOLD** Coverage approved for patients **≥ 12 years** with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 4, 5, or 6 • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) HCV guidelines. PA expires after one year.
• sofosbuvir (Sovaldi) **Hepatitis C Virus: Direct Acting Antivirals (HCV DAA)**	**Changes from May 2017 meeting are in BOLD** <u>Manual PA criteria</u>: Ledipasvir / sofosbuvir (Harvoni) is the preferred HCV DAA; coverage is approved for sofosbuvir (Sovaldi) if : • Contraindications exist to Harvoni (advanced kidney disease [CrCl < 30 mL/min]) • The patient is likely to experience significant adverse reactions or drug-drug interactions to Harvoni that is NOT expected with the requested non step-preferred HCV DAA (e.g., concurrent high-dose PPI) • The patient has experienced or is likely to experience an inadequate response or therapeutic failure to Harvoni that is NOT expected with requested non step-preferred HCV DAA • There is no formulary alternative (e.g., Harvoni is not indicated for HCV GT2 or GT3) AND Coverage approved for patients **≥ 12 years** with: • A prescription written by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C o Document HCV RNA viral load • Has hepatitis C genotype 1, 2, 3, or 4 • Used in combination with another HCV DAA (not used as monotherapy) • Does not have advanced kidney disease (CrCl < 30 mL/min) Applies to new users only. Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) HCV guidelines. PA expires after one year.

Drug / Drug Class	Prior Authorization Criteria
• fluticasone/azelastine (Dymista) **Nasal Allergy Drugs**	**Changes from May 2017 meeting are in BOLD** Manual PA criteria apply to all new users of Dymista who are older than 4 years of age. Automated PA criteria: The patient has filled a prescription for azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Dymista is approved (e.g., trial of azelastine 137 mcg, flunisolide, fluticasone propionate, or ipratropium is NOT required) if: • Patient has experienced any of the following issues with **at least two** of the following step-preferred nasal allergy drugs (fluticasone propionate, flunisolide, azelastine 137 mg, or ipratropium), which is not expected to occur with the non-preferred nasal allergy drugs: o inadequate response to the step-preferred drugs o intolerable adverse effects (persistent epistaxis, significant nasal irritation, pharyngitis) o contraindication
• eszopiclone (Lunesta) and zolpidem ER (Ambien CR) **Newer Sedative Hypnotics**	**Changes from May 2017 meeting are in BOLD** Automated PA criteria: The patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria: Coverage is approved if: The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR, zaleplon, **zolpidem ER, or eszopiclone**. • Step-preferred agents include: zolpidem IR, zaleplon, zolpidem ER, and eszopiclone • Non step-preferred agents include: ramelteon (Rozerem), zolpidem SL (Edluar and Intermezzo), zolpidem spray (Zolpimist), doxepin (Silenor), suvorexant (Belsomra), and tasimelteon (Hetlioz) • Suvorexant (Belsomra) and tasimelteon (Hetlioz) have additional manual PA criteria PA applies to new users. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• mirabegron (Myrbetriq) **Overactive Bladder (OAB) Drugs**	**Changes from May 2017 meeting are in BOLD** Updated PA criteria apply to all new users of Myrbetriq <u>Automated PA criteria</u>: • The patient has filled a prescription for tolterodine ER (Detrol LA), oxybutynin ER, oxybutynin IR, or generic trospium IR (Sanctura) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. <u>Manual PA criteria</u>—If automated criteria are not met, Myrbetriq is approved if: 1. Patient has confirmed diagnosis of OAB with symptoms of urge incontinence, urgency, and urinary frequency **AND** 2. **Patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, AND** 3. Patient has had a 12-week trial with **2** formulary step-preferred products and had therapeutic failure **OR** 4. Patient has experienced central nervous system AEs with oral OAB medications **OR** is at increased risk for such central nervous system effects due to comorbid conditions or other medications, **AND** 5. **Patient does not have a CrCl < 15 mL/min OR** 6. **If CrCl 15-29 mL/min, dosage does not exceed 25 mg QD** PA does not expire.

Appendix D—Table of Quantity Limits

Drug / Drug Class	Quantity Limits
• pirfenidone (Esbriet) **Pulmonary 1-s Pulmonary Miscellaneous Subclass**	▪ Retail Network, Mail Order, and MTF: 267 mg caps, #270 capsules (30-day supply)
• nintedanib (Ofev) **Pulmonary 1-s Pulmonary Miscellaneous Subclass**	▪ Retail Network, Mail Order, and MTF: 100 and 150 mg capsules, #60 caps (30-day supply)
• Ribociclib (Kisqali) **Oral Oncologic Drugs**	▪ Retail: 28 days supply ▪ MTF/Mail: 56 days supply
• Panobinostat (Farydak) **Oral Oncologic Drugs**	▪ Retail: 6 capsules in 28 days ▪ MTF/Mail: 12 capsules in 56 days
• Niraparib (Zejula) **Oral Oncologic Drugs**	▪ Retail: 90 capsules in 30 days ▪ MTF/Mail: 180 capsules in 60 days
• Fluticasone/azelastine (Dymista) **Nasal Allergy Drugs**	▪ Retail: #1 inhaler in 30 days ▪ MTF/Mail: #3 inhalers in 90 days
• Dupilumab (Dupixent) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	▪ Retail: 28 days supply ▪ MTF/Mail: 56 days supply
• Crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Immune Modulators Subclass**	▪ Retail: 120gm (2 tubes) in 28 days ▪ MTF/Mail: 240gm (4 tubes) in 56 days

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

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Crisaborole (Eucrisa)	Corticosteroids – Immune Modulators – Immune Modulators Subclass	• Topical Steroids • Tacrolimus 0.3% ointment • Elidel 1% cream	Atopic Dermatitis (AD) – mild to moderate	• Unique mechanism of action (MOA): topical boron containing molecule that selectively inhibits PDE-4 in target cells • 2 short-term pivotal trials: 28-day & no active comparator – Slightly more patients achieved a response than placebo following short-term Rx (32.2% vs. 22.0%) – Relative efficacy compared with more established therapies is unknown • Eucrisa is a therapeutic alternative among the available topical therapies for mild-moderate AD, notably topical corticosteroids and topical calcineurin inhibitors	• NF • Add to mail list
Deflazacort (Emflaza)	Corticosteroids – Immune Modulators	• Prednisone	Duchenne muscular dystrophy (DMD) in patients 5 years of age and older	• Corticosteroid prodrug indicated for Duchenne muscular dystrophy in patients age 5 years and older • First oral agent approved for DMD • Dosing at 0.9 mg/kg/day showed statistical significance compared to prednisone at 52 weeks in improvement of muscle strength and motor function • Due to only slight increases in muscle strength over prednisone, clinical significance is unclear • Better tolerated and resulted in less weight gain and psychiatric AEs compared to prednisone • Two-fold higher risk of cataract development over 52-week period • First oral agent with DMD indication, but uncertain place in therapy; provides another option to patients with DMD over prednisone	• UF • Exempt from mail
Deutetra-benazine (Austedo)	Neurological Agents Miscellaneous	• tetrabenazine (Xenazine) • neuroleptics	Chorea associated with Huntington's disease (HD)	• Vesicular monoamine transporter 2 (VMAT2) inhibitor results in decreased reuptake and availability of dopamine, which reduces chorea; some serotonin and norepinephrine depletion • 1st "deuterated" product approved by FDA • Deuterium (heavy hydrogen isotope) substituted for two molecules; proposed to have a longer t ½ and have less variable plasma levels than tetrabenazine • 2nd drug FDA-approved for HD chorea • Do not use concurrently with tetrabenazine (Xenazine) • Only improves the motor dysfunction part of the disease • Likely similar efficacy as tetrabenazine, with decreased dosing frequency and AEs.	• UF • Exempt from mail

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Dupilumab (Dupixent)	Corticosteroids – Immune Modulators – Immune Modulators Subclass	• Topical Steroids • Tacrolimus 0.3% oint • Elidel 1% cream • Prednisone • Cyclosporine • Azathioprine • Methotrexate	Atopic Dermatitis (AD) – moderate to severe	• Unique MOA: IL-4RA monoclonal antibody inhibiting IL-4 & IL-13 • 3 pivotal trials: 16 to 52 weeks & no active comparator – More patients achieved a response than placebo (38% vs. 10%) – Relative efficacy compared with more established therapies is unknown • First SC agent approved for AD • Indicated for carefully selected adult patients with mod-severe AD who are inadequately treated with other modalities or pharmacologic therapies	• UF • Add to mail list
Insulin degludec/ liraglutide (Xultophy)	GLP1RA	• Bydureon • Tanzeum • Victoza • Lantus • Tresiba • Soliqua	Adjunct to diet and exercise in adults with T2DM not controlled on basal insulin ≤ 50 units daily or liraglutide ≤ 1.8 mg daily	• Xultophy is one of two available basal insulin/GLP1RA combinations • Statistically and clinically significant in lowering A1c compared to the individual components • Addition of liraglutide to insulin may mitigate the expected weight gain • Limitations to use: fixed dose, difficult to titrate insulin • Should not be used in treatment naïve patients; patients must be on one of the individual components separately first, before using the combination agent • Xultophy offers the patient convenience of a fixed-dose combination; however, there are no additional compelling advantages over existing UF agents	• NF and non step-preferred • Add to mail list
Morphine sulfate (Arymo ER)	Narcotic Analgesics & Combinations	• Morphine/naltrexone (Embeda) • Morphine ER (MS Contin)	Pain severe enough to require daily, around-the-clock, long-term opioid therapy and where alternative tx options are inadequate	• 2nd FDA approved abuse deterrent long-acting morphine formulation, and the first morphine product using a physical/chemical barrier • Clinical Practice Guidelines do not recommend for or against abuse deterrent agents • Several UF alternatives are available for individuals who need a long-acting narcotic analgesic	• NF • Exempt from mail
Oxymetaz-oline (Rhofade)	Acne Agents: Topical Acne and Rosacea Agents Subclass	• metronidazole (MetroGel, MetroCream, MetroLotion) • azelaic acid (Finacea) • brimonidine (Mirvaso)	Topical treatment of persistent facial erythema associated with rosacea in adults	• Topical oxymetazoline formulation for rosacea • Minimal improvement of persistent erythema over vehicle-arm, with significant cost • Step therapy exists in the topical acne/rosacea class; all patients must try step-preferred agent(s): metronidazole gel, cream or lotion • No compelling advantage over existing UF agents	• NF and non step-preferred • Add to mail list

Generic (Trade)	UF Class	Comparators	Indications	Place in Therapy	Recommended UF Status
Plecanatide (Trulance)	GI-2 Misc Agents	• Linaclotide (Linzess)	Chronic idiopathic constipation (CIC)	• 2nd available guanylate cyclase-C agonist indicated for chronic idiopathic constipation • Studied in 2 placebo controlled trials of 12 weeks duration • Response rate for plecanatide (21%) compared to placebo (10%) • Study limitations: significant placebo effect, lack of head-to-head trials, and unknown long-term safety • Similar efficacy and safety profile to linaclotide • May be taken without regard to food • Plecanatide has no compelling advantage over current formulary agents	• NF • Add to mail list
Ribociclib (Kisqali)	Oral Oncologic Agents	• Palbociclib (Ibrance)	Breast Cancer	• NCCN guidelines find Category 1 evidence to support use of ribociclib in combination with letrozole, similar to the available alternative, palbociclib (Ibrance) • While improvement in progression free survival (PFS) was shown in the pivotal study, extensive experience with palbociclib and lack of head-to-head data may limit utilization of ribociclib • Under investigation for additional breast cancer indications • 2nd CDK4/6 inhibitor option for HR+/HER2- endocrine-based therapy for advanced breast cancer, with similar safety profile	• UF • Exempt from mail
Telotristat (Xermelo)	GI-2 Misc Agents	• No similar agent	Carcinoid syndrome diarrhea	• Indicated for carcinoid syndrome diarrhea in adults • Approved for patients inadequately controlled on somatostatin analog (SSA) therapy alone • Novel MOA; inhibits tryptophan hydroxylase • Results from one phase III trial showed a decrease of 1.7 bowel movements (BM)/day over a 12-week period with telotristat compared to placebo (0.9 BM per day) • Response rate: 44% of pts with telotristat vs.20% of pts with placebo • Most common AEs: nausea, headache, & depression • Offers another option to patients with carcinoid syndrome diarrhea in users who are inadequately controlled on a somatostatin analog	• UF • Exempt from mail

Appendix F—Mail Order Status of Medications Designated Nonformulary During the May 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)
May 2017	**IPF Agents** ▪ pirfenidone (Esbriet) ▪ nintedanib (Ofev) **Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")** ▪ dupilumab (Dupixent) ▪ insulin degludec/liraglutide (Xultophy) ▪ oxymetazoline (Rhofade) ▪ crisaborole (Eucrisa) ▪ plecanatide (Trulance)	**Ophthalmic-1 Antihistamine/Mast Cell Stabilizers** Acute use exception applies ▪ alcaftadine (Lastacaft) ▪ bepotastine (Bepreve) ▪ emadastine (Emadine) ▪ olopatadine 0.2% (Pataday) **Newly-Approved Drugs per 32 CFR 199.21(g)(5) (formerly known as "Innovator Drugs")** Limited distribution exception applies ▪ deflazacort (Emflaza) ▪ deutetrabenazine (Austedo) ▪ telotristat (Xermelo) CII controlled substances exception applies ▪ morphine sulfate ER tablets (Arymo ER) ▪ addition of oral breast cancer agents such as ribociclib (Kisqali) to the EMMPI program should be considered at a future date

Appendix G—Pharmacy and Therapeutics Processes and Recommendations/Approval Authorities

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 Representative (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 Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits (QLs). The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to QLs 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 edit limitations (Pharmacy Data Transaction Service [PDTS]), 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. The PA criteria will be reviewed by the DoD P&T Committee at the next meeting. ▪ 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 PA 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, QLs 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. ▪ Designated drugs newly approved by the FDA after August 26, 2015, with no formulary alternatives to adjudicate as Uniform Formulary (Tier 2 copayment), 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 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 (EMMPI). ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Agreements Act (TAA) 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 Agreements Act 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 copayment 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. ▪ 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 forTPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA www.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.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of PA criteria, and implementation plan (including effective date). ▪ Changes to existing PA criteria (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the UF, and designating products recommended for a copayment waiver. ▪ Removal of copayments or reducing copayments for an individual drug (e.g., branded product available at the Tier 1 copayment). ▪ Designating individual generic drugs as nonformulary (Tier 3 copayment).

Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)	▪ Establishment of QLs for a medication or class of medications, deletion of existing QLs, or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs. ▪ Addition or deletion of medications listed on the BCF or ECF. ▪ Addition or deletion of drugs or drug classes on the Expanded MFT/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 2017	**Pulmonary-1 Agents – Pulmonary Miscellaneous Subclass**	UF subclass review	▪ Basic Core Formulary: No IPF drug selected Pulmonary-1 drugs on the BCF include ▪ salmeterol oral inhaler (Serevent) ▪ fluticasone oral inhaler (Flovent) ▪ salmeterol / fluticasone oral inhaler (Advair)	**UF Step-Preferred** ▪ pirfenidone (Esbriet) **UF Non Step-Preferred** ▪ nintedanib (Ofev)	▪ None	Pending signing of the minutes / 30 days The effective date is August 30, 2017	▪ Manual PA required ▪ QLs apply; 30-day supply	▪ Must try Esbriet first in all new users before Ofev See Appendix C.
May 2017	**Ophthalmic-1 – Antihistamine and Dual Acting Antihistamine/ Mast Cell (AH/MCS) Stabilizers Subclass**	UF subclass; previously reviewed August 2010	▪ olopatadine 0.1% (Patanol generic)	▪ olopatadine 0.7% (Pazeo) ▪ azelastine 0.05% (Optivar generic) ▪ epinastine 0.05% (Elestat generic)	▪alcaftadine 0.25% (Lastacaft) ▪bepotastine 1.5% (Bepreve) ▪emedastine 0.05% (Emadine) ▪olopatadine 0.2% (Pataday)	Pending signing of the minutes / 90 days The effective date is November 1, 2017.	▪ Manual PA applies to the subclass	▪ Note: Patanol moves to NF status, and Pazeo moves to UF status ▪ See Appendix C

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

Appendix I—Table of Abbreviations

AEs	adverse events
AH/MCS	antihistamine/mast cell stabilizers
BCF	Basic Core Formulary
BIA	budget impact analysis
CFR	Code of Federal Regulations
CMA	cost minimization analysis
CrCl	creatinine clearance
DAA	direct acting antiviral agent
DHA	Defense Health Agency
DMD	Duchenne muscular dystrophy
DoD	Department of Defense
DR	delayed release
ECF	Extended Core Formulary
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
ESRD	end stage renal disease
FVC	forced vital capacity
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GI	gastrointestinal
GLP1RA	glucagon-like peptide-1 receptor agonist
HCV	hepatitis C virus
HypoPP/HyperPP	hypo/hyperkalemic periodic paralysis
IPF	idiopathic pulmonary fibrosis drugs
IR	immediate release
MHS	Military Health System
MN	medical necessity
MTF	Military Treatment Facility
NCCN	National Comprehensive Cancer Network
NF	nonformulary
OAB	overactive bladder
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PPI	proton pump inhibitor
QLs	quantity limits
SSA	somatostatin analog
SR	sustained release
SU	sulfonylurea
T2DM	type 2 diabetes mellitus
TRT	testosterone replacement therapies
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs
XR	extended release