DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

November 2018

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 7 and 8, 2018, 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 August 2018 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the August 2018 DoD P&T Committee meeting on November 1, 2018.

2. **Clarification of Previous Minutes**

   a) **May 2018 Meeting—Pancreatic Enzyme Replacement Therapies (PERTs):** Pertzye is currently nonformulary. The implementation for Pertzye, requiring a trial of Creon first, will be delayed from November 7, 2018 to January 2, 2019.

   b) **May 2018 Meeting—Growth Stimulating Agents (GSAs):** The manual prior authorization (PA) criteria for the nonformulary, non-step-preferred GSAs were revised to only require a trial of Norditropin FlexPro first. See Appendix C for full criteria.

   c) **August 2018 Meeting—Implementation Dates**: Implementation for all items scheduled for two weeks after signing of the minutes has been delayed from November 21st to November 28th, due to the volume of changes. Affected actions include the atopic dermatitis PA update, the newly approved drugs formulary status and PAs, utilization management items, and line extensions.

   d) **August 2018 Meeting—Baricitinib (Olumiant) PA:** New manual PA criteria for Olumiant will apply to both new and current users, due to the safety concerns of thrombosis.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5).

All Uniform Formulary (UF) and Basic Core Formulary (BCF) recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

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

IV. UF DRUG CLASS REVIEWS

A. Gastrointestinal (GI)-2 Agents – Chronic Idiopathic Constipation (CIC) and Constipation-Predominant Irritable Bowel Syndrome (IBS-C) and GI-2 Agents – Miscellaneous Subclasses

Background—The P&T Committee evaluated the relative clinical effectiveness of the drugs used for chronic idiopathic constipation (CIC), constipation-predominant irritable bowel syndrome (IBS-C), and diarrhea-predominant irritable bowel syndrome (IBS-D). The products in the CIC/IBS-C subclass include linaclotide (Linzess), plecanatide (Trulance), and lubiprostone (Amitiza). The agents in the Miscellaneous subclass approved for IBS-D include rifaximin (Xifaxan) and eluxadoline (Viberzi).

The Committee reviewed new data available since the previous formulary decisions in 2011 and 2015. Use of rifaximin for hepatic encephalopathy or traveler's diarrhea and the other products in the Miscellaneous subclass were previously reviewed, and were not a focus of this analysis. Fidaxomicin (Dificid) and nitazoxanide (Alinia) have specific unique indications outside of CIC, IBS-C, and IBS-D and will remain on the formulary, as will the generic products, including alosetron, metronidazole, neomycin, and vancomycin. Tegaserod (Zelnorm) has been discontinued from the market.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) the following:

Guidelines

- Guidelines from the American College of Gastroenterology (ACG) were updated for IBS in 2018. The ACG continues to recommend tricyclic antidepressants (TCAs) as a strong recommendation with high quality evidence for treating pain in IBS.
- Guidelines from several other organizations, including the American Gastroenterological Association Institute (AGAI) (2014), the Canadian guidelines published in the Canadian Journal of Gastroenterology and Hepatology (2017), the National Institute for Health and Care Excellence (NICE), and the World Gastroenterology Organization (WGO) (2015) were reviewed for treatment recommendations and for guiding development of the PA criteria.

- Most constipation-related guidelines for IBS-C and CIC include use of fiber, dietary and lifestyle modification, TCAs, antidiarrheals, and laxatives. Antispasmodics remain an option and are included in several guidelines.
- Guidelines for IBS-D include TCAs and antispasmodics/antidiarrheals as key components of therapy. In the 2018 ACG guidelines, TCAs remained a strong recommendation based on high quality evidence, while antispasmodics have a weak recommendation, based on low quality evidence. Other guidelines give a higher recommendation for antispasmodics, based on cost-effectiveness.

CIC and IBS-C Summary

- Linaclotide, plecanatide, and lubiprostone have all shown improvement in treating the constipation symptoms associated with IBS-C and CIC, compared to placebo.
- Lubiprostone (Amitiza) is indicated for CIC; however, its indication for IBS-C is limited to women. It is also indicated for opioid-induced constipation (OIC).
- In a 2018 systematic review from the American Journal of Gastroenterology by Shah and colleagues, linaclotide and plecanatide demonstrated similar efficacy, safety, and adverse effects in treating IBS-C and CIC. Additionally, there was no statistically significant difference between linaclotide 72 mcg and 145 mcg compared to plecanatide 3 mg in terms of efficacy in CIC, occurrence of the adverse effect of diarrhea, or patient withdrawals from the study due to diarrhea.
- The difference in the incidence of diarrhea occurring with plecanatide versus linaclotide cannot be fairly compared because diarrhea was measured differently in the respective studies.

IBS-D Summary

- The ACG 2018 guidelines for IBS-D added eluxadoline as a weak recommendation with moderate quality evidence; this is the same recommendation as for rifaximin.
- FDA approval of rifaximin (Xifaxan) for IBS-D was based on the TARGET 3 trial, which found that rifaximin was modestly more effective than placebo in relieving IBS-D symptoms. Rifaximin appears to have a greater impact on reducing abdominal pain and has less impact on improving stool consistency.
    - Since the last formulary review, there are no new studies for IBS-D for rifaximin.
    - Rifaximin is only approved for a 14-day treatment course for IBS-D, allowing for retreatment up to two times if symptoms recur.
- Rifaximin is not systemically absorbed and is therefore well tolerated with few safety concerns.
- Rifaximin has many potential off-label uses for which there is little or no supporting clinical data.
    - Although there is one systematic review for rifaximin in small intestinal bacterial overgrowth (SIBO) that showed a bacterial eradication rate of 71%, the

results are limited by observational study design, significant heterogeneity of studies, and varied durations of therapy and administered doses.

  - Use of rifaximin in non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD) is limited due to small numbers of patients, varying doses and dosing regimens, and conflicting results.
  - At this time, unsupportable uses of rifaximin include SIBO, NASH, NAFLD, Crohn's disease, ulcerative colitis, diabetes, cirrhosis, Graft vs Host disease, primary sclerosing cholangitis, chronic abdominal pain, Celiac disease, bowel preparation for colonoscopy, constipation, colorectal cancer prevention, opioid-induced constipation, spontaneous bacterial peritonitis (SBP), and functional dyspepsia.

- Eluxadoline was evaluated in two placebo-controlled trials for IBS-D. Overall, eluxadoline appears to improve stool consistency and has less of an impact on relieving abdominal pain.
- A 2017 United Kingdom NICE technology appraisal of eluxadoline recommended its use only in refractory patients or those with contraindications to other treatments (e.g., antimotility agents, antispasmodics, or TCAs). Additionally, NICE recommends discontinuing eluxadoline if no response is seen after four weeks of therapy.
- The FDA issued a warning for eluxadoline in March 2017 to avoid use in patients who have had a cholecystectomy, due to an increased risk of pancreatitis and death.
- Eluxadoline limitations include numerous drug interactions and contraindications, lack of long-term safety data, and potential for abuse.

Overall Conclusion

- Studies with Linzess, Amitiza, and Trulance for IBS-C and CIC, and Xifaxan and Viberzi for IBS-D showed statistically significant results compared to placebo. However, for all the drugs, the clinical significance of the study results remains unclear, and all studies showed a significant placebo effect.
- At this time, comparative efficacy statements between the GI-2 drugs cannot be made, due to widely differing mechanisms of action, lack of head-to-head studies, lack of consistent diagnostic criteria, and variable subjective endpoints.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the GI-2 agents. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results for the CIC/IBS-C subclass showed that linaclotide (Linzess), lubiprostone (Amitiza), and plecanatide (Trulance) were all cost-effective agents.
- BIA was performed for the CIC/IBS-C subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating linaclotide (Linzess), lubiprostone (Amitiza), and plecanatide

(Trulance) as formulary demonstrated significant cost avoidance for the Military Health System (MHS).

- CMA results for the GI-2 Miscellaneous subclass showed that alosetron (Lotronex), eluxadoline (Viberzi), fidaxomicin (Dificid), nitazoxanide (Alinia), and rifaximin (Xifaxan) were all cost-effective agents.
- BIA was performed for the GI-2 Miscellaneous subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating alosetron (Lotronex, generics), eluxadoline (Viberzi), fidaxomicin (Dificid), nitazoxanide (Alinia), and rifaximin (Xifaxan) as formulary demonstrated significant 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 for the GI-2 agents, as outlined below, based on clinical and cost effectiveness:
    - UF

      CIC/IBS-C Subclass
        - linaclotide (Linzess)
        - lubiprostone (Amitiza)
        - plecanatide (Trulance)

      Miscellaneous Subclass
        - alosetron (Lotronex, generics)
        - eluxadoline (Viberzi)
        - rifaximin (Xifaxan)
        - nitazoxanide (Alinia)
        - fidaxomicin (Dificid)
        - vancomycin oral (generics)
        - neomycin (generics)
        - metronidazole (Flagyl, generics)
    - NF
        - None

      Note that vancomycin 25 and 50 mg oral solution (Firvanq) was reviewed as a new drug at the May 2018 meeting and will remain UF.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining metronidazole (250 mg and 500 mg) on the BCF. The Committee decided it is not in the best interest of the government to choose a CIC/IBS-C or IBS-D agent for BCF placement at this time based on cost effectiveness.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***— New manual PA criteria for lubiprostone (Amitiza) and linaclotide (Linzess) were recommended by the P&T Committee (16 for, 0 opposed, 0 abstained, 0 absent) for all new and current users, requiring a trial of drugs from at least two standard laxative classes first, unless contraindicated. Off-label use of Linzess for opioid-induced constipation (OIC) is allowed. The P&T Committee also recommended updating the current PA criteria for all new users of plecanatide (Trulance) to reflect the criteria for Amitiza and Linzess, with the exception that use of Trulance for OIC is not allowed.

   The Committee also recommended updating the current PAs for rifaximin (Xifaxan) and eluxadoline (Viberzi) to require a trial of lifestyle modifications including dietary fiber and stress reduction. Any non-FDA-approved use for rifaximin is not allowed. There were no changes recommended to the PA criteria for rifaximin for hepatic encephalopathy or traveler's diarrhea. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) changing the current QLs for rifaximin 550 mg (Xifaxan) to now allow three treatment courses for IBS-D in 365 days and 42 tablets per prescription fill. See Appendix D.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee agreed that branded agents in this class were suitable for the EMMPI program, with the exception of nitazoxanide (Alinia), Xifaxan 200 mg (the dose used for traveler's diarrhea), and fidaxomicin (Dificid). The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding lubiprostone (Amitiza), linaclotide (Linzess), plecanatide (Trulance), rifaximin 550 mg (Xifaxan) for hepatic encephalopathy and IBS-D, and eluxadoline (Viberzi) to the EMMPI program. See Appendix F.

2. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR THE GASTROINTESTINAL-2 DRUGS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) excluding lubiprostone (Amitiza), linaclotide (Linzess), plecanatide (Trulance), rifaximin (Xifaxan), and eluxadoline (Viberzi) from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy due to the symptomatic nature of CIC/IBS-C and IBS-D. Fidaxomicin (Dificid) and nitazoxanide (Alinia) were also excluded due to the short treatment courses for infectious diseases.

3. ***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 in all points of service, 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 May 15, 2019.

B. Neurological Agents Miscellaneous – Movement Disorders Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the Movement Disorder subclass, which includes the vesicular monoamine transporter type 2 (VMAT2) inhibitors. The drugs evaluated were tetrabenazine (Xenazine, generics), deutetrabenazine (Austedo), and valbenazine (Ingrezza). Tetrabenazine and deutetrabenazine are approved for treating Huntington's disease chorea, while both deutetrabenazine and valbenazine are indicated for tardive dyskinesia. Deutetrabenazine and valbenazine were previously reviewed as newly approved drugs in 2017, so the clinical review focused on clinical practice guidelines, meta-analyses, and systematic reviews.

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

Huntington's disease (HD) chorea

- Professional clinical practice guidelines from the American Academy of Neurology (AAN) in 2012 listed tetrabenazine as likely effective in decreasing chorea associated with Huntington's disease to a very important degree, based on level B evidence.
- There are no head-to-head trials comparing tetrabenazine with Austedo. However, a published indirect comparison concluded that tetrabenazine and deutetrabenazine (Austedo) do not differ in efficacy, based on low-quality evidence.
- With regard to safety, both tetrabenazine and deutetrabenazine (Austedo) carry a black box warning for increased depression and suicidality when used for Huntington's disease chorea.
- Common adverse effects associated with tetrabenazine include sedation, somnolence, insomnia, and depression. The package insert for Austedo lists fewer neuropsychiatric adverse effects than tetrabenazine.
- There is insufficient evidence to determine whether there is a clinically significant difference in safety between tetrabenazine and deutetrabenazine (Austedo), due to the lack of head-to-head trials and conflicting results from two published indirect comparisons that used the same data.

Tardive dyskinesia

- Guidelines from the AAN in 2016 graded tetrabenazine as having level C evidence that it reduces symptoms and may be considered in treating tardive dyskinesia. Based on level B evidence, clonazepam was considered probably effective in decreasing tardive

dyskinesia symptoms in the short-term, and ginkgo biloba extract was also probably useful, with the data limited to an inpatient population.

- A 2018 systematic review from the Journal of Neurological Science considered deutetrabenazine and valbenazine as effective for tardive dyskinesia, based on level A evidence. The authors also recommended that for patients who have no access to Austedo or Ingrezza, to consider tetrabenazine, despite the lesser evidence available than with clonazepam or ginkgo biloba.
- A report from the Institute for Clinical Effectiveness Research (ICER) found promising but inconclusive data for both deutetrabenazine (Austedo) and valbenazine (Ingrezza). Individual placebo-controlled trials with the two drugs reported statistically significant differences over placebo in measures on the Abnormal Involuntary Movement Scales (AIMS), but inconclusive results on both the Patients' and Clinicians' Global Impression of Change scores.
- There is insufficient evidence to determine whether there is a clinically relevant difference in efficacy between deutetrabenazine (Austedo) and valbenazine (Ingrezza) when used for tardive dyskinesia.
- Based on the ICER report, evidence for tetrabenazine for treating tardive dyskinesia symptoms suggests a possible benefit, but is rated as insufficient.
- In terms of safety, deutetrabenazine (Austedo) lacks a black box warning for depression and suicidality when used for treating symptoms of tardive dyskinesia. Both Austedo and Ingrezza report similar adverse events, including QTc interval prolongation.

Other factors

- There is a high degree of therapeutic interchangeability between tetrabenazine and deutetrabenazine (Austedo) for treating Huntington's disease chorea based on efficacy and safety.
- There is a high degree of therapeutic interchangeability between valbenazine (Ingrezza) and deutetrabenazine (Austedo) for treating tardive dyskinesia based on similar efficacy and safety.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the Movement Disorder agents. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that generic tetrabenazine was the most cost-effective Movement Disorder drug, followed by valbenazine (Ingrezza), deutetrabenazine (Austedo), and brand tetrabenazine (Xenazine).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating generic tetrabenazine, valbenazine (Ingrezza), and deutetrabenazine (Austedo) as formulary demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

    - UF
        - tetrabenazine
        - deutetrabenazine (Austedo)
        - valbenazine (Ingrezza)
    - NF
        - None

    Note that as part of this recommendation, a movement disorder drug was not added to the BCF or extended core formulary (ECF) due to the very limited treatment population and varied FDA indications between the drugs in the class.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Manual PA criteria have been in place for both Austedo and Ingrezza since they were reviewed as new drugs in 2017. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to manual PA criteria for deutetrabenazine (Austedo) and valbenazine (Ingrezza) in new users. PA was not recommended for generic tetrabenazine.

    For Huntington's disease chorea, the PA for Austedo will still require a trial of generic tetrabenazine first, based on the AAN guidelines and cost-effectiveness. For both Austedo and Ingrezza for tardive dyskinesia, updates to the PA included adding the package insert warning for QTc prolongation; removing the requirement for a trial of gingko biloba and clonazepam, based on the clinical practice guidelines; and adding renewal PA criteria after one year showing efficacy and continued evaluation of the patient for depression and suicidality. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) quantity limits for deutetrabenazine (Austedo) and valbenazine (Ingrezza) allowing a 30-day supply at all points of service. See Appendix D.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 0 absent) that the VMAT2 inhibitors not be added to the EMMPI program/Select Maintenance List, due to limited distribution requirements and flat pricing across points of service.

5. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR THE MOVEMENT DISORDER DRUGS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) excluding the VMAT2 drugs from the Auto-Refill program administered by

Express Scripts, Inc.at the TRICARE Mail Order due to the limited distribution requirements.

6. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—*** The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is March 6, 2019.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (15 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the November 2018 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
    - cannabidiol oral solution (Epidiolex) – Anticonvulsants-Antimania Agent for Lennox-Gastaut Syndrome or Dravet Syndrome
    - dacomitinib (Vizimpro) – Oncological Agent for Non-Small Cell Lung Cancer (NSCLC)
    - darunavir/cobicistat/emtricitabine/tenofovir alafenamide (TAF) (Symtuza) – Combination Antiretroviral for HIV
    - darunavir/lamivudine/tenofovir disoproxil fumarate (TDF) (Delstrigo) – Combination Antiretroviral for HIV
    - doravirine (Pifeltro) – Antiretroviral for HIV
    - duvelisib (Copiktra) – Oncological Agent for Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
    - fremanezumab-vfrm injection (Ajovy) – Migraine Agent (calcitonin gene-related peptide [CGRP]) for Migraine Headache Prophylaxis
    - galcanezumab-gnlm injection (Emgality) – Migraine Agent (calcitonin gene-related peptide [CGRP]) for Migraine Headache Prophylaxis
    - glycopyrronium 2.4% topical cloth (Qbrexza) – Antiperspirant for Primary Axillary Hyperhidrosis
    - ivosidenib (Tibsovo) – Oncological Agent for Acute Myelogenous Leukemia (AML)

- lanadelumab (Takhzyro) injection – Corticosteroid-Immune Modulator for Hereditary Angioedema (HAE) Prophylaxis
- lumacaftor/ivacaftor granules (Orkambi) – Cystic Fibrosis Agent
- lusutrombopag (Mulpleta) – Hematologic Agent: Platelets for Thrombocytopenia in Chronic Liver Disease
- metoprolol extended-release (ER) capsules (Kapspargo Sprinkle) – Beta-Blocker
- migalastat (Galafold) – Miscellaneous Metabolic Agent for Fabry Disease
- PEG3350/Na ascorbate/NaSO4/ascorbic acid/NaCl/KCl powder packets (Plenvu) – Laxatives-Cathartics-Stool Softener for Bowel Prep
- pegfilgrastim-jmdb injection (Fulphila) – Hematologic Agent: White Blood Cell Stimulant
- PEGylated Factor VIII (Jivi) – Antihemophilic Factor
- sodium zirconium cyclosilicate packet for oral suspension (Lokelma) – Binders Chelators Overdose Agents Hyperkalemia

- NF:
  - adapalene 0.1% topical solution (external pad/swab) (Plixda) – Topical Acne Agent
  - adapalene 0.1% topical solution – Topical Acne Agent
  - amikacin liposome inhaled suspension (Arikayce) – Aminoglycoside Antibiotic for Mycobacterium Avium Complex (MAC)
  - butalbital 50 mg and acetaminophen 300 mg capsules – Analgesics and Combinations
  - doxycycline monohydrate ER capsules (Okebo) – Oral Tetracycline Agent
  - elagolix (Orilissa) – Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists for Endometriosis
  - filgrastim-aafi injection (Nivestym) – Hematologic Agent: White Blood Cell Stimulant
  - lidocaine 1.8% topical patch (ZTlido) – Topical Pain Agent
  - minocycline ER tablets (Minolira) – Oral Tetracycline Agent
  - ozenoxacin 1% cream (Xepi) – Quinolone Antibiotic for Impetigo
  - tildrakizumab-asmn injection (Ilumya) – Targeted Immunomodulatory Biologic (TIB) for Plaque Psoriasis
  - tretinoin 0.05% topical lotion (Altreno) – Topical Acne Agent

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for adapalene 0.1% topical solution, Altreno, Arikayce, butalbital 50 mg/acetaminophen 300 mg capsule, Ilumya, Minolira, Nivestym, Okebo, Orilissa, Plixda, Xepi, and ZTlido. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- TIBS: Applying the same manual PA criteria for Ilumya in new users, as is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Ilumya, a trial of both secukinumab (Cosentyx) and ustekinumab (Stelara) is required if the patient cannot be treated with Humira.
- Topical Acne Agents: Applying the same manual PA criteria for adapalene topical solution, adapalene 0.1% external swab/pad (Plixda), and tretinoin 0.05% topical lotion (Altreno) in new and current users as is currently in place for the other non-step-preferred topical retinoid acne agents. Patients must first try at least three step-preferred topical acne products.
- Oral Tetracycline Agents: Applying the same manual PA criteria for doxycycline monohydrate capsules (Okebo) and minocycline ER 105 mg and 135 mg tablets (Minolira) that is currently in place for the other non-step-preferred oral tetracyclines. Patients must first try one generic doxycycline IR product, either the hyclate or monohydrate salt (for Okebo), or one generic minocycline IR product (for Minolira).
- CGRPs for Migraine Headache Prophylaxis: Applying manual PA criteria to new users of Ajovy and Emgality as is currently in place for erenumab injection (Aimovig).
- Cystic Fibrosis Agents: Applying manual PA criteria to new users of Orkambi granules as is currently in place for Orkambi tablets to include the FDA-approved age range, and to not allow concomitant use of the tablets and granules or concomitant use of Orkambi with other CF drugs, including Kalydeco or Symdeko.
- Applying manual PA criteria to new users of Arikayce, Copiktra, Epidiolex, Kapspargo Sprinkle, Mulpleta, Takhzyro, Tibsovo, Vizimpro, and Xepi.
- Applying manual PA criteria to new and current users of butalbital 50 mg/acetaminophen 300 mg capsule, Galafold, Orilissa, Qbrexza, and ZTlido.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday 30 days after signing of the minutes in all points of service.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

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

   a) **Basal Insulins: Insulin degludec (Tresiba)—**The basal insulin drug class was reviewed for formulary placement in August 2017. Insulin glargine (Lantus) is now the step-preferred basal insulin and is required before use of other products. Insulin glargine 300 U/mL (Toujeo) is UF and non-step-preferred. Insulin degludec (Tresiba) is NF and non-step-preferred. The PA and MN criteria for new users of Tresiba were updated to encourage use of the formulary cost-effective basal insulins, prior to use of non-formulary less cost-effective agents.

   b) **Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass: dupilumab injection (Dupixent)—**Dupixent was most recently reviewed for formulary placement at the August 2018 DoD P&T Committee meeting. Manual PA criteria have been in place since May 2017. In October 2018, The FDA granted Dupixent an additional indication as maintenance treatment in patients with moderate to severe asthma aged 12 years and older. The PA criteria were updated to match the additional FDA indication.

   c) **Anti-Gout Drugs: Febuxostat (Uloric)**—Manual PA criteria were previously recommended for febuxostat at the May 2013 P&T Committee meeting. Results from the recent CARES Trial, a large cardiovascular (CV) outcomes trial in patients with gout at risk for major CV events, showed an increased risk for a secondary endpoint of cardiovascular death for febuxostat compared to allopurinol. The primary endpoint for the study (a composite of the first occurrence of CV death, nonfatal myocardial infarction, or need for urgent revascularization) showed no difference between febuxostat and allopurinol. The febuxostat PA criteria were updated to ensure that patients and providers are aware of the results of the trial.

   d) **Antipsychotic Agents – Atypical: pimavanserin (Nuplazid)—**Nuplazid was reviewed as a new drug in August 2016 with PA criteria due to safety concerns of the black box warning of the increased risk of death in elderly patients with dementia-related psychosis. The FDA recently raised a new safety concern associating pimavanserin with increased mortality and serious adverse drug events when used in combination with antipsychotics or other QT-prolonging agents. The P&T Committee updated the Nuplazid PA criteria to include these new safety concerns.

   e) **Antihemophilic Factors: emicizumab-kxwh (Hemlibra)—**Hemlibra was reviewed as a new drug in February 2018 with manual PA criteria

recommended. In October 2018, the FDA approved Hemlibra in newborns and expanded the treatment population to patients with or without factor VIII inhibitors. The PA criteria were updated to match FDA indications.

f) **Targeted Immunomodulatory Biologics (TIBs)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Since then, several new products have entered the market, and there are now 17 TIBs available. The P&T Committee reviewed the PA criteria, the step therapy, and MN forms for all the products to ensure they were updated with current or additional FDA-approved indications, safety warnings, and similar formatting.

1. ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA—***The P&T Committee recommended the following: (See Appendix C for the full criteria.)

   - (15 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Tresiba, Uloric, Nuplazid, and Hemlibra; updates to the manual PA criteria and step therapy for the TIBs; and also recommended updates to the MN criteria for Tresiba, Taltz, and Siliq.
   - (14 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Dupixent.

2. New Manual PA Criteria

a) **Pain Agents—Non-steroidal Anti-inflammatory Drugs (NSAIDs): diclofenac potassium liquid filled capsules (Zipsor), diclofenac submicronized (Zorvolex), indomethacin submicronized (Tivorbex), naproxen CR (controlled-release) (Naprelan/generics), meloxicam submicronized (Vivlodex)**

The NSAIDs were reviewed for UF placement in August 2011, with several generic products designated as UF, including naproxen, diclofenac potassium, diclofenac sodium, indomethacin, and meloxicam. Zipsor, Zorvolex, Tivorbex, and Naprelan are branded products that contain the same active ingredients and have the same indications as the generic UF NSAIDs. These branded products lack data showing improved efficacy or safety over the generic NSAIDs and are not cost-effective. Cost-effective generic formulations of naproxen and several other NSAIDs are available on the UF without PA required.

1. ***COMMITTEE ACTION: DICLOFENAC POTASSIUM LIQUID-FILLED CAPSULES (ZIPSOR), DICLOFENAC SUBMICRONIZED (ZORVOLEX), INDOMETHACIN SUBMICRONIZED (TIVORBEX), NAPROXEN CR (NAPRELAN/GENERICS), MELOXICAM SUBMICRONIZED (VIVLODEX) MANUAL PA CRITERIA***—The

P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Zipsor, Zorvolex, Tivorbex, Naprelan and naproxen CR generics and Vivlodex due to the significant cost differences and lack of clinically compelling benefits between these products and generic NSAIDs. New and current users of Zipsor, Zorvolex, Tivorbex, Naprelan CR, and Vivlodex are required to try four formulary generic NSAIDs, three of which must include BCF agents, first. See Appendix C for the full criteria.

b) **Skeletal Muscle Relaxants and Combinations: chlorzoxazone 250 mg tablets**

Generic formulations of the skeletal muscle relaxant chlorzoxazone are available in 250 mg tablets and 500 mg scored tablets. Chlorzoxazone 250 mg tablets are from a single source, while several manufacturers produce the 500 mg tablets. Skeletal muscle relaxants are not considered first-line therapy for musculoskeletal conditions. Cost-effective generic formulations of chlorzoxazone and multiple comparable muscle relaxants (e.g., cyclobenzaprine, methocarbamol) are available on the UF without PA required.

1. ***COMMITTEE ACTION: CHLORZOXAZONE 250 MG MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of the single-source chlorzoxazone 250 mg tablets, due to the significant cost differences and lack of clinically compelling benefits compared with administering half of a 500 mg tablet or using other generic muscle relaxants. See Appendix C for the full criteria.

c) **Oncological Agents for unresectable or metastatic melanoma: cobimetinib (Cotellic)**

Cobimetinib (Cotellic) was approved for treating unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. It is used exclusively in combinations of a specific BRAF drug with a specific mitogen-activated extracellular signal regulated kinase (MEK) inhibitor, vemurafenib (Zelboraf). Due to the risk of enhanced toxicity if other combinations of BRAF with MEK inhibitors are administered together, the PA criteria were updated to prevent the use of concurrent therapies outside of the FDA-approved combination.

1. ***COMMITTEE ACTION: COTELLIC MANUAL PA CRITERIA***— The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria in new users of Cotellic to ensure it is used only in combination with vemurafenib (Zelboraf). See Appendix C for the full criteria.

d) **Anti-infectives: Miscellaneous: crotamiton 10% lotion (Eurax and Crotan)**

The committee reviewed two treatments for scabies, Eurax and Crotan, which are both crotamiton 10% generic lotions, and are approved for patients 18 years and older. According to the Centers for Disease Control and Prevention (CDC), first-line treatment for scabies remains permethrin 5% cream. Permethrin 5% cream is indicated for patients 2 months and older and has a lower failure rate than crotamiton. Cost-effective generic formulations of permethrin cream and oral scabies agents (e.g., ivermectin) are available on the UF without a PA required.

2. ***COMMITTEE ACTION: CROTAMITON 10% LOTION (EURAX AND CROTAN) MANUAL PA CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Eurax and Crotan due to concern regarding the limited age range and higher treatment failure rate of these two products, compared to permethrin 5% cream. New users of Crotan or Eurax must document therapeutic failure of permethrin 5% cream first. See Appendix C for the full criteria.

B. QLs

QLs were reviewed for nine drugs from drug classes where there are existing QLs, including the oncological agents and TIBs. QLs were also discussed for 21 drugs where QLs are not currently in place, including one adjustment to a recently implemented QL for Aimovig to align the CGRP class.

1. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) QLs for Aimovig, Ajovy, Arikayce, butalbital and acetaminophen capsules, Copiktra, Emgality, Epidiolex, Fulphila, Galafold, Ilumya, Kalydeco, Mulpleta, Orkambi, Sprix, Symdeko, Takhzyro, Tibsovo, the transmucosal immediate release fentanyl (TIRF) products, Vizimpro, and Xepi. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

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

   - (15 for, 0 opposed, 0 abstained, 1 absent) New PAs for Zipsor, Zorvolex, Tivorbex, Vivlodex, Naprelan and naproxen CR generics, chlorzoxazone 250 mg, Cotellic, and Eurax and Crotan become effective 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for the NSAIDs and chlorzoxazone 250 mg, as new and current users will be subject to the PA.
   - (15 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria for Tresiba, Uloric, Nuplazid, and Hemlibra; updates to the manual PA criteria and step therapy for the TIBs (Humira, Enbrel, Cimzia, Simponi, Xeljanz/Xeljanz

XR, Orencia, Actemra, Kevzara, Kineret, Stelara, Otezla, Cosentyx, Siliq, Taltz, Tremfya, and Olumiant); and also updates to the MN criteria for Tresiba, Taltz, and Siliq become effective 30 days after the signing of the minutes.

- (14 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA for Dupixent become effective 30 days after the signing of the minutes.
- (15 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 21 drugs listed in section VI, B, above, and in Appendix D, become effective on the first Wednesday two weeks after the signing of the minutes in all POS.

VII. REMOVAL OF BRAND OVER GENERIC AUTHORITY AND BRAND OVER GENERIC PA CRITERIA AUTHORIZATION FOR SILDENAFIL TABLETS (VIAGRA)

TRICARE policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, when AB-rated generic formulations for sildenafil (Viagra) were launched in December 2017, pricing for the branded product was significantly lower than the generic formulations. The manufacturer of Viagra offered a Distribution and Pricing Agreement (DAPA) and on January 24, 2018, brand over generic authority was implemented, which allowed for the continued dispensing of the branded product, and required prior authorization prior to dispensing a generic product instead of the brand. Additionally, at that time, the Tier 1 (generic) copayment was assigned to the branded product. PA criteria allowing a patient to receive generic sildenafil instead of branded Viagra (i.e., the reverse of the current brand to generic policy) were also recommended. The Committee was notified of these actions at the February 2018 DoD P&T Committee meeting.

In May 2016, the P&T Committee recommended the DHA Pharmacy Operations Division (POD) be given authority, after consulting with the Chair of the P&T Committee, to implement "brand over generic" authorization for drugs with recent generic entrants where the branded product is more cost-effective than generic formulations. Authority was also given to the POD to remove the "brand over generic" requirement when it is no longer cost-effective to the MHS.

As of September 2018, the AB-rated generic formulations for sildenafil (Viagra) are cost-effective compared to the branded Viagra product. On September 20, 2018, the brand over generic requirement was removed for sildenafil. Current PA requirements for the PDE-5 inhibitor class are still in effect.

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

See Appendix F for the mail order status of medications designated NF during the Nov 2018 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the non-formulary to mail requirement. The implementation date for all EMMPI

recommendations from the Nov 2018 meeting, including the newly approved drugs affected by the EMMPI, will be effective upon the first Wednesday two weeks after the signing of the minutes.

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

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

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent):

a) **Add**: none

b) **Do Not Add:**

1. *Agents that are effectively flat-priced across points of service:* the migraine prophylaxis agents fremanezumab-vfrm (Ajovy) and galcanezumab-gnlm (Emgality), the white blood cell stimulant pegfilgrastim-jmdb (Fulphila), glycopyrronium topical cloths (Qbrexza) for axillary hyperhidrosis, metoprolol succinate ER capsules (Kapspargo Sprinkle), sodium zirconium cyclosilicate (Lokelma) for hyperkalemia, and lumacaftor/ivacaftor oral granules (Orkambi granules) for cystic fibrosis.
2. *Not yet clear if feasible to provide through mail order:* cannabidiol (Epidiolex) for Lennox-Gastaut and Dravet syndromes; migalastat (Galafold) for Fabry disease; dacomitinib (Vizimpro) for non-small cell lung cancer; duvelisib (Copiktra) for relapsed or refractory chronic lymphocytic leukemia and small lymphocytic lymphoma; ivosidenib (Tibsovo) for relapsed or refractory acute myeloid leukemia with a susceptible IDH1 mutation; antihemophilic factor (recombinant), PEGylated-aucl (Jivi) for Hemophilia A; and lanadelumab-flyo (Takhzyro) for hereditary angioedema prophylaxis.
3. *Agents for acute or limited duration use:* PEG3350/Na ascorbate/NaSO4/ascorbic acid/NaCl/KCl powder packets (Plenvu), a single-use bowel prep agent and lusutrombopag (Mulpleta) as a 7-day pre-procedure regimen for patients with thrombocytopenia associated with liver disease.
4. *Agents in classes specifically not included on the Select Maintenance List:* three agents for HIV: darunavir ethanolate/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza), doravirine (Pifeltro), and doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo).

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

The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent):

a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: elagolix (Orilissa) for endometriosis pain, the white blood cell stimulant filgrastim-aafi (Nivestym), tildrakizumab-asmn (Ilumya) for plaque psoriasis, lidocaine 1.8% topical patch (ZTlido) for postherpetic neuralgia, and the following five acne agents: adapalene 0.1% topical solution swab (Plixda), adapalene 0.1% topical solution, tretinoin 0.05% topical lotion (Altreno), doxycycline monohydrate ER 50-, 75-, and 100-mg capsules (Okebo), and minocycline 105- and 135-mg ER tablets (Minolira).

b) **Do Not Add:** The P&T Committee recommended exceptions from the mail order requirement for the following medications: ozenoxacin 1% cream (Xepi), a topical antibiotic used as a 5-day course for impetigo and butalbital 50 mg/acetaminophen 300 mg capsule for headache, due to the existing exception for acute use medications. In addition, the P&T Committee recommended not adding amikacin liposome suspension for inhalation (Arikayce), for treatment of *Mycobacterium avium* complex lung disease, pending more information about availability of this product at mail order.

IX. RE-EVALUATION OF NF GENERICS

A. ADHD/Wakefulness: Stimulants Subclass

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The P&T Committee's process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, TMA, on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes.

Attention Deficit Hyperactivity Disorder (ADHD)/wakefulness promoting agents drug class: dexmethylphenidate ER (Focalin XR)—The P&T Committee reviewed the current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per unit, for generic dexmethylphenidate ER (Focalin XR). Currently, the drug has been designated NF since the original ADHD class review in February 2007 and reaffirmed at the most recent class review status in November 2015. The unit cost of generic formulations of dexmethylphenidate ER has dropped significantly from the previous generic and brand cost.

1. ***COMMITTEE ACTION: DEXMETHYLPHENIDATE ER FORMULARY STATUS AND IMPLEMENTATION—***The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 3 absent) returning dexmethylphenidate ER to formulary status, effective the first Wednesday two weeks after the signing of the minutes.

X. DRUGS LOSING RX STATUS AND MOVING TO OTC STATUS (VITAMIN B REPLACEMENT PRODUCTS, IRON REPLACEMENT PRODUCTS, AND URINARY pH MODIFIERS)

The P&T Committee discussed a list containing 387 National Drug Codes (NDCs) that the First DataBank (FDB) drug database will transition from designation as prescription legend products to non-prescription products as of 1 January 2019. This list comprises a subset of products changing status in FDB that was initially discussed by the P&T Committee in August 2017. The original implementation date of January 2018 was delayed by litigation, which has now been resolved for the current list of agents. The list does not include prenatal vitamins, which remain under litigation. None of the products on the list have been approved by the FDA.

The change in status means that, with the exception of pediatric fluoride products, as of January 1, 2019, products on this list will no longer adjudicate as covered products through the Pharmacy Data Transaction Service (PDTS) at mail, retail, or MTF sites where the new electronic health record system (MHS GENESIS) has been implemented. The most commonly dispensed categories on the list include vitamin B preparations (various combinations of vitamin B complex and folic acid, along with vitamins D3, C, biotin, zinc, selenium, etc.), iron replacement products (various combinations of iron with folic acid, along with vitamins C, B, B12, calcium, zinc, biotin, docusate sodium, etc.), and urinary pH modifiers (e.g., sodium and/or potassium citrate with citric acid).

The P&T Committee noted that 1) folic acid 1 mg as a stand-alone product will remain a prescription product; 2) the more commonly used iron replacement products without folic acid (e.g., ferrous sulfate, ferrous gluconate) are already OTC and therefore not covered at retail or mail order; both are on the current MHS GENESIS OTC list; 3) an FDA-approved urinary pH modifier (potassium citrate, Urocit-K and generics) will remain available as a prescription product; and 4) various vitamin B preparations and multivitamin combinations are widely available at low cost as non-prescription products.

The P&T Committee agreed that none of these products are suitable for inclusion on the OTC TRICARE pharmacy benefit for coverage across all points of service, considering their non-FDA-approved status and the ready availability of either prescription alternatives or low-cost non-prescription products. The change will affect beneficiaries across all points of service. Letters are being prepared for delivery to affected beneficiaries.

The P&T Committee considered utilization of the various product categories at MHS GENESIS sites and recommended addition of one product to the MHS GENESIS OTC list: B complex w-C no. 20/folic acid (GSN 033515; e.g., Nephrocaps). A total of 98 prescriptions were filled by MHS GENESIS sites for this product during fourth quarter FY 2018; most of the remaining 420 GENESIS site prescriptions for products on this list were for fluoride products, which remain covered. The P&T Committee noted that further review of products included on the MHS GENESIS OTC list would occur at upcoming meetings.

1. ***COMMITTEE ACTION: PRODUCTS LOSING PRESCRIPTION STATUS IN FIRST DATABANK RECOMMENDATION***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) the

following, effective upon signing of the minutes: adding B complex w-C no. 20/folic acid (GSN 033515; e.g., Nephrocaps) to the MHS GENESIS OTC list.

XI. TRICARE MAIL ORDER AUTO-REFILL REQUIREMENTS FOR SELF-MONITORING BLOOD GLUCOSE SYSTEMS (SMBGS) TEST STRIPS AND LANCETS

Background—The Committee was briefed on the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, including opt-in requirements, alert notifications, and auto-refill logic. The SMBGS test strips are in the top ten list of drugs that individual patients request for removal from the program.

The SMBGS test strips were reviewed for formulary status at the November 2014 DoD P&T Committee meeting. The Precision Xtra and FreeStyle Lite test strips are BCF and step-preferred, with all other test strips NF and non-step-preferred. Quantity limits are currently in place. Lancets have not been reviewed for formulary status, but are part of the TRICARE pharmacy benefit, and all popular brands of lancets are available at the TRICARE Mail Order Pharmacy. Mail Order and MTF utilization and refill date trends for the test strips were presented.

A. ***COMMITTEE ACTION: SMBGS TEST STRIPS AND LANCETS AUTO-REFILL PROGRAM RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the SMBGS test strips and lancets from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy. Reasons for removing the test strips and lancets include the large volume of patient requests for removal; the fact that both test strips and lancets are widely available OTC; the current QLs exceed typical usage patterns; overrides are available for clinical reasons; and to reduce the potential for wastage, as the test strips do expire. Beneficiary outreach will occur via letters.

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

The P&T Committee reviewed two drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were 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 be exempt from movement to the Mail Order POS due to the potential for acute use; and will remain available at the Retail POS with pre-authorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) that the Section 703 non-compliant NDCs of the following products be designated NF on the UF:

- Genericus, Inc.: tobramycin inhalation solution pak (*New Drug Application-authorized generic; NDC 70644-0899-99*) 300 mg/5 mL ampule-nebulizer
- Genus Lifesciences Pharma: oxycodone hydrochloride solution (*New Drug Application; NDC 64950-0354-50*) 5 mg/5 mL oral solution

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs of tobramycin inhalation solution pak and oxycodone hydrochloride solution:

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.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for the Section 703 non-compliant NDCs of tobramycin inhalation solution pak and oxycodone hydrochloride solution, and 2) DHA send letters to beneficiaries affected by this decision.

XIII. ITEMS FOR INFORMATION

A. MHS Prescribing and Cost Trends

The Committee was briefed on various aspects of MHS prescribing and cost trends, including overall trends and spends, specialty spend, top 25 drug classes, and cost avoidance from previously conducted drug class reviews.

XIV. ADJOURNMENT

The meeting adjourned at 1500 hours on November 8, 2018. The next meeting will be in February 2019.

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

1 FEB 2019
Date

Appendix A—Attendance: November 2018 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner for Mr. David Bobb	Chief, DHA Pharmacy Operations Branch
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MC	Army, Pharmacy Officer
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Shaun Carstairs, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Lt Col Lisa Seltman for Col Melissa Howard	Air Force, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Kelly Echevarria, PharmD for Jennifer Zacher, PharmD	Department of Veterans Affairs
COL Clayton Simon MC	TRICARE Regional Office Representative
Voting Members Absent	
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
LCDR Danielle Barnes, MC	Navy, Pediatrics Rep
Nonvoting Members Present	
Mr. Brian Wheeler	DHA, Deputy General Counsel
Eugene Moore, PharmD, BCPS for Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Ms. Kimberlymae Wood	DHA Contract Operations Division
Maj Kevin Bourne, MSC	DLA Troop Support
Ms. Catherine Gilbert	DLA Troop Support
Geannette Green	University of Texas at Austin/University of Texas Health Science Center PharmD Student

Appendix A—Attendance (continued)

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

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• adapalene 0.1% topical solution • adapalene 0.1% topical solution pad (Plixda) **Acne Agents: Topical Acne and Rosacea**	• Patient has tried and failed or experienced significant adverse effects from at least three formulary agents, including adapalene 0.1% and two different strengths of tretinoin **Formulary Alternatives:** adapalene (cream, gel, lotion), tretinoin (cream, gel, liquid/solution), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel
• amikacin liposome inhalation suspension (Arikayce) **Antibiotics: Aminoglycosides**	• Formulary agents have resulted in therapeutic failure • Use of formulary agents is contraindicated **Formulary Alternatives:** IV amikacin
• butalbital 50 mg/acetaminophen 300 mg capsule **Analgesics and Combinations**	• No alternative formulary agent: Patient requires capsule over tablet **Formulary Alternatives:** butalbital/APAP tablet, butalbital/APAP/caffeine tablet/capsule
• doxycycline monohydrate ER (Okebo) **Antibiotics: Tetracyclines**	• Patient has experienced significant adverse effects from formulary agents – e.g., Gastrointestinal adverse events from generic doxycycline IR AND generic minocycline products **Formulary Alternatives:** Doxycycline IR 50 mg or 100 mg, minocycline IR 50 mg or 100 mg
• elagolix (Orilissa) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists/Antagonists**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** leuprolide (Lupron Depot) intramuscular kit, nafarelin (Synarel) nasal solution
• filgrastim-aafi (Nivestym) injection **Hematological Agents: White Blood Cell Stimulants**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk • **Formulary Alternatives:** Granix, Zarxio, Neupogen
• lidocaine 1.8% patch (ZTlido) **Pain Agents: Pain Topical**	• Formulary agent has resulted in therapeutic failure **Formulary Alternatives:** lidocaine 5% patch (Lidoderm)
• minocycline ER (Minolira) **Antibiotics: Tetracyclines**	• The patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic minocycline immediate release products **Formulary Alternatives:** minocycline IR 50 mg or 100 mg

Drug / Drug Class	Medical Necessity Criteria
• Ozenoxacin 1% cream (Xepi) **Antibiotics: Quinolones**	• Use of formulary agents is contraindicated **Formulary Alternatives:** mupirocin 2% cream or ointment, cephalexin PO, dicloxacillin PO, clindamycin PO
• tildrakizumab (Ilumya) injection **Targeted Immunomodulatory Biologics (TIBs)**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** Humira (BCF), Cosentyx, Stelara
• tretinoin 0.05% topical lotion (Altreno) **Acne Agents: Topical Acne and Rosacea**	• Patient has tried and failed or experienced significant adverse effects from at least three formulary agents, including two different strengths of tretinoin **Formulary Alternatives:** adapalene (cream, gel, lotion), tretinoin (cream, gel, liquid/solution), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel
• guselkumab (Tremfya) injection **Targeted Immunomodulatory Biologics (TIBs)**	**November 2018 updates are in BOLD** • Use of adalimumab (Humira) **and secukinumab (Cosentyx)** are contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) **and secukinumab (Cosentyx)** • Adalimumab (Humira) **and secukinumab (Cosentyx)** have resulted in therapeutic failure **Formulary Alternatives:** adalimumab (Humira) **and secukinumab (Cosentyx)**
• insulin degludec (Tresiba) **Insulins: Basal**	**November 2018 updates are in BOLD** • Patient has been adherent to insulin glargine (Lantus) **and Toujeo, and** has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus), **insulin glargine (Toujeo)**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• linaclotide (Linzess) • lubiprostone (Amitiza) **Gastrointestinal-2 Agents: CIC/IBS-C**	Manual PA criteria apply to all new and current users of Linzess and Amitiza. <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Age ≥ 18 years OR for Amitiza, prescribed in consultation with a pediatric gastroenterologist for ages < 18 y/o • Patient has documented symptoms for ≥ 3 months • Patient has diagnosis of IBS-C or CIC or OIC in adults with chronic, non-cancer pain ▪ Amitiza or Linzess: Patient is currently taking an opioid if used for OIC ▪ Amitiza: Patient is female if used for IBS-C • Patient has documentation of failure of an increase in dietary fiber/dietary modification to relieve symptoms • Patient has absence of GI obstruction • Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as ▪ osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories) ▪ bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids; ▪ stool softener (e.g., docusate); ▪ stimulant laxative (e.g., bisacodyl, sennosides) • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik) Linzess: Non-FDA-approved uses other than OIC are NOT approved. Amitiza: Non-FDA-approved uses are NOT approved Prior authorization expires after 1 year. <u>Renewal PA Criteria</u>: Coverage will be approved for 1 year for continuation of therapy if: • Patient has had improvement in constipation symptoms and • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik)

Drug / Drug Class	Prior Authorization Criteria
• plecanatide (Trulance) **Gastrointestinal-2 Agents: CIC/IBS-C**	**November 2018 updates are in BOLD and strikethrough** Manual PA criteria apply to all new users of Trulance. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is ≥ 18 years of age • **Patient has documented symptoms for ≥ 3 months** • Patient has diagnosis of IBS-C or CIC • Patient has absence of GI obstruction • ~~Written by or in consultation with a gastroenterologist~~ • **Patient has documentation of failure of an increase in dietary fiber/dietary modification** • **Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as** ▪ **osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories)** ▪ **bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids** ▪ **stool softener (e.g., docusate)** ▪ **stimulant laxative (e.g., bisacodyl, sennosides)** • **Patient is not taking any of these agents concomitantly (Trulance, Amitiza, Linzess, Symproic, Relistor, or Movantik)** • ~~Must have failed/intolerant to linaclotide (Linzess)~~ • ~~Must have failed/intolerant to lubiprostone (Amitiza)~~ **Non-FDA-approved uses are NOT approved.** Prior authorization expires after 1 year. Renewal PA Criteria: Coverage will be approved for 1 year for continuation of therapy if: • Patient has had improvement in constipation symptoms and • Patient is not taking any of these agents concomitantly (Amitiza, Linzess, Symproic, Trulance, Relistor, or Movantik)

Drug / Drug Class	Prior Authorization Criteria
• eluxadoline (Viberzi) **Gastrointestinal-2 Agents: Miscellaneous**	**November 2018 updates are in BOLD and strikethrough** Manual PA criteria apply to all new users of Viberzi. <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Age ≥ 18 years • Written by or in consultation with a gastroenterologist • Patient has no history of alcoholism, alcohol abuse, or alcohol addiction, or in patients who drink alcohol, they drink < 3 alcoholic beverages per day • Patient has no history of marijuana use or illicit drug use in the previous 6 months • Patient does not have severe hepatic impairment (Child-Pugh C) • Patient has a documented diagnosis of IBS-D • **Patient has tried and failed dietary changes (including fiber), stress reduction, or cognitive behavioral therapy** • Patient has not had a cholecystectomy • The patient has had failure, intolerance, or contraindication to at least one antispasmodic/**antidiarrheal** agent; e.g., dicyclomine, Librax, hyoscyamine **[Levsin],** Donnatal, loperamide [Imodium]) • The patient has had failure, intolerance, or contraindication to at least one TCA (to relieve abdominal pain); e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline ~~• The patient has tried and failed rifaximin~~ Non-FDA approved uses are NOT approved. ~~PA does not expire.~~ PA expires after 4 months. <u>Renewal PA Criteria</u>: Coverage will be approved for 1 year if: • The patient has had documented improvement in IBS-D symptoms
• rifaximin 550 mg (Xifaxan) **Gastrointestinal-2 Agents: Miscellaneous**	**November 2018 updates for the indication of IBS-D are in BOLD. No changes for the indications of hepatic encephalopathy or traveler's diarrhea.** Manual PA criteria apply to all new users of Xifaxan 550 mg for IBS-D. <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Age ≥ 18 years • Patient has a diagnosis of IBS-D, without constipation with symptoms of moderate abdominal pain and bloating • **The prescription is written by or in consultation with a gastroenterologist** • **Patient has documentation of failure of dietary changes (including fiber), stress reduction, or cognitive behavioral therapy** • Patient has tried and failed or had intolerance, or a contraindication to at least <u>one antispasmodic/antidiarrheal agent</u> (e.g., dicyclomine [Bentyl], Librax, hyoscyamine [Levsin], Donnatal, loperaimde [Imodium]) • Patient has tried and failed or had intolerance or a contraindication to at least <u>one tricyclic antidepressant</u> (e.g., amitriptyline, desipramine, doxepin, imipramine, nortriptyline, protriptyline) **Non-FDA-approved uses are NOT approved including: small intestinal bacterial overgrowth (SIBO), non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), spontaneous bacterial peritonitis (SBP), functional dyspepsia, diabetes, cirrhosis (ascites/alcohol-related), graft vs host disease, primary sclerosing cholangitis, Celiac disease, ulcerative colitis, Crohn's disease, diverticular disease, bowel preparation, constipation, colorectal cancer prevention, opioid-induced constipation, chronic abdominal pain, or other disease states.** ~~PA expires after 6 months~~. **Prior authorization expires after 1 year. No renewal allowed. Note that a maximum of 3 treatment courses for IBS-C are allowed in 1 year.**

Drug / Drug Class	Prior Authorization Criteria
• deutetrabenazine (Austedo) **Neurological Agents Miscellaneous: Movement Disorders**	**Changes from the November 2018 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Austedo. Manual PA Criteria: Coverage is approved for initial therapy for one year if all criteria are met: • **Patient does not have congenital or acquired long QT syndrome or arrhythmias associated with QT prolongation** • Patient does not have severe hepatic impairment • Patient is not taking any of the following: MAOI within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine (Ingrezza)) Huntington's Disease Chorea • Prescribed by or in consultation with a neurologist • Patient has a diagnosis of chorea associated with Huntington's disease • Patient does ~~is~~ not have ~~actively~~ suicidal ideation • Patient does not have depression or is being adequately treated for depression • Patient has had an adequate trial of tetrabenazine for 12 weeks and has experienced treatment failure or experienced an adverse event that is not expected to occur with Austedo Tardive Dyskinesia • Age ≥ 18 years • Prescribed by or in consultation with a neurologist or psychiatrist • Patient does not have ~~is actively~~ suicidal ideation • **Patient does not have depression or is being adequately treated for depression** • Patient has moderate to severe tardive dyskinesia **causing functional impairment** along with schizophrenia, schizoaffective disorder, or a mood disorder • ~~Provider has considered gingko biloba or clonazepam~~ • **Provider has considered a dose reduction, tapering, or discontinuation of the dopamine receptor blocking agent suspected of causing the symptoms** PA expires in one year. Non-FDA-approved uses are NOT approved (e.g., Tourette's, ~~tardive dyskinesia,~~ dystonia). Renewal PA Criteria: Coverage is approved indefinitely for continuation of therapy if all criteria are met: • ~~Patient has demonstrated improvement in chorea based on clinician assessment and is being monitored for depression and suicidal ideation~~ • **Huntington's Disease Chorea: Patient has demonstrated improvement in symptoms based on clinician assessment. Patient is being monitored for depression and suicidal ideation.** • **Tardive Dyskinesia: Patient has demonstrated improvement in symptoms based on an improvement of at least 2 on the AIMS. Patient is being monitored for depression and suicidal ideation.**

Drug / Drug Class	Prior Authorization Criteria
• valbenazine (Ingrezza) **Neurological Agents Miscellaneous: Movement Disorders**	**Changes from the November 2018 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Ingrezza. Manual PA Criteria: Coverage is approved if all criteria are met: • Age > 18 years • Prescribed by or in consultation with a neurologist or psychiatrist • Patient does not have ~~is actively~~ suicidal ideation • **Patient does not have depression, or is being adequately treated for depression** • Patient has moderate to severe tardive dyskinesia **causing functional impairment** along with schizophrenia, schizoaffective disorder, or a mood disorder • ~~Patient has had an adequate trial and has failed or has a contraindication to tetrabenazine or deutetrabenazine~~ • ~~Provider has considered use of clonazepam and gingko biloba~~ • **Provider has considered a dose reduction, tapering, or discontinuation of the dopamine receptor blocking agent suspected of causing the symptoms** • Patient does not have congenital **or acquired** long QT syndrome or arrhythmias associated with QT prolongation • Patient is not taking any of the following: ▪ MAOI, CYP3A4 inhibitors, CYP2D6 inhibitors, CYP3A4 inducers, another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine [Austedo]) Non-FDA-approved uses are NOT approved (i.e., Tourette's, dystonia). ~~PA does not expire~~ **PA expires in one year.** Renewal PA Criteria: **Coverage is approved indefinitely for continuation of therapy if all criteria are met:** • **Patient has demonstrated improvement in symptoms based on an improvement of at least 2 on the Abnormal Involuntary Movement Scale (AIMS). Patient is being monitored for depression and suicidal ideation.** • **Note that patients currently with an approved PA will not be subject to the renewal criteria**

Drug / Drug Class	Prior Authorization Criteria
• adapalene 0.1% topical solution • adapalene 0.1% topical solution external pad/swab (Plixda) • tretinoin 0.05% topical lotion (Altreno) **Acne Agents: Topical Acne and Rosacea Agents: Topical Retinoids and Combinations**	All new and current users of adapalene 0.1% topical solution, Plixda, Altreno and generics are required to try three step-preferred topical acne products, including at least two different strengths of tretinoin and adapalene 0.1% (for Plixda and adapalene 0.1% topical solution). Automated PA Criteria: • The patient has filled a prescription for at least three step-preferred topical acne products (e.g., adapalene, tretinoin, clindamycin, clindamycin/benzoyl peroxide), including at least two different strengths of tretinoin and 0.1% adapalene (for adapalene 0.1% solution and Plixda) 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, adapalene 0.1% topical solution, Plixda, and tretinoin 0.05% topical lotion (Altreno) will be approved if: • The patient has a diagnosis of acne vulgaris AND • Patient has tried and failed at least three step-preferred topical acne products, including at least two different strengths of tretinoin and, 0.1% adapalene (for adapalene 0.1% topical solution and Plixda) (e.g., generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, adapalene, or sulfacetamide sodium/sulfur) OR • The patient has experienced an adverse reaction or an inadequate response with formulary, step-preferred topical tretinoin and adapalene agents that is not expected to occur with the non-formulary, non-step-preferred product Non-FDA-approved uses are NOT approved. PA expires in 1 year. PA renewal is not allowed.
• amikacin sulfate liposomal inhalation suspension (Arikayce) **Antibiotics: Aminoglycosides**	Manual PA criteria apply to all new users of Arikayce. Manual PA Criteria: Arikayce is approved if ALL of the following criteria are met: • Age ≥ 18 • Prescription is written by or in consultation with an Infectious Disease Specialist and/or Pulmonologist. • Patient has a diagnosis of refractory *Mycobacterium avium* complex (MAC) lung disease as defined as a patient who does not achieve negative sputum cultures after a minimum of 6 consecutive months of conventional therapy. • Patient continues to have a susceptible infection to amikacin. • Patient is on a concomitant multidrug background (baseline) regimen therapy. • Provider must explain why the patient cannot use IV amikacin (fill in the blank) • Provider acknowledges and patient has been informed that Arikayce carries a boxed warning for risk of increased respiratory adverse reactions that can lead to hospitalization. • Provider acknowledges and patient has been informed that warnings and precautions of Arikayce include hypersensitivity pneumonitis, hemoptysis, bronchospasm, exacerbation of underlying pulmonary disease, ototoxicity, nephrotoxicity, neuromuscular blockade, and embryo-fetal toxicity. • Provider acknowledges (and patient has been informed) the patient will be monitored for adverse reactions that include but are not limited to: (from package insert occurring at an incidence of ≥ 10% and higher than control) dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia, exacerbation of underlying pulmonary disease, diarrhea, and nausea. Non-FDA-approved uses are NOT approved (including for *Pseudomonas Aeruginosa*). PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• butalbital 50 mg/acetaminophen 300 mg capsule **Analgesics and Combinations**	Manual PA criteria apply to all new and current users of butalbital 50 mg/acetaminophen 300 mg capsules. Manual PA Criteria: Coverage will be approved for butalbital 50 mg/acetaminophen 300 mg capsule if all criteria are met: • Patient has a diagnosis of tension or muscle headaches • Patient cannot tolerate generic oral tablet or capsule formulations of butalbital/acetaminophen or butalbital/acetaminophen/caffeine. Non-FDA-approved uses are NOT approved. PA does not expire.
• cannabidiol oral solution (Epidiolex) **Anticonvulsant/Anti-Mania Agents**	Manual PA criteria apply to all new users of Epidiolex. Manual PA Criteria: Epidiolex is approved if all criteria are met: • Must be prescribed by a pediatric neurologist or neurologist • Patient has been diagnosed with either Lennox-Gastaut Syndrome or Dravet Syndrome Non-FDA-approved uses are NOT approved. PA does not expire.
• dacomitinib (Vizimpro) **Oncological Agents: Non-Small Cell Lung Cancer**	Manual PA criteria apply to all new users of Vizimpro. Manual PA Criteria: Vizimpro is approved if all criteria are met: • Patient ≥ 18 years old • Patient has histologically or cytopathologically confirmed stage IIIB/IV or recurrent non-small cell lung cancer with the presence of at least one documented epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutation as detected by an FDA-approved test • Patient has no evidence of active infection, non-infectious pneumonitis, nor interstitial lung disease • Patient has no previous use of an epidermal growth factor kinase inhibitor (e.g., Tarceva, Iressa, Gilotrif, or Tagrisso) • Drug is prescribed by or in consultation with a hematologist/oncologist Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• doxycycline monohydrate ER 50, 75 and 100 mg capsules (Okebo) • minocycline 105 and 135 mg ER tablets (Minolira) • **Oral Tetracyclines**	PA applies to both new and current users of to Okebo and Minolira. Automated PA Criteria: • Patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) **AND** one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 days Manual PA Criteria: If automated PA criteria are not met, the non-step-preferred product is allowed if: **Acne Vulgaris or Rosacea** • For Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Monodoxyne NL, **or Okebo:** The patient has tried and had an inadequate response to or failed to tolerate the following: ▪ one generic immediate-release doxycycline product (hyclate or monohydrate salt) AND ▪ one generic immediate-release minocycline product • For Solodyn or generic minocycline ER **or Minolira**: The patient has acne with inflammatory lesions AND ▪ the patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events **Susceptible Infections** • For Doryx, Doryx MPC, Acticlate, **and Okebo**: if used for susceptible infections, the patient has failed or had clinically significant adverse events to generic IR doxycycline Non-FDA-approved uses are NOT approved PA expires in 1 year Renewal Criteria: Okebo or Minolira will be approved for an additional year, if: • The patient's therapy has been re-evaluated within the last 12 months • The patient is tolerating treatment, and there is continued medical need for the medication • The patient has had disease stabilization or improvement in disease on therapy

Drug / Drug Class	Prior Authorization Criteria
• duvelisib (Copiktra) **Oncological Agents for Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma**	Manual PA criteria apply to all new users of Copiktra. Manual PA Criteria: Copiktra is approved if all criteria are met: • Patient ≥ 18 years old • Patient has evidence and pathologic confirmation of relapsed or refractory chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or relapsed or refractory follicular lymphoma (FL) • Patient has undergone at least two prior systemic therapies • Provider is aware and has informed patient of the risk of serious, life-threatening, and fatal infections, including *Pneumocystis jiroveci* pneumonia (PJP) and cytomegalovirus (CMV); diarrhea; colitis; cutaneous reactions, including drug rash with eosinophilia and systemic symptoms (DRESS) and Stevens Johnson Syndrome spectrum reactions, including Toxic Epidermal Necrolysis; pneumonitis; hepatotoxicity; and neutropenia • Patient has no evidence of active infection, diarrhea, colitis, serious cutaneous disease, pneumonitis, hepatitis, significantly elevated liver-associated enzymes, nor neutropenia • Female patients of childbearing age are not pregnant confirmed by (-) HCG test and agree to use contraception • Male patients are informed that Copiktra may cause male infertility • Drug is prescribed by a hematologist/oncologist • Prescriber agrees to advise patient of the toxicities of the drug, as outlined in the REMS program found at http://www.copiktrarems.com Non-FDA-approved uses are NOT approved. PA does not expire.
• elagolix (Orilissa) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists/Antagonists**	Manual PA applies to all new and current users of elagolix (Orilissa). Manual PA Criteria: Elagolix is approved if all criteria are met: • Age ≥ 18 • Patient is a premenopausal woman with endometriosis • Patient has had inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, unless contraindicated • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have severe hepatic impairment (Child-Pugh Class C) • Patient does not have osteoporosis • Patient is on concurrent calcium supplementation. • Patient is not using Orilissa concomitantly with cyclosporine or gemfibrozil Non-FDA approved uses are NOT approved. PA Expiration 9 months; Renewal expiration 24 months Renewal Criteria: PA will be approved for an additional 15 months (lifetime usage not to exceed 24 months) if all criteria are met • The patient meets the original PA criteria • Patient does not have moderate hepatic impairment (Child-Pugh Class B); • Patient is taking the Orilissa 150 mg dose (note that the 200 mg dose is only approved for up to 6 months)

Drug / Drug Class	Prior Authorization Criteria
• fremanezumab-vfrm injection (Ajovy) injection • galcanezumab-gnlm injection (Emgality) **Migraine Agents**	Manual PA criteria apply to all new users of Ajovy and Emgality. <u>Manual PA Criteria</u>: Ajovy or Emgality is approved if all criteria are met: • Patient ≥ 18 years old and not pregnant • Must be prescribed by or in consultation with a neurologist • Patient has a migraine diagnosis with at least 8 migraine days per month for 3 months • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: ▪ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate ▪ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol ▪ Prophylactic antidepressants: amitriptyline, venlafaxine • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed • For Emgality, loading doses will be allowed Non-FDA-approved uses are NOT approved. PA expires after 6 months. <u>Renewal Criteria</u>: Coverage will be approved indefinitely for continuation of therapy if: • The patient has shown improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication)
• glycopyrronium 2.4% topical cloth (Qbrexza) **Antiperspirants**	Manual PA criteria apply to all new and current users of Qbrexza. <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Age ≥ 9 years • Patient has had a diagnosis of primary axillary hyperhidrosis for ≥ 6 months • Patient has tried and failed at least one topical 20% or higher aluminum salt (either OTC or prescription) and at least one additional option (e.g., Botox, MiraDry, iontophoresis, oral anticholinergics [glycopyrrolate, oxybutynin, propantheline], propranolol, clonidine, or diltiazem) • Prescribed by a dermatologist Non-FDA-approved uses are NOT approved. Not for palmar, plantar, facial, or other forms of hyperhidrosis. PA does not expire.
• ivosidenib (Tibsovo) **Oncological Agents: Acute Myelogenous Leukemia**	Manual PA criteria apply to all new users of Tibsovo. <u>Manual PA Criteria</u>: Tibsovo is approved if all criteria are met: • Patient ≥ 18 years old • Has laboratory evidence of relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test • The patient will be monitored for differentiation syndrome • The patient will be monitored for Guillain-Barre syndrome • Prescribed by or in consultation with a hematologist/oncologist For non-FDA-approved uses, please cite supporting literature. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• lanadelumab-flyo injection (Takhzyro) **Corticosteroids-Immune Modulators: Hereditary Angioedema Agents**	Manual PA applies to all new users of Takhzyro. Manual PA Criteria: lanadelumab is approved if all apply: • The patient is ≥ 12 years old • Patient is not pregnant or breastfeeding • The patient must be diagnosed with hereditary angioedema (HAE) Type I, II, or III (HAE with normal C1-esterase inhibitor) • The drug is prescribed by an allergist, immunologist, or rheumatologist or in consultation with an HAE specialist • The patient must experience baseline of ≥ 2 HAE attacks per month • The patient has tried and failed an attenuated androgen (danazol) **OR** ▪ Patient has experienced or is expected to experience serious adverse effects from the use of an androgen (e.g., virilization of women, stroke, myocardial infarction, venous thromboembolism) OR ▪ Patient is female of childbearing age Non-FDA-approved uses NOT approved. PA does not expire.
• lidocaine 1.8% topical patch (ZTlido) **Pain Agents: Pain Topical**	Manual PA applies to all new and current users of lidocaine 1.8% topical patch (ZTlido). Manual PA Criteria: ZTlido is approved if: • The patient has a diagnosis of post-herpetic neuralgia AND • Provider must explain why patient cannot use lidocaine 5% patch (Lidoderm, generics). ▪ Acceptable response: patient has failed an adequate course of Lidoderm ▪ Not an acceptable response: Adhesive issues with Lidoderm is not a valid reason for ZTlido approval. Non-FDA-approved uses are NOT approved. PA does not expire.
• lumacaftor/ivacaftor (Orkambi granules) **Cystic Fibrosis Agents**	Manual PA criteria apply to all new users of Orkambi granules. Manual PA Criteria: Coverage is approved if all criteria are met: • Orkambi is prescribed for the treatment of cystic fibrosis in an age appropriate patient population according to the product label. ▪ For Orkambi granules – the patient is between the ages of 2 to 5 years; or the patient is older than 5 years with documented swallowing difficulties ▪ For Orkambi tablets – the patient is 6 years of age or older • The patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected/confirmed by an FDA-approved test • Concomitant use of Orkambi granules with Orkambi tablets is not allowed. • Concomitant use of Orkambi granules or tablets is not allowed with ivacaftor (Kalydeco) or tezacaftor/ivacaftor (Symdeko). Non-FDA-approved uses are NOT approved, including: • Patients who are heterozygous for the F508del mutation in the CFTR gene Non-FDA approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• lusutrombopag (Mulpleta) **Hematological Agents: Platelets**	Manual PA criteria apply to all new users of Mulpleta. Manual PA Criteria: Mulpleta is approved if all criteria are met: • Patient ≥ 18 years old • Diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 10^9/L) • Will be undergoing a procedure *with a moderate to high bleeding risk* within 8-14 days • Has no evidence of current thrombosis • Prescribed by or in consultation with a gastroenterologist Non-FDA-approved uses are NOT approved. PA expires in 60 days. PA renewal is not allowed.
• metoprolol succinate ER capsules (Kapspargo Sprinkle) **Beta Blockers**	**PA does not apply to patients less than 18 years of age (age edit).** Manual PA criteria apply to all new users of Kapspargo older than 18 years of age. Manual PA Criteria: Coverage is approved if all criteria are met: • Age > 18 years of age • Diagnosis of hypertension, angina pectoris, or heart failure • Drug will be dosed at a maximum of once daily • Provider must explain why the patient requires metoprolol succinate sprinkle and cannot take alternative formulary beta blockers ▪ Acceptable responses include the following: the patient requires metoprolol succinate and cannot take tablets due to some documented medical condition e.g., dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience, or requires NG tube admin Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• migalastat (Galafold) **Metabolic Agents-Miscellaneous**	Manual PA applies to all new and current users of migalastat (Galafold). Manual PA Criteria: Migalastat is approved if all criteria are met: • Age ≥ 18 years old • Has laboratory evidence of GLA gene variant based on *in vitro* assay data • Galafold is prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease • Must not be used concomitantly with Fabrazyme Non-FDA-approved uses are NOT approved. PA does not expire.
• ozenoxacin 1% cream (Xepi) **Antibiotics: Quinolones**	Manual PA criteria apply to all new users of Xepi. Manual PA Criteria: Xepi is approved if ALL criteria are met: • Patient is 2 months of age or older • Patient has a diagnosis of impetigo • Patient has failed a trial of mupirocin 2% ointment or cream (unless contraindicated or clinically significant adverse effects have been experienced) • Patient has a contraindication to or has failed a trial of an oral antibiotic for (e.g., cephalexin, dicloxacillin, clindamycin) • The Xepi dose will not exceed twice daily topical application for 5 days Non-FDA-approved uses are NOT approved. Prior authorization expires after 1 month; renewal will require PA to be completed again.

Drug / Drug Class	Prior Authorization Criteria
• tildrakizumab (Ilumya) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor Inhibitors**	Manual PA criteria apply to all new and current users of Ilumya. The patient must have tried Humira, Cosentyx AND Stelara first. Manual PA Criteria: Ilumya is approved if all criteria are met: • The patient has a contraindication or has had an inadequate response to Humira, Cosentyx, AND Stelara OR • The patient has had an adverse reaction to Humira, Cosentyx, AND Stelara that is not expected with requested non-step-preferred TIB AND • Patient ≥ 18 years old • The patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy • Patient has tried and had an inadequate response to non-biologic systemic therapy) (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) • Coverage NOT provided for concomitant use with other TIBs • The patient has had a negative TB test result in past 12 months (or TB is adequately managed) Non-FDA-approved uses are NOT approved. PA does not expire.
• chlorzoxazone 250 mg **Skeletal Muscle Relaxants and Combinations**	Manual PA criteria apply to all new and current users of chlorzoxazone 250 mg. Note: Chlorzoxazone 500 mg tablets are scored and available without a PA; providers are encouraged to consider changing the prescription to ½ of a 500 mg tablet if the patient requires a 250 mg dose. Manual PA Criteria: Coverage for chlorzoxazone 250 mg tablets will be approved if: • The provider explains why the patient requires chlorzoxazone 250 mg tablets and why the patient cannot take ½ of a 500 mg tablet • Acceptable responses are approved if ALL of the criteria are met: ▪ The patient has experienced allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available chlorzoxazone 500 mg tablets Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• cobimetinib (Cotellic) **Oncological Agents: Melanoma**	Manual PA criteria apply to all new users of Cotellic. Manual PA Criteria: Coverage will be approved if: • Age ≥ 18 years • Has unresectable metastatic melanoma • Has confirmed BRAF V600E or V600K mutation by an FDA-approved test • Cotellic is being taken in combination with vemurafenib (Zelboraf) • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist) • Prescribed by or in consultation with an oncologist Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• crotamiton 10% Lotion (Eurax/Crotan) **Antiinfectives: Miscellaneous**	Manual PA criteria apply to all new users of Eurax/Crotan. Crotan/Eurax is approved if <u>ALL</u> criteria are met: • Age ≥ 18 years • Patient has a diagnosis of scabies caused by *Sarcoptes scabiei* • Patient must have tried and failed permethrin 5% cream in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced Non-FDA-approved uses are NOT approved. Prior authorization expires in 30 days. Renewal of PA is not allowed.
• dupilumab injection (Dupixent) **Corticosteroids – Immune Modulators: Atopic Dermatitis**	**November 2018 updates are in BOLD.** Manual PA criteria apply to all new users of Dupixent. <u>Manual PA Criteria:</u> Coverage will be approved for initial therapy for 6 months if all criteria are met: • Patient has moderate to severe or uncontrolled atopic dermatitis • Patient must be 18 years of age or older • Prescribed by a dermatologist, allergist, or immunologist • Patient has a contraindication to, intolerability to, or failed treatment with at least ONE high potency/class 1 topical corticosteroid • Patient has a contraindication to, intolerability to, or failed treatment with at least ONE systemic immunosuppressant • Patient has a contraindication to, intolerability to, inability to access treatment, or failed treatment with Narrowband UVB phototherapy • **The 200 mg/1.14 mL formulation is NOT approved for atopic dermatitis** **OR** • **Patient has moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma** • **Patient must be 12 years of age or older** • **Prescribed by a pulmonologist, asthma specialist, allergist, or immunologist** • **Patient has baseline eosinophils ≥ 300 cells/mcL** • **Patient's symptoms are not adequately controlled on stable high-dose inhaled corticosteroid AND either an inhaled Long-Acting Beta Agonist or a Leukotriene Receptor Antagonist for at least 3 months** • **Dupixent will not be used for relief of acute bronchospasm or status asthmaticus** • **Dupixent will be only used as add-on therapy to other asthma controller medications** Non-FDA-approved uses are NOT approved. PA expires after 6 months. <u>Renewal PA Criteria:</u> Coverage will be approved indefinitely for continuation of therapy if: • **Atopic Dermatitis:** The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1) • **Asthma: The patient has had a positive response to therapy with a decrease in exacerbations, improvements in FEV_1, or decrease in oral corticosteroid use.**

Drug / Drug Class	Prior Authorization Criteria
• diclofenac potassium liquid filled capsules (Zipsor) • diclofenac submicronized (Zorvolex) • indomethacin submicronized (Tivorbex) • naproxen CR (Naprelan/generics) • meloxicam submicronized (Vivlodex) **Pain Agents: NSAIDs**	Manual PA criteria apply to all new and current users of naproxen CR (Naprelan/generics), Zorvolex, Tivorbex, Vivlodex, and Zipsor. Manual PA Criteria: Coverage for naproxen CR (Naprelan/generics), Zorvolex, Tivorbex, Vivlodex, Zipsor will be approved if: • Note: Multiple formulary NSAIDs are available for DoD beneficiaries without a PA. Please state clinical rationale of why patient cannot take any of the formulary NSAIDs: (blank write in) • Acceptable responses are approved if ALL of the criteria are met (no prompting): ▪ The patient medical history includes trial and failure of four formulary generic NSAIDs, including three of the following BCF agents: ▪ ibuprofen 400 mg, 600 mg, 800 mg, 125 mg/5 mL susp (generic) ▪ indomethacin 25 mg, 50 mg (generic) ▪ meloxicam 7.5 mg, 15 mg (generic) ▪ naproxen IR 250 mg, 500 mg (generic) Non-FDA-approved uses are NOT approved. Prior authorization expires in one year. Renewal criteria: PA will be renewed for an additional year if a new PA form is completed.
• emicizumab-kxwh (Hemlibra) **Antihemophilic Factors**	**Changes from the November 2018 meeting are in BOLD and strikethrough.** Manual PA criteria apply to all new users of Hemlibra. Manual PA Criteria: Coverage will be approved if ALL criteria are met: • ~~The patient must have a documented diagnosis of Hemophilia A~~ • Patients is using Hemlibra as routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients newborn and older with hemophilia A with or without factor VIII inhibitors • ~~The patient must have a history of a high titer of factor VIII inhibitor (greater than or equal to 5 Bethesda units per mL)~~ • The patient must NOT have been treated within the last 12 months for thromboembolic disease or have current signs of thromboembolic disease • The drug is being prescribed by or in consultation with a hematologist • **Medication is not being used in combination with Immune Tolerance Induction (ITI)** Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• febuxostat (Uloric) **Anti-Gout Agents: Chronic**	**November 2018 updates are in BOLD.** **Manual PA criteria apply to all new users of Uloric.** <u>Automated PA Criteria:</u> The patient has received a prescription for allopurinol at any Military Health System pharmacy point of service (Military Treatment Facilities, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated criteria are not met, febuxostat (Uloric) is approved (e.g., a trial of allopurinol is not required) if: • The patient has experienced any of the following issues with at least one of the following with allopurinol, which is not expected to occur with febuxostat (Uloric): ▪ The patient has had an inadequate response to allopurinol (failure to achieve serum uric acid levels < 6 mg/day) after an adequate trial (at least 300 mg per day of allopurinol) ▪ The patient has had intolerable adverse effects (e.g., hypersensitivity) to allopurinol ▪ The patient has a contraindication to allopurinol (e.g., renal impairment) • **Patients with major cardiovascular (CV) disease should be informed of the potential CV risks when using this drug** • **The Healthcare provider should consider CV safety information from the CARES trial and the label when prescribing febuxostat** Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• insulin degludec (Tresiba) **Basal Insulins**	**November 2018 updates are in BOLD.** Manual PA criteria apply to all new users of Tresiba. <u>Manual PA Criteria:</u> Tresiba is approved if <u>ALL</u> criteria are met: • Patient is age ≥ 1 year • **The provider must explain why the patient cannot use Lantus (fill in the blank)** • **The provider must explain why the patient cannot use Toujeo (fill in the blank)** • ~~Patient must have tried and failed or is intolerant to insulin glargine (Lantus)~~ Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• pimavanserin (Nuplazid) **Antipsychotic Agents: Atypical**	**November 2018 updates are in BOLD.** Manual PA criteria apply to all new users of pimavanserin. Manual PA Criteria: Nuplazid is approved if all of the following criteria are met: • Patient is age ≥ 18 years. • Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis. • **Nuplazid is being prescribed by or in consultation with a neurologist, psychiatrist, or gerontologist (i.e., geriatric medicine specialist).** • Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin. • The patient's baseline Mini-Mental State Examination (MMSE) score ≥ 21. • **Patient does NOT have history of known QT prolongation, cardiac arrhythmias, or other circumstances that would increase the risk of Torsades de Pointes and/or sudden death.** • **Patient is NOT taking additional antipsychotics.** Non-FDA approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
Step-Preferred • Norditropin FlexPro **Non-Step-Preferred** • Genotropin • Humatrope • Nutropin AQ Nuspin • Omnitrope • Saizen • Serostim • Zomacton **Growth Stimulating Agents (GSAs)**	**May 2018 changes are bolded.** **Norditropin FlexPro is the preferred Growth Stimulating Agent.** **All new and current users of the non-step-preferred Growth Stimulating Agents must try Norditropin FlexPro first.** Manual PA Criteria: Norditropin FlexPro, Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton are approved if: • The patient is younger than 18 years of age and has the following indications: ▪ Growth hormone deficiency ▪ Small for Gestational Age ▪ Chronic Renal Insufficiency **associated with growth failure** ▪ Prader-Willi Syndrome **(in patients with a negative sleep study for obstructive sleep apnea)** ▪ Turner Syndrome ▪ Noonan's Syndrome ▪ Short stature homeobox (ShoX) gene mutation • For patients younger than 18 years of age who do not have one of the indications above, document the diagnosis below: _____ • For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment **OR** • The patient is older than 18 years of age and has the following indications: ▪ Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood ▪ HIV/AIDS wasting/cachexia ▪ Short Bowel Syndrome • For patients older than 18 years of age, the prescription is written by **or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist)** **AND** For Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim and Zomacton: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton: • The patient has a contraindication to Norditropin FlexPro OR • The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with the non-step-preferred product (e.g., because of different preservative) Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim or Zomacton. • Use of a Growth Stimulating Agent is not approved for idiopathic short stature, the normal ageing process, obesity, or depression • Use of a Growth Stimulating Agent is not approved for other non-FDA-approved uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment) • Concomitant use of multiple Growth Stimulating Agents is not approved Prior authorization expires in one year.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
▪ amikacin (Arikayce) **Antibiotic: Aminoglycosides**	▪ MTF/Mail/Retail: 28-day supply
▪ butalbital 50 mg and acetaminophen 300 mg capsules **Analgesics and Combinations**	▪ MTF/Mail: 180 caps/90 days ▪ Retail: 60 caps/30 days
▪ cannabidiol oral solution (Epidiolex) **Anticonvulsants-Antimania Agents**	▪ MTF/Mail/Retail: 6 bottles/30 days
▪ dacomitinib (Vizimpro) **Oncological Agents: Lung Cancer**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
▪ deutetrabenazine (Austedo) ▪ valbenazine (Ingrezza) **Neurological Agents Miscellaneous: Movement Disorders**	▪ MTF/Mail/Retail: 30-day supply
▪ duvelisib (Copiktra) **Oncological Agents: CLL or SLL**	▪ MTF/Mail/Retail: 28-day supply
▪ erenumab-aooe injection (Aimovig) **Migraine Agents**	**Update from August 2018 P&T meeting** ▪ MTF/Mail: 3 syringes or pens/90 days ▪ Retail: 1 syringe or pen/30 days ▪ Adequate trial of lower strength required for 3 months before trying the higher strength (either 2 of the 70 mg syringes or 1 of the 140 mg syringe/30 days)
▪ fremanezumab-vfrm injection (Ajovy) **Migraine Agents**	▪ MTF/Mail: 3 syringes/90 days ▪ Retail: 1 syringe/30 days; multiple co-pays allowed for multiple fills at Retail if patient is using quarterly regimen
▪ galcanezumab-gnlm injection (Emgality) **Migraine Agents**	▪ MTF/Mail: 3 syringes or pens/90 days ▪ Retail: 1 syringe or pen/30 days
▪ fentanyl and fentanyl citrate (Abstral, Actiq, Fentora, fentanyl citrate lozenge (generic), Lazanda, and Subsys) **Narcotic Analgesics and Combinations: Transmucosal Immediate Release Fentanyl (TIRF) Products**	▪ MTF/Mail/Retail: 30-day supply

Drug / Drug Class	Quantity Limits
▪ ivacaftor (Kalydeco) granules **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 56 packets/28 days
▪ ivacaftor (Kalydeco) tablets **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 60 tablets/30 days
▪ ivosidenib (Tibsovo) **Oncological Agents: Acute Myelogenous Leukemia**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
▪ ketorolac (Sprix) nasal spray **Pain Agents: NSAID**	▪ MTF/Mail/Retail: 5 bottles/5-day supply
▪ lanadelumab-flyo (Takhzyro) **Corticosteroids-Immune Modulators: Hereditary Angioedema Agents**	▪ MTF/Mail: 6 vials/90 days ▪ Retail: 2 vials/30 days
▪ lidocaine 1.8% (ZTlido) topical system **Pain Agents: Pain Topical**	▪ MTF/Mail: 270 patches/90 days ▪ Retail: 90 patches/30 days
▪ lumacaftor/ivacaftor (Orkambi) granules **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 56 packets/28 days
▪ lumacaftor/ivacaftor (Orkambi) tablets **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 112 tablets/28 days
▪ lusutrombopag (Mulpleta) **Hematological Agents: Platelets**	▪ MTF/Mail/Retail: 7-day supply
▪ migalastat (Galafold) **Metabolic Agents-Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply
▪ ozenoxacin 1% cream (Xepi) **Antibiotics: Quinolones**	▪ MTF/Mail/Retail: 110-, 30- or 45 mg tube/30 days

Drug / Drug Class	Quantity Limits
▪ pegfilgrastim-jmdb (Fulphila) **Hematological Agents: White Blood Cell Stimulants**	▪ MTF/Mail: 2 syringes/45 days ▪ Retail: 1 syringe/21 days
• rifaximin 550mg tab (Xifaxan) **Gastrointestinal-2 Agents: Miscellaneous**	For the indication of IBS-D: ▪ MTF/Mail/Retail: 42 tabs per prescription fill; maximum of 3 treatment courses in 365 days
▪ tezacaftor/ivacaftor + ivacaftor (Symdeko) **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 56 tablets/28 days
▪ tildrakizumab (Ilumya) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor Inhibitors**	▪ MTF/Mail: 2 syringes/84 days ▪ Retail: 1 syringe/28 days

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
adapalene 0.1% topical solution (external pad/swab) (Plixda)	Acne Agents: Topical Acne & Rosacea	adapalene 0.1% lotion, cream, gel	Acne vulgaris	• New topical pad formulation (Plixda) and new topical solution formulation of adapalene 0.1% initially approved in 2016 and recently launched. • Three different formulations and two different strengths (0.1% & 0.3%) of adapalene are available on the formulary. • Plixda has no unique indications and does not offer any compelling evidence of clinical efficacy relative to existing topical retinoid (e.g., adapalene 0.1% gel, cream, or lotion) on the uniform formulary.	• NF and non-step-preferred • Add to EMMPI list
adapalene 0.1% topical solution	Acne Agents: Topical Acne & Rosacea	adapalene 0.1% lotion, cream, gel	Acne vulgaris	• New formulation of adapalene available in a topical solution. • Three different formulations and two different strengths (0.1% & 0.3%) of adapalene are available on the formulary. Adapalene 0.1% topical solution has no unique indications and does not offer any compelling evidence of clinical efficacy relative to existing topical retinoid (e.g., adapalene 0.1% gel, cream, or lotion) on the uniform formulary.	• NF and non-step-preferred • Add to EMMPI list
amikacin liposome inhaled suspension (Arikayce)	Antibiotics: Aminoglycosides	Amikacin IV and inhaled	Mycobacterium avium complex (MAC)	• New liposomal inhalation formulation of amikacin. • First drug granted approval under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs. • Indicated for adults with limited/no alternatives for MAC lung disease as part of a combination antibacterial regimen in patients who have not achieved negative sputum cultures after a minimum of six consecutive months of treatment. • One clinical efficacy non-RCT found proportion of patients achieving culture conversion by month six was statistically significantly greater for Arikayce plus background regimen compared to background regimen alone. • FDA is requiring a post-marketing study to describe the clinical benefits of Arikayce. • Place in therapy remains unclear; additional data providing clear association with clinically meaningful outcomes, most appropriate treatment population, comparative efficacy, and relative safety versus other currently available options has not been established.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
butalbital 50 mg with acetaminophen 300 mg capsules	Analgesics & Combinations	• butalbital-acetaminophen-caffeine (Fioricet, generics) • butalbital-acetaminophen (Bupap, generics) • butalbital-acetaminophen (Allzital) tabs	Tension headache	• Another formulation of butalbital and acetaminophen in capsule form. • There are similar strengths of the active ingredients formulated in both tablets and capsules with or without caffeine that are available on the formulary. • No new clinical data to review. • Provides little to no clinical benefit relative to existing formulary agents.	• NF • Do not add to EMMPI list
cannabidiol oral solution (Epidiolex)	Anticonvulsants-Antimania agents	• clobazam • topiramate • lamotrigine	Treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older	• 1st cannabidiol approved for refractory seizures disorders (Lennox-Gastaut and Dravet syndromes). • Epidiolex decreases drop seizures in Lennox-Gastaut syndrome by 20% and decreases convulsive seizures in Dravet syndrome by 22%. • Short-term studies show some safety risk; elevated AST/ALT. • Studies show low addiction risks. • Cannabidiol under investigation for several additional indications	• UF • Do not add to EMMPI list
dacomitinib (Vizimpro)	Oncological Agents: Lung Cancer	• afatinib (Gilotrif) • gefitinib (Iressa) • osimertinib (Tagrisso) • erlotinib (Tarceva)	First-line treatment for metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.	• 5th EGFR kinase inhibitor for NSCLC. • 2nd irreversible 2nd generation inhibitor • Improved progression-free survival over reversible EGFR kinase inhibitor in newly diagnosed advanced disease • Equivalent overall survival relative to reversible EGFR kinase inhibitor in late stage, heavily treated disease • No efficacy over placebo in EGFR kinase inhibitor previously treated disease • Poorly tolerated relative to reversible EGFR kinase inhibitors • Provides an additional treatment option in a subset of patients where clinical benefit may outweigh toxic risk.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status

darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide (TAF) (Symtuza)	Antiretrovirals: Combinations	• Odefsey
		• Atripla
			Single-tablet regimen (STR) for HIV-1 infection (for naïve or switching)	• 5th second-line STR treatment option for HIV.
				• Contains a dual nucleoside reverse transcriptase inhibitor (NRTI)-based regimen + protease inhibitor (PI).
				• Approved for initial therapy in adults with HIV; however, the CDC recommends Symtuza as a 2nd-line agent.
				• Evaluated in two phase 3 trials.
				  • AMBER: showed non-inferiority to DRV/c/FTC/TDF
				  • EMERALD: showed non-inferiority to boosted PI + F/TDF
				• Not studied in pediatric, breastfeeding, or pregnant populations.
				• The side effect profile was generally mild, including nausea, headache, diarrhea, and rash.
				• More data on efficacy, safety, and long-term clinical consequences of increased lipid levels is necessary to better characterize strengths and weaknesses.
				• Provides an additional STR option for patients requiring aprotease inhibitor as the 3rd drug in a complete regimen.
					• UF
					• Do not add to EMMPI list

doravirine (Pifeltro)	Antiretrovirals: NNRTIs	• rilpivirine • efavirenz • delavirdine • etravirine • nevirapine	In combination with two other agents for HIV treatment	• Pifeltro is a single-ingredient non-nucleoside reverse transcriptase inhibitor (NNRTI) that should be utilized with two NRTI antiretroviral agents. • Doravirine-treated recipients had much lower rates of adverse effects compared to Atripla specifically with regard to dizziness, sleep disturbances, and other neuropsychiatric symptoms. • More data on switching regimens, resistance patterns, and long-term clinical outcomes of favorable lipid profiles is necessary to better characterize strengths and weaknesses for both drugs.	• UF • Do not add to EMMPI list

doravirine/ lamivudine/ tenofovir disoproxil fumarate (TDF) (Delstrigo)	Antiretrovirals: Combinations	• Atripla
		• Complera
			STR for HIV-1 infection (for naïve or switching)	• Delstrigo is the 6th second-line single tablet complete treatment regimen option for HIV.
				• Delstrigo was evaluated in two phase 3 trials.
				  • DRIVE-FORWARD study, Delstrigo showed non-inferiority to darunavir plus ritonavir plus two NRTIs.
				  • DRIVE-AHEAD study, Delstrigo showed non-inferiority to Atripla.
				• Doravirine-treated recipients had much lower rates of adverse effects compared to Atripla specifically with regard to dizziness, sleep disturbances, and other neuropsychiatric symptoms.
				• More data on switching regimens, resistance patterns, and long-term clinical outcomes of favorable lipid profiles is necessary to better characterize strengths and weaknesses for both drugs.
					• UF
					• Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
doxycycline monohydrate ER capsules (Okebo)	Antibiotics: Tetracyclines	• Generic doxycycline monohydrate IR 75 mg and 100 mg cap/tablet	Susceptible infections	• New formulation of extended-release doxycycline. • Doxycycline monohydrate IR generics and doxycycline hylcalte IR generics are step-preferred in this class. • No new studies were submitted to the FDA. • No studies of added benefit of treatment with a capsule compared to a tablet in acne vulgaris. • Provides little to no clinical benefit relative to existing formulary agents.	• NF and non-step-preferred • Add to EMMPI list
minocycline ER 105 mg and 135 mg tablets (Minolira)	Antibiotics: Tetracyclines	• minocycline IR 50 mg, 75 mg 100 mg • Solodyn • Ximino	Acne 12 years of age and older	• New formulation of extended release minocycline • Minocycline IR generics are step-preferred in this class • No new studies were submitted to the FDA; same formulation as Solodyn. • No studies of added benefit in acne vulgaris of treatment with an extended-release formulation compared to IR were performed. • Provides little to no clinical benefit relative to existing formulary agents.	• NF and non-step-preferred • Add to EMMPI list
duvelisib (Copiktra)	Oncological Agents	• idelalisib (Zydelig) • copanlisib (Aliqopa) • ibrutinib (Imbruvica) • acalabrutinib (Calquence), • venetoclax (Venclexta)	Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies.	• 3rd phosphatidylinositol 3-kinase (PI3K) inhibitor indicated for CLL/SLL and/or FL. • Statistically significant superior efficacy to ofatumumab (CD-20 inhibitor), but clinically insignificant progression-free survival advantage. • There is substantial risk for serious toxicity including death warranting a black box warning and a REMS program • The indication is restricted to late-stage, heavily pretreated disease. Copiktra is useful as a last-line treatment option.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
elagolix sodium (Orilissa)	Luteinizing Hormone-Releasing Hormone Agonists-Antagonists	• nafarelin nasal solution • leuprolide intramuscular kit • goserelin subcutaneous implant • triptorelin intramuscular suspension	GnRH antagonist for pain with endometriosis	• 1st GnRH antagonist and first oral agent for this indication • Evaluated in four phase 3 studies which showed statistically significant reductions in dysmenorrhea and nonmenstrual pelvic pain compared to placebo. Elagolix improved dysmenorrhea more than nonmenstrual pelvic pain and dyspareunia. • Higher dose therapy is superior to placebo for treating dyspareunia and provided greater improvements in pain, quality of life, and decreased use of rescue opioids than lower dose therapy. • Elagolix therapy is limited to 24 months for lower dose treatment and 6 months for higher dose treatment due to bone mineral density loss. • Elagolix effects have been measured only for relatively short periods (up to 12 months). Criteria used to define a clinically meaningful reduction in symptoms has not been previously used or validated. • Elagolix offers the first oral agent for pain associated with endometriosis, however numerous alternative agents are available, place in therapy is unclear, and no benefits in terms of side effect profile.	• NF • Add to EMMPI list
filgrastim-aafi injection (Nivestym)	Hematological Agents: White Blood Cell Stimulants	• filgrastim (Neupogen) • filgrastim-sndz (Zarxio) • tbo-filgrastim (Granix)	Biosimilar to Neupogen, like Granix and Zarxio	• Nivestym is a new biosimilar formulation of filgrastim. • 6th agent in the white blood cell stimulant subclass. • No new clinical data • Offers no clinically compelling advantages over existing formulary agents.	• NF • Add to EMMPI list
pegfilgrastim-jmdb injection (Fulphila)	Hematological Agents: White Blood Cell Stimulants	• pegfilgrastim (Neulasta, Neulasta OnPro)	Biosimilar to Neulasta	• Fuphila is a new biosimilar formulation of pegfilgrastim. • 7th agent in the white blood cell stimulant subclass. • No new clinical data • No clinically compelling advantages over existing agents.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
fremanezumab-vfrm (Ajovy)	Migraine Agents: CGRP Preventative	• erenumab-aooe (Aimovig) • topiramate IR and ER • galcanezumab-gnlm (Emgality)	Preventive treatment of migraine in adults	• 2nd CGRP inhibitor for chronic and episodic migraine prevention. • Pivotal trials with baseline monthly migraine days < 15 ▪ Difference between fremanezumab and placebo ranged from 1.3 and 1.5 fewer migraine headache days per month. ▪ There was significant placebo effect. • Pivotal trial with baseline headache days > 15 ▪ Difference between fremanezumab and placebo ranged from 1.8 to 2.1 fewer migraine headache days per month. • Botulinum toxin is also approved for chronic migraine. • Ajovy and current preventive therapy (e.g., generic anticonvulsants, beta blockers or antidepressants) decrease the number of migraine days at similar rates of two per month. • Ajovy is approved as 225 mg monthly dose or 675 mg quarterly dose. Trial data showed similar efficacy and safety between both dosing regimens. • ICER concludes that in patients with chronic or episodic migraine who have other treatment options available, cost-effectiveness will likely exceed commonly accepted thresholds. • Current study data showed minor safety issues, but longer duration studies are needed to validate long-term safety and efficacy.	• UF • Do not add to EMMPI list
galcanezumab-gnlm (Emgality)	Migraine Agents: CGRP Preventative	• erenumab-aooe (Aimovig) • topiramate IR and ER • fremanezumab-vfrm (Ajovy)	Preventive treatment of migraine in adults	• 3rd CGRP inhibitor for chronic and episodic migraine prevention. • Pivotal trials with baseline monthly migraine days < 15 ▪ Difference between galcanezumab and placebo ranged from 1.9 and 2.0 fewer migraine headache days per month. ▪ There was significant placebo effect. • Pivotal trial with baseline headache days > 15 ▪ The difference between galcanezumab and placebo was 2.1 fewer migraine headache days per month. • Botulinum toxin is approved for chronic migraine. • Emgality and current preventive therapy (e.g., generic anticonvulsants, beta blockers or antidepressants) decrease the number of migraine days at similar rates of two per month. • Emgality is approved as a 120 mg monthly dose in a pen or syringe. • ICER concludes that in patients with chronic or episodic migraine who have other treatment options available, cost-effectiveness will likely exceed commonly accepted thresholds. • Current study data showed minor safety issues, but longer duration studies are needed to validate long-term safety and efficacy.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
glycopyrronium 2.4% topical cloth (Qbrexza)	Antiperspirants	• aluminum chloride hexahydrate (Drysol 20%, Xerac AC 6.25%) • glycopyrrolate tab • onabotulinum toxin A (Botox)	Primary axillary hyperhidrosis	• New topical formulation of glycopyrronium indicated for primary axillary hyperhidrosis. • Evaluated in two Phase 3 studies in which one study showed a statistically significant decrease in perspiration and the other study did not. • No head-to-head studies with other agents indicated for hyperhidrosis. • Most common adverse effects include dry mouth, mydriasis, oropharyngeal pain, and headache. • Not studied beyond 4 weeks, in pregnancy, breastfeeding, or renal failure. • Provides another treatment option for primary axillary hyperhidrosis.	• UF • Do not add to EMMPI list
ivosidenib (Tibsovo)	Oncological Agents: Acute Myelogenous Leukemia (AML)	• none	AML with IDH1 mutation	• New class known as isocitrate dehydrogenase-1 inhibitor (IDH1) for treatment of AML with the specific IDH1 mutation. • Increases survival in ~40% of patients by ~6 months. • High adverse event rate including QTc prolongation (hERG K^+ channel blocker). • Discontinuation rate is approximately 30%, and the combined discontinuation rate plus dose modification rate is ~50%.	• UF • Do not add to EMMPI list
lanadelumab injection (Takhzyro)	Corticosteroids-Immune Modulators: Hereditary Angioedema Agents (HAE)	• C1-INH (Cinryze) • C1-INH (Haegarda)	For prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older	• Takhzyro is superior to placebo in preventing attacks. • First kallikrein inhibitor and first monocloncal antibody for HAE prophylaxis. • Similar adverse events as other HAE agents with the exception of 60% reporting injection site reactions. • Another option for prophylaxis with indirect comparison showing relatively similar efficacy in attack frequency with othe HAE drugs • Easier to administer compared to IV. • Providers feel Takhzyro could be a first-line treatment for HAE prophylaxis.	• UF • Do not add to EMMPI list
lidocaine 1.8% topical system (ZTlido)	Pain Agents: Pain Topical	• lidocaine 5% patch (Lidoderm, generics)	For relief of pain associated with post-herpetic neuralgia	• New formulation of lidocaine patch. • One ZTlido 1.8% patch provides equivalent lidocaine exposure to one Lidoderm 5% patch. • Different absorption but equivalent area under the curve (AUC) and maximal plasma concentrations (Cmax) as Lidoderm. • No new clinical data to review. • Provides little to no clinical benefit relative to existing formulary agents.	• NF • Add/Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lumacaftor/ ivacaftor (Orkambi granules)	Cystic Fibrosis agents	• lumacaftor/ ivacaftor (Orkambi tablets)	Treatment of CF in patients 2 years and older who are homozygous for the F508del mutation in the CFTR gene	• New oral granule formulation of Orkambi for pediatrics ages 2-5 years. Orkambi tablets are approved for ages ≥ 6 years. • A 24-week, open-label safety and pharmacokinetic study of Orkambi granules in patients 2-5 years found the safety profile was similar to that observed in similar patients ≥ 6 years. • Efficacy was extrapolated from studies of patients ≥ 12 years; population pharmacokinetic analyses showed similar drug exposure levels in patients ≥ 12 years & ages 2-11 years. • Orkambi granules have a niche for pediatric patients < 6 years or those with swallowing difficulty.	• UF • Do not add to EMMPI list
lusutrombopag (Mulpleta)	Hematological Agents: Platelets	• avatrombopag (Doptelet)	Thrombocytopenia associated with chronic liver disease (CLD)	• 4th thrombopoietin indicated for patients with CLD and severe thrombocytopenia 9-14 days prior to a planned procedure. • Most useful for procedures with an intermediate to high bleeding risk.	• UF • Do not add to EMMPI list
metoprolol extended-release (ER) capsules (Kapspargo Sprinkle)	Beta Blockers & HCTZ Combinations	• metoprolol succinate ER tablets • metoprolol tartrate • atenolol	200 mg ER metoprolol for hypertension (HTN), angina pectoris, and heart failure	• 2nd once daily metoprolol succinate ER formulation and 1st "sprinkle" formulation. • Approved via 505(b)(2) for treatment of hypertension (HTN), angina pectoris, and heart failure; no clinical trials conducted • Capsules contain a multitude of controlled release pellets; each coated pellet is a separate drug delivery unit, which releases drug over 24 hours. • Pediatric HTN dosing for ≤ 6 years contained in label (similar to metoprolol succinate ER tabs). • Can open capsules, sprinkle contents into applesauce, pudding, or yogurt, and consume within 1 hour. • Nasogastric administration information in label • Kapspargo provides no advantages compared to generic metoprolol succinate ER other than convenience to patients who cannot take tablets.	• UF • Do not add to EMMPI list
migalastat (Galafold)	Metabolic Agents-Miscellaneous	• agalsidase beta (Fabrazyme) IV infusion	Fabry disease	• 1st FDA-approved oral medication indicated for Fabry disease. • Eevaluated in one study, AT1001, and the primary endpoint was not statistically significant in comparison to placebo. • Fabrazyme and supportive renal care are the only other therapies currently available for Fabry disease. • Galafold currently provides an additional option for the treatment of Fabry disease relative to Fabrazyme.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
Ozenoxacin 1% cream (Xepi)	Antibiotics: Quinolones	• mupirocin ointment • retapamulin ointment	Impetigo	• New non-fluorinated topical quinolone antibiotic indicated for impetigo. • 3rd topical antibiotic option for impetigo (bullous and non-bullous). • Provides additional treatment option for *S. aureus* and *S. pyogenes*, including MRSA which is a bacteria not commonly associated with impetigo. • While Xepi offers an additional option for the treatment of impetigo, alternative formulary agents are available, its use is limited to a single indication, and there is no comparative efficacy data with mupirocin.	• NF • Do not add to EMMPI list
PEG3350/Na ascorbate/NaSO4/a scorbic acid/NaCl/KCl powder packets (Plenvu)	Laxatives-Cathartics-Stool Softeners	• MoviPrep • GoLytely • ClenPiq • OsmoPrep	Bowel cleansing prior to colonoscopy	• Polyethylene glycol (PEG) bowel prep with added ascorbic acid to reduce total volume. • Two packets each mixed with 500 mL water that must be followed with an additional 500 mL. The total volume is 2 L. • Same manufacturer and ingredients as MoviPrep but contains 6-fold more ascorbic acid which allows for 2 L total volume compared to 3 L with MoviPrep. • Lowest-volume PEG solution, 4th low volume bowel prep, and 13th bowel prep regimen available. • Clinical trials showed similar efficacy to MoviPrep and a trisulfate preparation (Suprep). • No clinically compelling advantages over other bowel regimens.	• UF • Do not add to EMMPI list
PEGylated factor VIII (Jivi)	Antihemophilic Factors	• PEGylated Factor VIII (Adynovate)	Hemophilia A	• Jivi is a new formulation of pegylated factor VIII. • 2nd pegylated formulation (extended half-life) and 13th agent in the antihemophilic factor class. • Jivi was studied in an unpublished phase 2/3 multi-center, open-label partially RCT in patients with severe Hemophilia A. • No clinically compelling advantages over formulary agents.	• UF • Do not add to EMMPI list
sodium zirconium cyclosilicate (Lokelma)	Binders-Chelators-Antidotes-Overdose Agents	• patiromer (Veltassa) • sodium polystyrene sulfonate (Kayexalate)	Hyperkalemia	• Lokelma is the 3rd available potassium binder. • Study pool limited and no head-to-head studies with other potassium-lowering agents. • Faster efficacy may not be beneficial. • No known risk of bowel necrosis. • Provides another treatment option for hyperkalemia.	• UF • Do not add to EMMPI list
tildrakizumab-asmn injection (Ilumya)	TIBSs: Non-TNF Inhibitors	• adalimumab (Humira) • secukinumab (Cosentyx) • ustekinumab (Stelara) • guselkumab (Tremfya) • brodalumab (Siliq)	Plaque psoriasis	• Ilumya is the 2nd IL-23 inhibitor for moderate to severe plaque psoriasis and 6th agent in the IL-17/23 subclass. • 17th TIB marketed • Superior efficacy to etanercept; however, no head-to-head trial with appropriate comparator (i.e., Tremfya). • No significant safety concerns. • Provides no additional benefit relative to the other TIBs currently on the formulary.	• NF and non-step-preferred • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tretinoin 0.05% topical lotion (Altreno)	Acne Agents: Topical Acne and Rosacea	tretinoin 0.05% solution, cream, gel	Acne vulgaris	• Altreno is the 11th topical tretinoin. • Whilethe tretinoin lotion formulation is indicated for once daily treatment of acne vulgaris, an alternative topical retinoid combination product, adapalene plus benzoyl peroxide (Epiduo Gel, generics) is also available to treat acne in patient ages 9 years and older. • Multiple other topical retinoids (e.g., tretinoin, tazarotene, adapalene) formulations and strengths are available on the uniform formulary. • This drug offers no other advantages in clinical efficacy relative to existing topical tretinoin formulations on the uniform formulary.	• NF and non-step-preferred • Add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Nonformulary During the November 2018 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Do NOT Add to the Mail Order Requirement (Excepted from Mail Order Requirement)
November 2018	**Gastrointestinal-2 Agents: CIC/IBS-C and Miscellaneous** Add the following UF drugs to the EMMPI ▪ linaclotide (Linzess) ▪ plecanatide (Trulance) ▪ lubiprostone (Amitiza) ▪ rifaximin 550 mg (Xifaxan) ▪ eluxadoline (Viberzi) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** ▪ adapalene 0.1% solution ▪ adapalene 0.1% external pad (Plixda) ▪ doxycycline monohydrate (Okebo) ▪ elagolix (Orilissa) ▪ filgrastim-aafi (Nivestym) ▪ lidocaine 1.8% topical system (ZTlido) ▪ minocycline ER (Minolira) ▪ tildrakizumab (Ilumya) ▪ tretinoin 0.05% topical lotion (Altreno)	**Gastrointestinal-2 Agents: CIC/IBS-C and Miscellaneous** ▪ nitazoxanide (Alinia) ▪ fidaxomicin (Dificid) ▪ rifaximin 200 mg (Xifaxan) **Neurological Agents Miscellaneous: Movement Disorders** ▪ deutetrabenazine (Austedo) ▪ valbenazine (Ingrezza) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** Acute use exception applies: ▪ butalbital/acetaminophen 50 mg/300 mg capsules ▪ ozenoxacin (Xepi) Do not add pending more information about availability at mail order: ▪ Amikacin liposome suspension for inhalation (Arikayce)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2018	**Gastro-intestinal-2 Agents: CIC/IBS-C Subclass and Miscellaneous Subclass**	UF Class Review Class previously reviewed in Nov 2015, Nov 2012, Feb 2011	▪ metronidazole 250mg and 500mg (Nov 2015)	<u>IBS-C/CIC Subclass</u> ▪ lubiprostone (Amitiza) ▪ linaclotide (Linzess) ▪ plecanatide (Trulance) <u>GI-Miscellaneous Subclass</u> ▪ rifaximin (Xifaxan) ▪ eluxadoline (Viberzi) ▪ alosetron (Lotronex, generic) ▪ nitazoxanide (Alinia) ▪ fidaxomicin (Dificid) ▪ vancomycin oral (generics) ▪ neomycin (generics) ▪ metronidazole (Flagyl, generic)	▪ None	Pending signing of the minutes / 90 days The effective date is May 15, 2019.	▪ Manual PA required for linaclotide, lubiprostone, plecanatide, rifaximin, and eluxadoline. ▪ QLs apply for rifaximin 550mg	▪ Eluxadoline (Viberzi) and plecanatide (Trulance) moved from NF to UF ▪ PA criteria added for linaclotide (Linzess) and lubiprostone (Amitiza) ▪ No preferred agent within the CIC/IBS-C subclass ▪ No preferred agent among the IBS-D agents ▪ See Appendix C for PA criteria.
Nov 2018	**Neurological Agents Miscellaneous – Movement Disorders Subclass**	UF Class Review	▪ None	▪ deutetrabenazine (Austedo) ▪ tetrabenazine (Xenazine, generics) ▪ valbenazine (Ingrezza)	▪ None	30 days after signing of the minutes The effective date is March 6, 2019.	▪ Manual PA criteria applies to all new users for deutetrabenazine (Austedo) and valbenazine (Ingrezza). ▪ QLs apply to both Austedo and Ingrezza	▪ See Appendix C for PA criteria.

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

Appendix H—Table of Abbreviations

AAN	American Academy of Neurology
ACG	American College of Gastroenterology
ADHD	Attention Deficit Hyperactivity Disorder
AE	adverse event
AGAI	American Gastroenterological Association Institute
AIDS	acquired immunodeficiency syndrome
AIMS	Abnormal Involuntary Movement Scale
ALT	alanine aminotransferase
AML	Acute Myelogenous Leukemia
AS	ankylosing spondylitis
AST	aspartate aminotransferase
BBW	black box warning
BCF	Basic Core Formulary
BIA	budget impact analysis
CAP	chronic abdominal pain
CAPS	Cryoprin Associated Period Syndrome
CD	Crohn's Disease
CDC	Centers for Disease Control and Prevention
CF	cystic fibrosis
CFR	Code of Federal Regulations
CFTR	cystic fibrosis transmembrane conductor regulator
CGIC	Clinical Global Impression of Change
CGRP	calcitonin gene-related peptide
CHF	congestive heart failure
CIC	chronic idiopathic constipation
CLD	chronic liver disease
CLL	chronic lymphocytic leukemia
CMA	cost minimization analysis
CMV	cytomegalovirus
CR	controlled release
CSBM	complete spontaneous bowel movement
CV	cardiovascular
CYP	cytochrome P450
DAPA	Distribution and Pricing Agreement
DHA	Defense Health Agency
DMARD	disease-modifying anti-rheumatic drug
DoD	Department of Defense
DR	delayed release
DRESS	Drug reaction with eosinophilia and systemic symptoms
ECF	Extended Core Formulary
EGFR	epidermal growth factor receptor
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER	extended release
FDA	U.S. Food and Drug Administration
FDB	First DataBank
FEV_1	forced expiratory volume in one second

FL	follicular lymphoma
FMB	Formulary Management Branch
FY	fiscal year
GCA	giant cell arthritis
GI	gastrointestinal
GLA	galactosidase alpha
GnRH	gonadotropin-releasing hormone
GSA	growth stimulating agent
HAE	hereditary angioedema
HCG	Human Chorionic Gonadotropin
HCTZ	hydrochlorothiazide
Hgb	hemoglobin
HIV	human immunodeficiency virus
HS	hidradenitis suppurativa
HTN	hypertension
IBS-C	constipation-predominant irritable bowel syndrome
IBS-D	diarrhea-predominant irritable bowel syndrome
ICER	Institute for Clinical and Economic Review
IDH1	isocitrate dehydrogenase-1 inhibitor
IR	immediate release
ISGA	Investigator's Static Global Assessment
ITI	Immune Tolerance Induction
IV	intravenous
JIA	juvenile idiopathic arthritis
MAC	Mycobacterium avium complex
MAOI	monoamine oxidase inhibitor
MEK	mitogen-activated extracellular signal regulated kinase
Mg	magnesium
MHS	Military Health System
MMD	monthly migraine days
MMSE	mini-mental state examination
MN	medical necessity
MRSA	Methicillin-resistant Staphylococcus aureus
MTF	Military Treatment Facility
NAFLD	non-alcoholic fatty liver disease
NASH	non-alcoholic steatohepatitis
NDAA	National Defense Authorization Act
NDC	National Drug Code
NF	nonformulary
NG	nasogastric
NICE	National Institute for Health and Care Excellence
NNRTI	non-nucleoside reverse transcriptase inhibitor
NOMID	Neonatal-Onset Multisystem Inflammatory Disease
NRTI	nucleoside reverse transcriptase inhibitor
NSAID	nonsteroidal anti-inflammatory drug
NSCLC	non-small cell lung cancer
OIC	opioid-induced constipation

OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PDE-5	phosphodiesterase-5
PDTS	Pharmacy Data Transaction Service
PEG	polyethylene glycol
PERT	Pancreatic Enzymes Replacement Therapy drug class
PGIC	Patient's Global Impression of Change
PI	protease inhibitor
PI3K	phosphatidylinositol 3-kinase
PJIA	polyarticular juvenile idiopathic arthritis
PJP	*Pneumocystis jiroveci* pneumonia
POD	Pharmacy Operations Division
POS	point of service
PsA	psoriatic arthritis
PT	patient
QL	quantity limit
RA	Rheumatoid arthritis
RCT	randomized controlled trial
REMS	Risk Evaluation and Mitigation Strategies
RS	rectal suppositories
SBP	spontaneous bacterial peritonitis
SIB	suicidal ideation and behavior
SIBO	small intestinal bacterial overgrowth
SJIA	systemic juvenile idiopathic arthritis
SLL	small lymphocytic lymphoma
SMBG	self-monitoring blood glucose system
SQ	subcutaneous
STR	single-tablet regimen
TAF	tenofovir alafenamide fumarate
TB	tuberculosis
TCA	tricyclic antidepressant
TD	tardive dyskinesia
TDF	tenofovir disoproxil fumarate
TIBs	targeted immunomodulatory biologics
TIRF	transmucosal immediate release fentanyl
TNF	tumor necrosis factor
UC	Ulcerative colitis
UF	Uniform Formulary
ULN	upper limit normal
VMAT2	vesicular monoamine transporter type 2
WGO	World Gastroenterology Organization
XR	extended release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2018

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 8 and 9, 2018, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May 2018 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the May 2018 DoD P&T Committee meeting on August 6, 2018.

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

A. Corticosteroids-Immune Modulators: Atopic Dermatitis Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the atopic dermatitis subclass, which has not been previously reviewed for formulary placement. The products in the subclass include tacrolimus 0.03% and 0.01% ointment (Protopic, generics), pimecrolimus 1% cream (Elidel), crisaborole 2% ointment (Eucrisa), and dupilumab injection (Dupixent). Other drugs used for treating atopic dermatitis, such as topical corticosteroids and systemic immunomodulatory agents were not included in this review.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

Professional Treatment Guidelines for Atopic Dermatitis

- The American Academy of Dermatology (AAD) 2014 guidelines recommend topical emollients as the basis for atopic dermatitis therapy. When additional intervention is required, topical corticosteroids are considered first-line therapies for mild to severe atopic dermatitis, while topical calcineurin inhibitors (pimecrolimus and tacrolimus) are considered second-line after topical corticosteroids.
- Concerns regarding adverse effects with topical corticosteroids include adrenal suppression, striae, and skin atrophy. Evidence from large systematic reviews show that mild to moderate potency corticosteroids pose little to no risk to patients when used appropriately. However, "steroid phobia" can affect patient compliance.
- For severe to uncontrolled atopic dermatitis, systemic therapies are options and include cyclosporine, azathioprine, mycophenolate, and methotrexate.
- The AAD 2017 consensus statement regarding the utilization of systemic therapy in patients with moderate to severe atopic dermatitis recommended use of topical treatments and phototherapy, prior to systemic therapy. Overall, no one therapy was preferred over the others, and individual patient factors should guide treatment selection.
- Crisaborole and dupilumab are not yet mentioned in the AAD guidelines.

Topical Calcineurin Inhibitors (TCIs): pimecrolimus and tacrolimus

- Pimecrolimus (Elidel) is FDA-approved for treating mild to moderate atopic dermatitis, while tacrolimus (Protopic) is approved for moderate to severe atopic dermatitis. Both drugs are approved for use in children as young as .two years of age.
- A 2016 AAD meta-analysis concluded that the TCIs and topical corticosteroids show similar rates of improvement of dermatitis and treatment success, but TCIs are associated with a higher incidence of adverse events including skin burning and pruritus on application.
- A 2007 Cochrane review reported moderate- to high-potency corticosteroids and tacrolimus 0.1% were more effective than pimecrolimus.. Similar results were reported in a 2015 Cochrane review that concluded tacrolimus 0.1% was more effective than low-potency corticosteroids, pimecrolimus 1%, and tacrolimus 0.03%.
- The product labeling for TCIs contain a black box warning for rare case reports of malignancy. A study published in JAMA Dermatology (2015) evaluated rates of cancer in over 7,400 pediatric pimecrolimus users. The authors concluded it was unlikely that pimecrolimus was associated with an increased risk of malignancy. No skin-related cancers were reported.

Topical Phosphodiesterase (PDE)-4 inhibitor: crisaborole (Eucrisa)

- Crisaborole (Eucrisa) is a non-steroidal phosphodiesterase (PDE)-4 inhibitor indicated for patients as young as 2 years of age with mild to moderate atopic dermatitis. In the two controlled trials used for FDA approval, crisaborole treatment resulted in statistically significant improvement in atopic dermatitis signs and symptoms, compared to placebo vehicle. Although the results were statistically significant, they were clinically modest at best. There are no trials available comparing crisaborole with topical corticosteroids or the TCIs.
- The 2017 Institute for Clinical and Economic Review (ICER) review of crisaborole noted that there is not an agreed-upon definition of "mild-to-moderate" or "moderate-to-severe" atopic dermatitis. ICER also concluded that for patients with mild to moderate atopic dermatitis, there is inadequate evidence on both the relative efficacy and safety of crisaborole compared to other treatment options.
- Common side effects for crisaborole are burning and itching on application.
- Overall, despite the novel mechanism of action, crisaborole has no compelling advantages over the current formulary drugs used for atopic dermatitis.

Systemic therapy: dupilumab injection (Dupixent)

- Dupilumab is an interleukin-4/interleukin-13 antagonist monoclonal antibody indicated for moderate to severe atopic dermatitis that is not adequately controlled with topical prescription therapies. The 2017 ICER review concluded there was high certainty that dupilumab provides at least a small net health benefit relative to treatment with emollients, with or without continued failed topical treatments. Additionally, there was moderate certainty that the net health benefit of dupilumab is comparable or better than that provided by cyclosporine.
- Limitations to dupilumab include the lack of comparative trials with standard systemic treatments, the lack of long-term safety data, and the fact that it is only approved in adults. Pediatric trials are ongoing.
- The most common side effects for dupilumab are injection-site reactions and conjunctivitis.
- Dupilumab has fewer known side effects and monitoring requirements compared to azathioprine, cyclosporine, methotrexate, and mycophenolate.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the atopic dermatitis agents. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic tacrolimus was the most cost-effective atopic dermatitis drug, followed by pimecrolimus (Elidel), branded tacrolimus (Protopic), crisaborole ointment (Eucrisa), and dupilumab injection (Dupixent).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating pimecrolimus (Elidel),

tacrolimus, and dupilumab (Dupixent) as formulary, with crisaborole (Eucrisa) as NF demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) maintaining the current formulary status of the atopic dermatitis drugs, as outlined below, based on clinical and cost effectiveness:

    - UF
        - pimecrolimus (Elidel)
        - dupilumab (Dupixent)
        - tacrolimus (Protopic, generics)
    - NF
        - crisaborole (Eucrisa)

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) maintaining pimecrolimus 1% on the BCF, due to existing high utilization in the MHS, and availability in a cream formulation. The Committee also recommended adding generic tacrolimus 0.03% and 0.1% ointment to the BCF, based on cost effectiveness.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—Manual PA criteria for both crisaborole ointment and dupilumab injection were recommended at the May 2017 P&T Committee meeting. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) updating the current PA criteria for dupilumab (Dupixent), to require a trial of phototherapy, if feasible, in all new users, due to the AAD 2017 consensus statement on systemic therapies. The Committee also recommended maintaining the current manual PA criteria for crisaborole (Eucrisa), which requires a two-week trial of at least two formulary medium to high potency topical corticosteroids or a TCI first. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) maintaining the current MN criteria for crisaborole (Eucrisa). See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for crisaborole (Eucrisa) and dupilumab (Dupixent) injection. See Appendix B.

6. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) maintaining dupilumab (Dupixent) on the EMMPI program, and also reaffirmed that there was no reason to exempt crisaborole (Eucrisa), from the mail order requirement. See Appendix F.

7. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR THE ATOPIC DERMATITIS DRUGS***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) excluding pimecrolimus, tacrolimus, crisaborole, and dupilumab from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, due to the fluctuating disease course of atopic dermatitis, and due to the high cost of dupilumab.

8. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service Based on the P&T Committee's recommendation, the effective date is November 21, 2018.

B. Hepatitis C Virus (HCV) Direct-Acting Antivirals (DAAs) Subclass

Background—The HCV DAAs subclass has previously been reviewed for formulary placement three times, most recently in February 2017. Two products, glecaprevir/pibrentasvir (Mavyret) and sofosbuvir/velpatasvir/voxilaprevir (Vosevi), were reviewed as new drugs at the November 2017 P&T Committee meeting. Since the last review, simplification of HCV treatment has occurred, including introduction of additional regimens lasting only 8 weeks, FDA approval of additional single-tablet regimens, and the availability of additional pangenotypic therapies.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- There were no major changes to the clinical effectiveness conclusion from the February 2017 meeting.
- The first-line HCV DAAs are Epclusa, Harvoni, and Mavyret.
- Advantages of Harvoni include approval for treatment courses as short as 8 weeks in treatment-naïve patients with HCV genotype (GT) 1, availability as a single table dosed once daily, and approval for use in patients with decompensated cirrhosis. Patients with GT 4, 5, and 6 require 12-week treatment courses. Harvoni should remain designated as UF, due to existing high utilization in DoD, provider familiarity, and the fact that the majority of MHS patients with HCV have GT 1.
- Advantages of Epclusa include that it was the first pangenotypic HCV DAA marketed, it is dosed as a single tablet once daily, and has an improved resistance profile. It

remains an option of HCV therapy for treatment-naïve patients, but requires a 12-week course of therapy. It can be used in patients with decompensated cirrhosis.

- Mavyret was the third pangenotypic HCV DAA to receive FDA approval. It provides an 8-week course of therapy in treatment-naïve patients and treatment-experienced patients who do not have cirrhosis. Mavyret can also be used in patients with moderate to severe renal disease, including those on dialysis. It is dosed as three tablets once daily, and must be given with food.
- Vosevi was the second pangenotypic HCV DAA approved. It is reserved for use in treatment-experienced patients, and fills a unique niche for this population. It is dosed as a single tablet once daily for 12 weeks in most patients. It is not indicated for patients with moderate to severe renal dysfunction, including those with end stage renal disease (ESRD).
- Daklinza, Olysio, Sovaldi, and Zepatier are no longer the standard of care for HCV, due to their longer treatment courses, limited genotype coverage, unfavorable tolerability and toxicity profiles, and/or higher pill burden.
- In the absence of head-to-head trials with all the DAAs, HCV treatment is based on individual patient characteristics, such as the HCV genotype and subtype, treatment history, stage of hepatic fibrosis, presence or absence of resistance-associated variants, comorbidities, concomitant medications, and cost.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the HCV DAA agents. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that glecaprevir/pibrentasvir (Mavyret), velpatasvir/sofosbuvir (Epclusa), and ledipasvir/sofosbuvir (Harvoni) were the most cost-effective HCV DAAs, followed by grazoprevir/elbasvir (Zepatier), paritaprevir/ritonavir/ombitasvir (Technivie), paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira Pak and Viekira XR), sofosbuvir/velpatasvir/voxilaprevir (Vosevi), daclatasvir (Daklinza), and sofosbuvir (Sovaldi).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Mavyret, Epclusa, Harvoni, Technivie, Viekira, Viekira XR, and Vosevi as formulary, and Daklinza, Olysio, Sovaldi, and Zepatier as NF demonstrated the largest cost avoidance for the MHS.

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

    - UF
        - sofosbuvir/velpatasvir (Epclusa)
        - ledipasvir/sofosbuvir (Harvoni)

- glecaprevir/pibrentasvir (Mavyret)
- paritaprevir/ritonavir/ombitasvir (Technivie)
- paritaprevir/ritonavir/ombitasvir/dasabuvir tablets pak (Viekira Pak)
- paritaprevir/ritonavir/ombitasvir/dasabuvir XR tablets (Viekira XR)
- sofosbuvir/velpatasvir/voxilaprevir (Vosevi)

- NF
  - daclatasvir (Daklinza)
  - simeprevir (Olysio)
  - sofosbuvir (Sovaldi)
  - grazoprevir/elbasvir (Zepatier)

- Note that as part of this recommendation, the current requirement for a trial of Harvoni prior to another HCV DAA ("step therapy") has been removed. Additionally, no HCV DAA products were recommended for Extended Core Formulary (ECF) addition. For the HCV drug class, ribavirin 200 mg capsules and peginterferon alfa-2a (Pegasys) were designated ECF in November 2012.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Manual PA criteria is currently required for all the HCV DAAs, including the use of Harvoni as the step-preferred product. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) revising the manual PA criteria for new users of Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira XR, Viekira Pak, and Zepatier, to remove the Harvoni step therapy requirement, and simplify the PA criteria by having these drugs on the same PA form.

   Additionally, the P&T Committee recommended maintaining separate PA criteria for Vosevi, since it is reserved for treatment-experienced patients. Minor updates to the Vosevi PA criteria were also recommended for new users, including removal of the Harvoni step. Coverage for any HCV DAA is only allowed for the FDA-approved indications or as outlined in the American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD/IDSA) HCV guidelines (www.HCVguidelines.org). See Appendix C for full criteria.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Daklinza, Olysio, Sovaldi, and Zepatier. See Appendix B.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***QLs currently apply to all the HCV DAAs. The P&T Committee recommended (14 for, 0 opposed,

0 abstained, 0 absent) maintaining the current QL of a 28-day supply for all the HCV DAAs, consistent with current manufacturer packaging. See Appendix D.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) that the HCV DAAs were not suitable for the EMMPI program, as they are administered for a limited duration (8-12 weeks). The P&T Committee also agreed that the HCV DAAs recommended for NF status be exempted from the requirement that NF agents generally be available only at mail order. See Appendix F.

6. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service, 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 January 2, 2019.

V. RE-EXAMINATION OF CLINICAL CONCLUSION FROM PREVIOUS UF DRUG CLASS REVIEWS

Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones (ACTH) Subclass

Background—The P&T Committee previously evaluated the ACTH subclass at the February 2018 meeting. The ACTH subclass is comprised solely of injectable corticotropin (H.P. Acthar Gel). The Committee designated H.P. Acthar with UF status, with manual PA allowing use exclusively for infantile spasms or exacerbation of multiple sclerosis (MS) and only after failure of or intolerance to a course of corticosteroids.

at this meeting the P&T Committee reviewed additional information received from providers and the FDA as it relates to the clinical effectiveness and safety of H.P. Acthar. There was no change to the cost effectiveness conclusion, Uniform Formulary recommendation, or PA criteria from the February 2018 P&T Committee meeting.

A comprehensive review of the evidence for H.P. Acthar Gel's efficacy for infantile spasms, multiple sclerosis exacerbation, other uses, and safety and tolerability across all indications and usages was performed for the February 2018 P&T Committee meeting. That comprehensive body of evidence guided the P&T's decision-making in that meeting.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 0 absent) the following for H.P. Acthar Gel:

- Infantile Spasms

- New information was presented that reaffirms and strengthens the clinical conclusions reached by the P&T Committee at the February 2018 meeting, including the following:
    - Patients with infantile spasms require urgent treatment that is better facilitated by oral corticosteroids, which are widely available, rather than the administratively burdensome H.P. Acthar Gel due to the limited distribution requirements by the manufacturer.
    - High-dose oral corticosteroids were reaffirmed as a frontline treatment alongside H.P. Acthar Gel and vigabatrin (Sabril).

- MS Exacerbation
    - Fundamentals of inflammation were reviewed, reaffirming the appropriateness of the requirement that patients try and fail the safer and more effective corticosteroid treatment option prior to approval of H.P. Acthar Gel for each multiple sclerosis exacerbation.
- Other Uses
    - There was no new data to support changing the original recommendation that uses other than infantile spasms and MS exacerbation be excluded from TRICARE coverage.[1]
- Safety
    - No new information was presented that helped allay the concerns of the Committee regarding the safety profile of the H.P. Acthar Gel. New data however, did cause the Committee to have more safety concerns than previously concluded.
- Other Factors
    - A review of coverage of H.P. Acthar Gel by several commercial health care plans performed for the February 2018 P&T Committee meeting found significant limitations or outright exclusions of H.P. Acthar Gel.
    - For the August 2018 meeting, the P&T Committee reviewed an update to several national health care plans and health systems' coverage policies. Of the 50 pharmacy benefit managers (PBMs) reviewed in the update, 9 health care plans did not cover H.P. Acthar Gel for any indication for their respective beneficiaries.
    - Several prominent health care plans and health systems require a trial of oral corticosteroids prior to using H.P. Acthar Gel for infantile spasms. These include Intermountain Health System in Utah and leading Academic Centers of Excellence in Pediatric Neurology, such as Johns Hopkins and UCLA.
    - The P&T Committee reviewed prior decisions in other drug classes where the recommendation was to require a trial of a drug lacking FDA approval for a

[1] As with any drug, an appeal is available for an eligible covered beneficiary or network or uniformed provider on behalf of the beneficiary to establish clinical justification for the use of a pharmaceutical agent that is not on the Uniform Formulary. See 10 U.S.C. § 1074g.

particular diagnosis prior to use of a drug that carries FDA approval for that particular diagnosis. One example is that patients with Duchenne's Muscular Dystrophy are required to try or have intolerance to prednisone prior to using deflazacort (Emflaza) [February 2017 DoD P&T Committee Meeting].

- Overall, the Committee evaluated the additional information presented and agreed that no new evidence was presented that would change the clinical conclusions reached by the P&T Committee at the February 2018 meeting. In fact, additional information for treatment of infantile spasms further confirmed the appropriateness of a trial of corticosteroids and the importance of early treatment, before using H.P. Acthar Gel. Additional safety concerns for H.P. Acthar Gel were raised by the new information. No changes to the existing manual PA criteria for H.P. Acthar Gel were recommended.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent; and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 2018 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
    - abiraterone acetate micronized (Yonsa) – Oral Oncologic Agent for Prostate Cancer
    - avatrombopag (Doptelet) – Hematological Agent: Platelets for Thrombocytopenia in Chronic Liver Disease
    - baricitinib (Olumiant) – Targeted Immunomodulatory Biologic (TIB) for Rheumatoid Arthritis
    - binimetinib (Mektovi) – Oral Oncologic Agent for Metastatic Melanoma
    - encorafenib (Braftovi) – Oral Oncologic Agent for Metastatic Melanoma
    - epoetin-alfa-epbx (Retacrit) injection – Hematological Agent: Red Blood Cell Stimulant for Erythropoiesis
    - erenumab-aooe (Aimovig) injection – Migraine Agent (calcitonin gene-related peptide [CGRP]) for Migraine Headache Prophylaxis
    - fostamatinib (Tavalisse) – Hematological Agent: Platelets for Chronic Immune Thrombocytopenia
    - hydroxyurea (Siklos) tablets – Hematological Agent: Sickle Cell Anemia Agent for Pediatrics
    - pegvaliase-pqpz (Palynziq) injection – Miscellaneous Metabolic Agent for Phenylketonuria

- tolvaptan (Jynarque) – Miscellaneous Nephrology Agent for Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)

- NF:
  - amantadine extended release tablets (Osmolex ER) – Parkinson's Agent
  - estradiol (Imvexxy) vaginal insert – Miscellaneous Gynecological Agent for Dyspareunia
  - levonorgestrel/ethinyl estradiol/ferrous (Balcoltra) – Oral Combined Contraceptive Agent
  - lofexidine (Lucemyra) – Alpha 2 Antagonist for Mitigation of Symptoms of Opioid Withdrawal
  - oxycodone IR (Roxybond) – Narcotic Analgesic Abuse Deterrent Formulation for Pain

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Osmolex ER, Imvexxy, Balcoltra, Lucemyra, and Roxybond. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent; and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Applying manual PA criteria to new users of Yonsa, Osmolex ER, Doptelet, Olumiant, Imvexxy, Mektovi, Braftovi, Lucemyra, Aimovig, Siklos, and Palynziq.
- Applying manual PA criteria to new and current users of Tavalisse and Jynarque.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent; and group 2: 13 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after signing of the minutes in all points of service.

VII. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications and drug shortages. The updated manual PAs outlined below will apply to new users.

a) **Epinephrine Auto-Injectors: Auvi-Q Temporary Removal of Manual PA Criteria—**The Auvi-Q device includes audible voice instructions and has a needle that automatically retracts following injection. Manual PA criteria were previously recommended for all epinephrine auto-injectors, including Epi-Pen, generic epinephrine auto-injectors, and Auvi-Q, at the February 2017 P&T Committee meeting. The PA requirements for Epi-Pen were administratively removed on May 23, 2018, due to a national shortage. There have been continued shortages of Epi-Pen, and intermittent availability of generic epinephrine auto-injectors.

   Although Auvi-Q is significantly more expensive than Epi-Pen, the manual PA requirements for Auvi-Q will be temporarily lifted, but re-instated administratively when the supply of Epi-Pen and generic epinephrine auto-injectors has stabilized. The Committee acknowledged, however, that it is doubtful that the current Auvi-Q supply will support the volume required to replace Epi-Pen.

b) **Renin Angiotensin Antihypertensive Agents (RAAs): candesartan and candesartan/HCTZ Step-Therapy—**Step therapy in the RAAs class requires a trial of losartan, telmisartan, valsartan, or irbesartan, or their respective combinations with hydrochlorothiazide (HCTZ), prior to use of non-step-preferred angiotensin receptor blockers (ARBs). Two ARBs, candesartan and irbesartan, are approved for treating heart failure with reduced ejection fraction (HFrEF), in addition to hypertension. Candesartan and candesartan/HCTZ are currently designated as UF but non-step-preferred.

   There is currently a national recall of valsartan, due to contamination with a carcinogen. There is no immediate risk to patients currently taking valsartan. However, availability of valsartan lots not affected by the recall are in limited supply, and it remains uncertain as to when the shortage will be resolved.

   A group of MHS cardiologists has requested removing the step therapy requirement for candesartan, due to the valsartan recall. Cost-effective formulations of candesartan and candesartan/HCTZ are now available. Candesartan and candesartan/HCTZ will now be designated as step-preferred, with the step therapy criteria and medical necessity criteria for the remaining non-step-preferred RAAs updated accordingly.

c) **Oncological Agents for unresectable or metastatic melanoma: dabrafenib (Tafinlar), trametinib (Mekinist), and vemurafenib (Zelboraf) Manual PA criteria—**These drugs are approved for treating unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. They are exclusively used in unique pair combinations of a specific BRAF drug with a specific mitogen-activated extracellular signal regulated kinase (MEK) inhibitor. Due to the risk of enhanced toxicity if other combinations of BRAF with MEK inhibitors are administered together, the PA criteria were updated to prevent the use of concurrent therapies outside of the FDA-approved combination.

Criteria were also updated for dabrafenib (Tafinlar) and trametinib (Mekinist) to include the new FDA-approved indication for combination use for locally advanced or metastatic anaplastic thyroid cancer without satisfactory locoregional treatment options.

d) **Oncological Agents: Prostate II - enzalutamide (Xtandi)—**In August 2012, manual PA criteria were recommended for Xtandi. PA criteria were updated in February 2015 to remove the co-administration requirement of docetaxel. Xtandi is now FDA-approved for treatment of castration-resistant prostate cancer, and does not require the presence of metastatic disease. Additionally, the PA criteria were also updated to include new product labeling that requires the patient receive concomitant therapy with a gonadotropin-releasing hormone (GnRH) analog, or have had bilateral orchiectomy.

e) **Targeted Immunomodulatory Biologics (TIBs): Tofacitinib (Xeljanz/Xeljanz XR)—**The TIBs were reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Xeljanz was originally approved for treating rheumatoid arthritis. In February 2018, PA criteria were updated to add the indication for active psoriatic arthritis in adults. The PA criteria were further expanded to include a new FDA-approved indication of ulcerative colitis.

1. ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA***—The P&T Committee recommended the following: (See Appendix C for the full criteria.)

    - (12 for, 0 opposed, 0 abstained, 2 absent) to temporarily remove the manual PA criteria for Auvi-Q, until adequate supply of the Epi-Pen auto-injector has been established.

    - (14 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria and step therapy for candesartan and candesartan/HCTZ.

    - (13 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Tafinlar, Mekinist, Zelboraf, Xeljanz/Xeljanz XR, and Xtandi.

B. QLs

QLs were reviewed for nine drugs from drug classes where there are existing QLs, including the oncologic agents, inhaled corticosteroids, and TIBs. QLs were also discussed for five drugs where QLs are not currently in place, including recommendations for QLs for Cordran Tape, due to a recent significant increase in cost. QLs were removed from three products.

1. ***COMMITTEE ACTION: QLs*—**The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 1 absent) QLs for Stelara, Olumiant, Yonsa, Imbruvica tablets, Braftovi, Mektovi, Aimovig, Lucemyra, Tavalisse, QVAR, QVAR RediHaler, Jynarque, Doptelet, Palynziq, and Cordran Tape. The P&T Committee also recommended removing the QLs from ondansetron tablets and orally disintegrating tablets (Zofran and Zofran ODT) and the oral contraceptive, Jolessa, due to the availability of cost-effective generic formulations for these products. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

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

    - (12 for, 0 opposed, 0 abstained, 2 absent) and (14 for, 0 opposed, 0 abstained, 0 absent) To administratively implement the removal of manual PA requirements for Auvi-Q and to designate candesartan and candesartan/HCTZ as step-preferred.
    - (13 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PAs for Tafinlar, Mekinist, Zelboraf, Xeljanz, Xeljanz XR, and Xtandi become effective on the first Wednesday two weeks after the signing of the minutes.
    - (13 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 14 drugs listed in section VII, B, above, and in Appendix D, become effective on the first Wednesday two weeks after the signing of the minutes in all POS.

VIII. LINE EXTENSIONS

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

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (13 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following three products to reflect the current formulary status and applicable step therapy, PA criteria, MN criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- Basal Insulin Analogs—insulin glargine 900 U/mL (Toujeo Max SoloStar pen). This new concentrated formulation contains 900 units of insulin glargine and provides up to 160 units/mL of glargine in a single injection. Insulin glargine 300 U/mL (Toujeo SoloStar pen) is currently designated as UF and non-step-preferred, requiring a trial of insulin glargine 100 U/mL (Lantus) first. The

P&T Committee recommended designating Toujeo Max SoloStar as UF and non-step-preferred, with the same step therapy and manual PA requirements as Toujeo SoloStar pen. Toujeo Max SoloStar pen will also be added to the EMMPI list.

- TIBs—sarilumab (Kevzara) pen is designated as NF and non-step-preferred, with the same MN, PA, and QLs as the Kevzara pre-filled syringe parent agent. There is no reason to exempt Kevzara pen from the EMMPI list. See Appendix D for the QLs.

- TIBs—adalimumab (Humira) is now available in several new formulations, including a starter pen for pediatric Crohn's disease and a pen for psoriasis. These new Humira formulations will be designated as UF and step-preferred, with the same manual PA requirements, and appropriate QLs as Humira. These formulations will also be added to the EMMPI list. See Appendix D for the QLs.

IX. BCF ADDITION—ULIPRISTAL ACETATE (ELLA)

The Committee received an MTF request to consider adding the emergency contraceptive ulipristal acetate (Ella) to the BCF. Ella was originally designated UF at the August 2011 meeting, while levonorgestrel (Plan B One Step) was designated with BCF status in May 2013. Ella is available via a prescription, while Plan B One Step is available without a prescription at MTF and retail pharmacies. The formulary status change was requested in order to allow for availability of an alternative emergency contraceptive with a wider window of efficacy than Plan B One Step.

There was no compelling new data to change the clinical conclusions from the most recent emergency contraceptive drug class review presented at the August 2016 P&T meeting. An updated cost analysis did show that Ella is more cost-effective than Plan B One Step. Based on the provider request and updated cost information, Ella was recommended for BCF addition. Plan B One Step will also remain on the BCF.

A. ***COMMITTEE ACTION: ULIPRISTAL (ELLA) BCF ADDITION***—The P&T Committee recommended (11 for, 1 opposed, 1 abstained, 1 absent) adding ulipristal acetate (Ella) to the BCF. Note that Plan B One Step will remain on the BCF.

B. ***COMMITTEE ACTION: ULIPRISTAL (ELLA) QLs:*** The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) maintaining the current QLs for Ella of one tablet per prescription.

C. ***COMMITTEE ACTION: ULIPRISTAL (ELLA) IMPLEMENTATION:*** The P&T Committee recommended (12 for, 0 opposed, 1 abstained, 1 absent) implementation upon signing of the minutes for the BCF addition of Ella.

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

See Appendix F for the mail order status of medications designated NF during the August 2018 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the August 2018 meeting, including the newly approved drugs affected by the EMMPI, will be effective upon the first Wednesday after the signing of the minutes.

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

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

   The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent; and group 2: 13 for, 0 opposed, 0 abstained, 1 absent):

   a) **Add**: baricitinib (Olumiant) and epoetin alfa-epbx injection (Retacrit); products in these classes have already been designated as suitable for addition to the EMMPI program. In addition, add erenumab-aooe injection (Aimovig), which is used for migraine prophylaxis.

   b) **Do Not Add:** the oral oncology agents binimetinib (Mektovi), encorafenib (Braftovi), and abiraterone acetate (Yonsa); the sickle cell agent hydroxyurea (Siklos), fostamatinib (Tavalisse), for chronic immune thrombocytopenia; pegvaliase-pqpz injection (Palynziq), for phenylketonuria, and tolvaptan (Jynarque), for rapidly progressing autosomal dominant polycystic kidney disease. It is not yet clear if these agents will be feasible to provide through mail order. In addition, do not add avatrombopag (Doptelet), which is approved for treatment of thrombocytopenia in adult patients with chronic liver disease scheduled to undergo a procedure, as it is used for a limited duration only (5 days).

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

   The P&T Committee recommended (group 1 and group 3: 14 for, 0 opposed, 0 abstained, 0 absent; and group 2: 13 for, 0 opposed, 0 abstained, 1 absent):

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: the Parkinson's disease agent amantadine ER (Osmolex ER) and estradiol vaginal insert (Imvexxy) for dyspareunia.

b) **Do Not Add:** The P&T Committee recommended exceptions from the mail order requirement for the following medications: levonorgestrel/ethinyl estradiol/iron (Balcoltra), due to the existing exception for contraceptives; oxycodone IR (Roxybond), due to the existing exception for C-II agents; and lofexidine (Lucemyra), which is used for a limited time period for opioid withdrawal.

3. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR ESTRADIOL (IMVEXXY) VAGINAL INSERT***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 0 absent) excluding estradiol (Imvexxy) vaginal insert from the Auto-Refill program administered by Express Scripts, Inc., at TRICARE Mail Order Pharmacy, to be implemented the first Wednesday after signing of the minutes.

XI. ITEMS FOR INFORMATION

A. UF Sub-Working Group Update: Aligning Over-the-Counter (OTC) Formularies

The P&T Committee was updated on the ongoing efforts to transition to a more uniform list of OTC products available across MTFs, and ultimately across the TRICARE pharmacy benefit. Utilization and costs of two drug classes currently included on the MTF OTC Test List, the topical corticosteroids and topical emollients, were presented to the Committee. There was discussion on several courses of action to take going forward. Refer to the May 2018 DoD P&T Committee meeting minutes for additional information on the MTF OTC Test List.

B. Prior Authorization, Step Therapy, and Utilization Management Effects

The P&T Committee was briefed on the effects of previous drug class formulary recommendations, including step therapy, prior authorization requirements, and QLs, on utilization and cost patterns in the MHS.

C. MHS Genesis Brief

The P&T Committee was briefed on some of the impacts that the new electronic health record system, MHS Genesis, will have on formulary management. MHS Genesis is currently in use at four MTF sites. There are plans for a phased expansion to all MTFs over the next several years. Topics discussed included a description of the claims adjudication process in the pharmacy, new capabilities for provider e-prescribing and electronic prior authorization submissions, and a description of the enterprise-level and local formulary management tools available in the system.

XII. ADJOURNMENT

The meeting adjourned at 1600 hours on August 9, 2018. The next meeting will be in November 2018.

Appendix A—Attendance: August 2018 DoD P&T Committee Meeting

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. For the Hepatitis C drugs recommended for nonformulary status will allow the current users of Daklinza, Sovaldi, Zepatier and Olysio to continue at the formulary copay.
2.
3.

☐ concurs with the recommendations, except for the following:

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

1 NOV 2018
Date

Appendix A—Attendance: August 2018 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder)
Col James Jablonski, MC	Air Force, Physician at Large
LTC John Poulin, MC	Army, Physician at Large
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
LTC Bryan R. Bailey, MSC	Army, Pharmacy Officer
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Voting Members Absent	
Col Paul Hoerner for Mr. David Bobb	Chief, DHA Pharmacy Operations Branch
Ms. Jennifer Zacher, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Lt Col Derek Underhill, BSC	DLA Troop Support
Mr. Erik Troff	DHA, Deputy General Counsel
Guests	
Ms. Kimberlymae Wood	DHA Contract Operations Division
Ms. Yvette Dluhos	DHA Contract Operations Division
Ms. Hilary Meckel	DHA Contracting
Simone Donnelly	PharmD Student, University of Texas at Austin

Appendix A—Attendance (continued)

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

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• crisaborole (Eucrisa) **Corticosteroids – Immune Modulators –Atopic Dermatitis Subclass**	**No change from February 2017** • Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Use of formulary agents has resulted in therapeutic failure **Formulary Alternatives:** high potency (Class 1) corticosteroids (various), tacrolimus (generic), pimecrolimus (Elidel)
• daclatasvir (Daklinza) • simeprevir (Olysio) • sofosbuvir (Sovaldi) • grazoprevir/elbasvir (Zepatier) • **Hepatitis C Virus Direct-Acting Antivirals**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Use of formulary agents has resulted or is likely to result in therapeutic failure **Formulary Alternatives:** Epclusa, Harvoni, Mavyret, Viekira Pak, Viekira XR, Vosevi
• amantadine ER (Osmolex ER) tablet **Parkinson's Agents**	• Patient has experienced significant adverse effects from the formulary alternative that are not expected to occur with Osmolex ER **Formulary Alternatives:** amantadine immediate release
• estradiol (Imvexxy) vaginal insert **Gynecological Agents Miscellaneous**	• Patient has experienced significant adverse effects from formulary agents **Formulary Alternatives:** estrogen cream, ospemifene (Osphena), prasterone (Intrarosa)
• levonorgestrel/ethinyl estradiol/ferrous bisglycinate (Balcoltra) **Contraceptive Agents: Monophasics with 20 mcg EE**	• The patient cannot be treated with formulary oral monophasic contraceptive with ethinyl estradiol (EE) 20 mcg AND an iron supplement due to the following reasons: (Prescriber must supply a reason on the Medical Necessity Form.) **Formulary Alternatives:** levonorgestrel 0.1 mg + EE 20 mcg (e.g., Sronyx, Lutera, and equivalent generics)
• lofexidine (Lucemyra) **Narcotic Analgesics and Combinations**	• Patient has experienced significant adverse effects from formulary agents **Formulary Alternatives:** clonidine
• oxycodone IR (Roxybond) **Narcotic Analgesics and Combinations**	• No alternative formulary agents: patient is at high risk of abusing non-abuse-deterrent opioid formulations **Formulary Alternatives:** oxycodone, codeine, morphine, hydrocodone
• sarilumab (Kevzara Pen) **Targeted Immunomodulatory Biologics (TIBs)**	• Use of adalimumab (Humira) is contraindicated • Patient has experienced significant or likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) and methotrexate have resulted in therapeutic failure • No alternative formulary agent: The patient has symptomatic congestive heart failure. **Formulary Alternative:** adalimumab (Humira)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• crisaborole (Eucrisa)
 	
Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass
	No Changes from the November 2017 meeting
	Manual PA criteria apply to all new users of Eucrisa.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Patient has mild to moderate atopic dermatitis
	• Prescribed by a dermatologist, allergist, or immunologist
	• Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of at least one medium to high potency topical corticosteroid
	AND
	• Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of a second agent including
	  • An additional medium - high potency topical corticosteroid OR
	  • Topical calcineurin inhibitor (i.e., tacrolimus, Elidel)
	
	Non-FDA-approved uses are NOT approved.
	Prior authorization does not expire.

• dupilumab (Dupixent) **Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass**	**August 2018 updates are in BOLD** Manual PA criteria apply to all new users of Dupixent. Manual PA Criteria: coverage will be approved for initial therapy for 6 months if all criteria are met: • Patient has moderate to severe or uncontrolled atopic dermatitis • Patient must be 18 years of age or older • Prescribed by a dermatologist, allergist, or immunologist • Patient has a contraindication to, intolerability to, or failed treatment with at least ONE high potency/class 1 topical corticosteroid • Patient has a contraindication to, intolerability to, or failed treatment with at least ONE systemic immunosuppressant • **Patient has a contraindication to, intolerability to, inability to access treatment, or failed treatment with Narrowband UVB phototherapy** Non-FDA-approved uses are NOT approved. PA expires after 6 months. Renewal PA Criteria: coverage will be approved indefinitely for continuation of therapy if: 1. 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)
• daclatasvir (Daklinza) • sofosbuvir/velpatasvir (Epclusa) • ledipasvir/sofosbuvir (Harvoni) • glecaprevir/pibrentasvir (Mavyret) • simeprevir (Olysio) • sofosbuvir (Sovaldi) • paritaprevir/ritonavir/ ombitasvir (Technivie) • paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira XR and Viekira Pak) • grazoprevir/elbasvir (Zepatier) **HCV DAAs Subclass**	**Changes from the August 2018 meeting will replace current PA criteria in place for the HCV DAAs. Note that the Harvoni step therapy requirement has been removed.** Manual PA criteria apply to all new users of Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira Pak, Viekira XR, and Zepatier. Manual PA criteria: The HCV DAA is approved if all of the following criteria are met: • ≥ 18 years of age • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of hepatitis C virus infection • The HCV genotype is documented. (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires in 1 year.

Drug / Drug Class	Prior Authorization Criteria
• sofosbuvir/velpatasvir/ voxilaprevir (Vosevi) **Hepatitis C Virus - Direct Acting Antivirals Subclass (HCV DAAs)**	**August 2018 updates are in BOLD and strikethrough.** Manual PA criteria apply to all new users of Vosevi. Manual PA criteria: Vosevi is approved if all the following criteria are met: • ≥ 18 years of age and diagnosed with chronic hepatitis C virus (HCV) • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician • Laboratory evidence of chronic hepatitis C • The HCV genotype is documented (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) • The patient does not have an estimated glomerular filtration rate (eGFR) ≤ 30 mL/min or end-stage renal disease (ESRD) requiring hemodialysis • The patient will not be receiving concomitant therapy with other hepatitis C drugs or rifampin • The treatment course will not exceed the maximum duration of treatment of 12 weeks • **Patient has one of the following:** ○ **Patient has HCV GT 1, 2, 3, 4, 5 or6 and was previously treated with an HCV regimen containing an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir).** **OR** ○ **Patient has HCV GT 1a or 3 and has previously been treated with an HCV regimen containing sofosbuvir with or without an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir).** ~~• Patient cannot use Harvoni (due to HCV GT2 or GT3) other agents (due to decompensation, etc.)~~ ~~• AND~~ ~~• Previously treated with an NS5A inhibitor OR~~ ~~• HCV GT-1a or-3 and treated with sofosbuvir without an NS5A inhibitor~~ Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires after 1 year; complete original PA form for renewal of therapy.
• abiraterone acetate micronized (Yonsa) **Oncological Agents: Prostate II**	Manual PA criteria apply to all new users of Yonsa. Manual PA criteria: Yonsa is approved if all criteria are met: • Provider is aware that Yonsa may have different dosing and food effects than other abiraterone acetate products (medication errors and overdose warning) • Patient has a documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC) • Patient must receive concomitant therapy with methylprednisolone • The patient is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy Non-FDA-approved uses are NOT approved, with exception for treatment in patients with metastatic high-risk castration-sensitive prostate cancer (mHRCSPC). PA does not expire.

• enzalutamide (Xtandi) **Oncological Agents: Prostate II**	**<u>Changes from the August 2018 meeting are in BOLD and strikethrough.</u>** Manual PA criteria apply to all new users of Xtandi. <u>Manual PA criteria</u>: Xtandi is approved if the following criteria are met: • The patient has a documented diagnosis of ~~metastatic~~ castration-resistant prostate cancer • **The patient is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or has had bilateral orchiectomy** Non-FDA-approved uses are NOT approved. PA does not expire.
• amantadine ER (Osmolex ER) **Parkinson's Agents**	Manual PA criteria apply to all new users of Osmolex ER. <u>Manual PA criteria</u>: Osmolex ER is approved if all criteria are met: • Patient is aged 18 years and older • Patient has a diagnosis of either Parkinson's disease or drug-induced extrapyramidal symptoms • Patient has had therapeutic failure of a trial of amantadine 300 mg per day given in divided doses using immediate release tablets. Non-FDA-approved uses are NOT approved. PA does not expire.
• avatrombopag (Doptelet) **Hematological Agents: Platelets**	Manual PA criteria apply to all new users of Doptelet. <u>Manual PA criteria</u>: Avatrombopag (Doptelet) is approved if all criteria are met: • Age ≥ 18 • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet count less than 50 x 10^9/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • The drug is prescribed by or in consultation with a gastroenterologist Non-FDA-approved uses are NOT approved. PA expires in 60 days.
• baricitinib (Olumiant) **Targeted Immunomodulatory Biologics (TIBs)**	Manual PA criteria apply to all new and current users of Olumiant. <u>Automated PA criteria</u>: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days AND <u>Manual PA criteria</u>: Baricitinib (Olumiant) is approved if all criteria are met: • Provider acknowledges that Humira is the preferred TIB to treat rheumatoid arthritis • Provider acknowledges that if a JAK inhibitor is desired, Xeljanz/Xeljanz XR is an alternative to baricitinib (Olumiant) without the black box warning risk of thrombosis • Age ≥ 18 • Has diagnosis of moderate to severe active rheumatoid arthritis • Has a contraindication, inadequate response, or had an adverse reaction to adalimumab (Humira) • Has a contraindication, inadequate response, or had an adverse reaction to methotrexate • Has no history of thromboembolic disease • Is not receiving other potent immunosuppressants (e.g., azathioprine or cyclosporine) • May not be used concomitantly with other TIB agents except for Otezla • Must be prescribed by or in consultation with a rheumatologist Non-FDA-approved uses are NOT approved. PA does not expire.

• binimetinib (Mektovi) **Oncological Agents**	Manual PA criteria apply to all new users of Mektovi. <u>Manual PA criteria</u>: Mektovi is approved if all criteria are met: • Age ≥ 18 years • Has unresectable or metastatic melanoma • Has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test • Mektovi is being taken in combination with Braftovi • Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • Prescribed by or in consultation with an oncologist Non-FDA-approved uses are NOT approved. PA does not expire.
• encorafenib (Braftovi) **Oncological Agents**	Manual PA criteria apply to all new users of Braftovi. <u>Manual PA criteria</u>: Braftovi is approved if <u>all</u> criteria are met: • Age ≥ 18 years • Has unresectable or metastatic melanoma • Has confirmed BRAF V600E or BRA FV600K mutation by an FDA-approved test • Braftovi is being taken in combination with Mektovi • Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • Prescribed by or in consultation with an oncologist Non-FDA-approved uses are NOT approved. PA does not expire.
• dabrafenib (Tafinlar) **Oncological Agents**	**<u>Changes from the August 2018 meeting are in BOLD.</u>** Manual PA criteria apply to all new users of Tafinlar. <u>Manual PA criteria</u>: Coverage will be approved if: • Utilized as a single agent for treatment of unresectable or metastatic melanoma with **BRAF V600E** or BRAF V600K mutation • Combination use with trametinib (Mekinist) in the treatment of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations OR • In combination with trametinib (Mekinist), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation • **Combination with trametinib (Mekinist) for locally advanced or metastatic anaplastic <u>thyroid cancer</u> with BRAF V600E mutation with no satisfactory locoregional treatment options** • **Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)** Non-FDA-approved uses are NOT approved. PA does not expire.
• trametinib (Mekinist) **Oncological Agents**	**<u>Changes from the August 2018 meeting are in BOLD.</u>** Manual PA criteria apply to all new users of Mekinist. <u>Manual PA criteria</u>: • Coverage will be approved if: o Treatment (alone or in combination with dabrafenib [Tafinlar]) of unresectable or metastatic melanoma with BRAF V600E or BRA FV600K mutation OR o In combination with dabrafenib (Tafinlar), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600Emutation • Coverage not approved as a single agent in patients who have received prior BRAF-inhibitor therapy • **Combination with dabrafenib (Tafinlar) for locally advanced or metastatic anaplastic <u>thyroid cancer</u> with BRAF V600E mutation with no satisfactory locoregional treatment options**

	• **Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic)** Non-FDA-approved uses are NOT approved. PA does not expire.

• vemurafenib (Zelboraf)
 	
Oncological Agents
	Changes from the August 2018 meeting are in BOLD.
	
	Manual PA criteria apply to all new users of Zelboraf.
	
	Manual PA criteria:
	• Coverage will be approved if:
	  • Documented diagnosis of unresectable or metastatic melanoma with BRAF V600E mutation AND
	  • Detected by an FDA-approved test (Cobas 4800)
	  OR
	  • Patient has Erdheim-Chester Disease with BRAF V600 mutation
	  • **Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist)**
	
	Non-FDA-approved uses are NOT approved.
	PA does not expire.

• erenumab-aooe (Aimovig)
 	
Migraine Agents
	Manual PA criteria apply to all new users of Aimovig.
	
	Manual PA criteria: Aimovig is approved if all criteria are met:
	• Patient ≥ 18 years old and not pregnant
	• Must be prescribed by or in consultation with a neurologist
	• Patient has a migraine diagnosis with at least 8 migraine days per month for 3 months
	• Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
	  ○ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
	  ○ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol
	  ○ Prophylactic antidepressants: amitriptyline, venlafaxine
	
	Non-FDA-approved uses are NOT approved.
	PA expires after 6 months.
	
	Renewal criteria: coverage will be approved indefinitely for continuation of therapy if:
	• The patient has shown improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication)

• estradiol (Imvexxy) vaginal insert
 	
Gynecological Agents Miscellaneous
	Manual PA criteria apply to all new users of Imvexxy.
	
	Manual PA criteria: Imvexxy is approved for 1 year if all criteria are met:
	• Patient is a postmenopausal woman with a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy
	• Patient has tried and failed or has a contraindication to a low-dose vaginal estrogen preparation (e.g., Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem)
	• Patient does not have any of the following:
	  ○ Undiagnosed abnormal genital bleeding
	  ○ Pregnant or breastfeeding
	  ○ History of breast cancer or currently has active breast cancer
	  ○ History of thromboembolic disease or currently have thromboembolism
	
	Non-FDA-approved uses are NOT approved.
	PA expires in 1 year.
	
	Renewal criteria: Coverage is approved for an additional year if:
	• Patient has an improvement in dyspareunia symptom severity

• fostamatinib (Tavalisse) **Hematological Agents: Platelets**	Manual PA criteria apply to all new and current users of Tavalisse. Manual PA criteria: Fostamatinib (Tavalisse) is approved if all criteria are met: • Age ≥ 18 • Has diagnosis of chronic primary idiopathic thrombocytopenic purpura (ITP) whose disease has been refractory to at least one previous therapy (including IVIG, thrombopoietin(s), corticosteroids, and/or splenectomy) • Has laboratory evidence of thrombocytopenia with average [platelet] count less than 30 x 10^9/L over three discrete tests • Has no evidence of active or chronic infection • Has no evidence of secondary thrombocytopenia • Does not have uncontrolled hypertension • Has had no cardiovascular event (including but not limited to MI, unstable angina, PE, CVA, and/or NYHA Stage III or IV CHF) within the last 6 months • Has no evidence of neutropenia or lymphocytopenia • Prescribed by or in consultation with a hematologist/oncologist • Tavalisse is not being used concomitantly with other chronic ITP therapy Non-FDA-approved uses are NOT approved. PA expires in 120 days. **Fostamatinib (Tavalisse)** can be renewed for an additional year if all criteria are met: • Has demonstrated a response to fostamatinib (Tavalisse) as defined by a sustained platelet count > 50 x 10^9/L or an increase in [platelet count] by ≥ 20 x 10^9/L above baseline. Sustained is defined by two separate tests (at least 2 or more weeks apart) meeting either or both of the aforementioned criteria • Has no evidence of active or chronic infection • Has no evidence of secondary thrombocytopenia • If patient carries a diagnosis of hypertension, it is well controlled according to national guidelines (e.g., JNC 8) • Has had no cardiovascular event (including but not limited to MI, unstable angina, PE, CVA, and/or NYHA Stage III or IV CHF) within the last 6 months • Has no evidence of neutropenia or lymphocytopenia • Prescribed by or in consultation with a hematologist/oncologist
• hydroxyurea (Siklos) **Hematological Agents: Sickle Cell Anemia Agents**	Manual PA criteria apply to all new users of Siklos older than 18 years of age. Automated PA criteria: Siklos will be approved for patients ≤ 18 years of age. Manual PA criteria: Siklos is approved if all criteria are met: • Age ≥ 19 years • The provider documents a patient-specific reason why the patient cannot use the preferred product (generic hydroxyurea or Droxia). • Acceptable responses would include ○ The patient has a diagnosis of sickle cell disease AND has swallowing difficulties • Note that use of Siklos for malignancy (e.g., chronic myelocytic leukemia or other cancers) is not approved Non-FDA-approved uses are NOT approved. PA expires after 1 year. Renewal criteria: Coverage will be approved indefinitely if all of the following apply: • Patient continues to have swallowing difficulties that preclude the use of hydroxyurea 200 mg, 300 mg, 400 mg, or 500 mg capsules • Patient has been monitored and has had at least two laboratory draws in the last year and has not developed hematologic toxicity (Toxic hematologic ranges: Neutrophils < 2,000/mm3; platelets < 80,000/mm3; hemoglobin < 4.5 g/dL; and reticulocytes < 80,000/mm3 if hemoglobin is < 9 g/dL) • Patient has achieved a stable dose with no hematologic toxicity for 24 weeks

• lofexidine (Lucemyra) **Narcotic Analgesics and Combinations**	Manual PA criteria apply to all new users of Lucemyra. <u>Manual PA criteria</u>: Lucemyra is approved if all criteria are met: • Lucemyra is prescribed for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation • Patient is ≥ 18 years old • Lucemyra will not be prescribed for longer than 14 days • The provider documents a patient-specific reason why the patient cannot use the preferred product, clonidine. Acceptable responses include that the patient has experienced orthostatic hypotension or severe bradycardia with previous clonidine use Non-FDA-approved uses are NOT approved (e.g., blood pressure control, nicotine withdrawal, Tourette syndrome, or ADHD). PA expires after 3 months. <u>Renewal criteria</u>: Renewal of therapy will not be allowed
• pegvaliase-pqpz (Palynziq) **Metabolic Agents Miscellaneous**	Manual PA criteria apply to all new users of Palynziq. <u>Manual PA criteria</u>: Palynziq is approved for initial therapy if all criteria are met: • Patient is ≥ 18 years of age • Patient has uncontrolled blood phenylalanine concentrations > 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, or prior treatment with Kuvan [sapropterin dihydrochloride tablets and powder for oral solution]) • Palynziq is prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses on the treatment of metabolic diseases) • Provider acknowledges and has educated the patient on the risk of anaphylaxis • Patient has a prescription for self-administered SQ epinephrine • Patient is not using Palynziq concomitantly with Kuvan Non-FDA-approved uses are NOT approved. PA expires in 6 months. <u>Renewal criteria (maintenance/continuation therapy)</u>: Coverage will be approved for 1 year if: • The patient's blood phenylalanine concentration is ≤ 600 micromol/L OR • The patient has achieved a ≥ 20% reduction in blood phenylalanine concentration from pre-treatment baseline (i.e., blood phenylalanine concentration before starting Palynziq therapy) AND • Patient is not using Palynziq concomitantly with Kuvan
• tolvaptan (Jynarque) **Nephrology Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Jynarque. <u>Manual PA criteria</u>: Jynarque is approved if all criteria are met: • Age ≥ 18 • Jynarque is prescribed by or in consultation with a nephrologist • Provider acknowledges that Jynarque requires liver function monitoring with evaluation of transaminases and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then continuing monthly for the first 18 months and every 3 months thereafter • Patient has rapidly progressing autosomal dominant polycystic kidney disease (ADPKD, defined as reduced or declining renal function [i.e., glomerular filtration rate {GFR} less than or equal to 65 mL/min/1.73 m^2] and high total kidney volume [i.e., greater than or equal to 750ml]) • Patient does not have Stage 5 chronic kidney disease (CKD) [GFR < 15 mL/min/1.73 m^2] • Patient is not receiving dialysis • Patient is not currently taking Samsca (tolvaptan) Non-FDA-approved uses are NOT approved. PA does not expire.

• tofacitinib (Xeljanz/Xeljanz XR)
 	
Targeted Immunomodulatory Biologics (TIBs)
	<u>Changes from the August 2018 meeting are in BOLD.</u>
	
	<u>Manual PA criteria</u>: Xeljanz/Xeljanz XR is approved if **ALL** of the following criteria are met:
	• Patient has diagnosis of:
	  • Moderately to severely active rheumatoid arthritis who has had an inadequate response or intolerance to methotrexate OR
	  • Active psoriatic arthritis OR
	  • **Moderately to severely active ulcerative colitis, and not in combination with biological therapies for ulcerative colitis**
	  • Not approved for use in combination with other biologics or potent immunosuppressants (e.g., azathioprine and cyclosporine)
	• ≥ 18 years of age
	• Contraindication/inadequate response to Humira
	• Adverse reactions to Humira not expected with requested non-step-preferred TIB
	• Medication will not be used concomitantly with other TIBs
	
	Non-FDA-approved uses are NOT approved.
	PA does not expire.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• Crisaborole (Eucrisa) **Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass**	**No change from May 2017 meeting** ▪ MTF/Mail: 240 gm (4 tubes) in 56 days ▪ Retail: 120 gm (2 tubes) in 28 days
• Dupilumab (Dupixent) **Corticosteroids – Immune Modulators – Atopic Dermatitis Subclass**	**No change from May 2017 meeting** ▪ MTF/Mail: 56-day supply ▪ Retail: 28-day supply
• daclatasvir (Daklinza) • sofosbuvir/velpatasvir (Epclusa) • ledipasvir/sofosbuvir (Harvoni) • glecaprevir/pibrentasvir (Mavyret) • simeprevir (Olysio) • sofosbuvir (Sovaldi) • paritaprevir/ritonavir/ombitasvir (Technivie) • dasabuvir tablets pak (Viekira Pak) • paritaprevir/ritonavir/ombitasvir/dasabuvir XR tablets (Viekira XR) • sofosbuvir/velpatasvir/voxilaprevir (Vosevi) • grazoprevir/elbasvir (Zepatier) **Hepatitis C Virus - Direct Acting Antivirals Subclass (HCV DAAs)**	**No change from Feb 2017 meeting, or Nov 2017 meeting (Mavyret and Vosevi)** ▪ MTF/Mail/Retail: 28-day supply
• abiraterone acetate (Yonsa) **Oncological Agents: Prostate II**	▪ MTF/Mail: 180 tablets/45 days ▪ Retail: 120 tablets/30 days
• adalimumab (Humira Pediatric Crohn's Start, Humira Pen-CD/UC/HS starter, Humira Pen-Ps/UV Pens) **Targeted Immunomodulatory Biologics (TIBs)**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• avatrombopag (Doptelet) **Hematological Agents: Platelets**	▪ MTF/Mail/Retail: 5-day supply
• baricitinib (Olumiant) **Targeted Immunomodulatory Biologics (TIBs)**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• beclomethasone (QVAR & QVAR RediHaler) **Pulmonary-1 Agents: Inhaled Corticosteroids**	▪ MTF/Mail: 3 inhalers /90 days ▪ Retail: 1 inhaler /30 days
• binimetinib (Mektovi) **Oncological Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply

Drug / Drug Class	Quantity Limits
• encorafenib (Braftovi) **Oncological Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• erenumab-aooe (Aimovig) **Migraine Agents**	▪ MTF/Mail/Retail: 1 syringe (70mg)/30 days ▪ Adequate trial of lower strength required for 3 months before trying the higher strength
• flurandrenolide (Cordran) Tape **Corticosteroids-Immune Modulators: High Potency**	▪ MTF/Mail/Retail: 1 roll of tape per prescription fill ▪ No refills allowed
• fostamatinib (Tavalisse) **Hematological Agents: Platelets**	▪ MTF/Mail/Retail: 30-day supply
• ibrutinib (Imbruvica) 420 mg tablets **Oncological Agents**	▪ MTF/Mail/Retail: 28 tabs/28-day supply
• levonorgestrel/EE (Jolessa) **Contraceptive Agents: Extended Cycle/ Continuous Use Regimen**	▪ QLs removed at all POS
• lofexidine (Lucemyra) **Narcotic Analgesics and Combinations**	▪ MTF/Mail/Retail: 96 tabs/14 days
• ondansetron ODT and oral tablet (Zofran) **Antiemetic-Antivertigo Agents**	▪ QLs removed at all POS
• pegvaliase-pqpz (Palynziq) **Metabolic Agents Miscellaneous**	▪ MTF/Mail: 45-day supply ▪ Retail: 30-day supply
• sarilumab (Kevzara Pen) **Targeted Immunomodulatory Biologics (TIBs)**	▪ MTF/Mail: 56-day supply ▪ Retail: 28-day supply
• tolvaptan (Jynarque) **Nephrology Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply
• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	Dosing for Crohn's disease, plaque psoriasis, and psoriatic arthritis ▪ MTF/Mail: 2 syringes/84 days ▪ Retail: 1 syringe/28 days

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
abiraterone acetate micronized (Yonsa)	Oncological Agents: Prostate II	• abiraterone acetate (Zytiga) • enzalutamide (Xtandi)	Metastatic castration-resistant prostate cancer (mCRPC)	• New micronized formulation of abiraterone acetate • Approved via 505(b)(2) pathway with no new clinical studies performed • Bioequivalence/dose-finding study completed comparing Yonsa to Zytiga and effects on testosterone levels and PSA-50 response • Has easier dosing with regards to food compared to Zytiga, but provides no additional benefit relative to current formulary agents	• UF • Do not add to EMMPI list
amantadine ER tablets (Osmolex ER)	Parkinson's Agents	• amantadine IR • amantadine ER (Gocovri ER)	Parkinson's disease drug-induced extra-pyramidal reactions in adults	• Second ER once daily amantadine formulation, with no clinically significant differences between either IR or ER • Extended-release amantadine tablet formulation marketed to reduce nocturnal side effects in patients who may experience adverse effects from immediate-release (IR) medication • FDA approval based on pharmacokinetic comparison to the IR amantadine formulation with no new clinical efficacy and safety data	• NF • Add to EMMPI list
avatrombopag (Doptelet)	Hematological Agents: Platelets	• eltrombopag (Promacta) • romiplostim (Nplate)	Thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	• 3rd thrombopoietin marketed • Indicated for patients with chronic liver disease (CLD) and severe thrombocytopenia to be given 10-13 days prior to a planned procedure • Most useful for procedures with an intermediate to high bleeding risk • Clinically useful for a subset of patients	• UF • Do not add to EMMPI list
baricitinib (Olumiant)	TIBs: Miscellaneous	• Xeljanz • Xeljanz XR • Kevzara • Actemra • Kineret • Orencia • Otezla	Moderate to severe active rheumatoid arthritis (RA) that has had an inadequate response to one or more TNF antagonist therapies	• 2nd oral JAK inhibitor for RA • Only approved for RA in patients refractory to tumor necrosis factor (TNF) inhibitors • Efficacy superior to a DMARD alone • Similar efficacy to Xeljanz by indirect comparison • Black box warning includes unique safety risk for thrombosis	• UF • Add to EMMPI list
binimetinib (Mektovi)	Oncological Agents	• see encorafenib below	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	• Only used in combination with Braftovi (see encorafenib below)	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
encorafenib (Braftovi)	Oncological Agents	• dabrafenib (Tafinlar) plus trametinib (Mekinist) • vemurafenib (Zelboraf) plus cobimetinib (Cotellic)	Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation	• Only used in combination with binimetinib (Mektovi) • Braftovi/Mektovi is the third unique combination to treat *BRAF*(+) metastatic melanoma • No properly designed head-to-head trials to determine superiority, non-inferiority, or inferiority between the three combinations for *BRAF*(+) metastatic melanoma • Braftovi/Mektovi demonstrates progression-free survival in *BRAF*(+) metastatic melanoma and appears to have a fairly comparable adverse event profile to other BRAF/MEK inhibitor combinations	• UF • Do not add to EMMPI list
epoetin-alfa-epbx injection (Retacrit)	Hematological Agents: Red Blood Cell Stimulants	• epoetin alfa (Procrit, Epogen)	Anemia due to: CKD, zidovudine treatment, or myelosuppressive chemotherapy; reduction of allogeneic RBC transfusions in patients undergoing elective, non-cardiac, nonvascular surgery	• Biosimilar of epoetin alfa, human recombinant erythropoietin • Approved via 351(k) biosimilar pathway • No new trials; identical efficacy and safety profiles • Black box warning for increased mortality, myocardial infarction, stroke, VTE, tumor progression/recurrence in cancer, seizure risk in CKD; must control HTN prior to initiation and during therapy; may cause severe cutaneous reactions; contains phenylalanine	• UF • Add to EMMPI list

erenumab-aooe injection (Aimovig)	Migraine Agents	• divalproex
		• metoprolol
		• atenolol
		• amitriptyline
		• venlafaxine
		• propranolol
		• nadolol
		• topiramate IR tabs
		• topiramate ER (Qudexy XR)
		• topiramate ER (Trokendi XR)
			Calcitonin gene-related peptide (CGRP) antagonist for migraine prophylaxis	• Aimovig is the first approved CGRP inhibitor for migraine prevention.
				• Approved for prevention of episodic migraine (EM) and chronic migraine (CM) in adults.
				• Guidelines recommend preventive treatment of headaches starting at ≥ 4 monthly migraine days (MMD).
				• Baseline MMD averages were 8 for EM and 18 for CM in Aimovig clinical trials.
				• Episodic Migraine
				  • Treatment led to about 3 to 4 fewer migraine headache days/month.
				  • Significant placebo effect
				  • The difference between erenumab and placebo was approximately 2 fewer migraine headache days/month.
				• Chronic Migraine
				  • Phase 2 study showed similar efficacy as that of botulinum toxin; erenumab decreased MMD by 7 from a baseline of 18 MMD
				  • Can treat with current preventive therapy (topiramate, etc.)
				  • Botulinum toxin is approved for chronic migraine
				• Aimovig and current preventive therapy decrease the number of migraine headache days at similar rates of 2 per month.
					• UF
					• Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
				• The 140-mg dose was not more effective than the 70-mg dose; 70-mg and 140-mg doses have a relatively flat dose response. • ICER concludes the cost-effectiveness of Aimovig is likely below the upper bound of commonly accepted thresholds.	
estradiol vaginal insert (Imvexxy)	Gynecological Agents Miscellaneous	• estradiol cream (Premarin) • ospemifene (Osphena) • prasterone (Intrarosa)	Dyspareunia	• New vaginal insert formulation of estradiol FDA-approved for dyspareunia. • Unlike vaginal creams, Imvexxy cannot be titrated • There are no head-to-head comparisons of Imvexxy with other estradiol formulations or similar drugs with an indication for dyspareunia; only one placebo-controlled trial available. • Contains the usual warning for increased risk of endometrial cancer in women who have an intact uterus who use unopposed systemic estrogen therapy • Provides little to no clinical benefit relative to other estradiol formulations or similar drugs for the treatment of dyspareunia	• NF • Add to EMMPI list • No auto refill
fostamatinib (Tavalisse)	Hematological Agents: Platelets	• eltrombopag (Promacta) • romiplostim (Nplate)	Chronic immune thrombocytopenia (ITP) in patients who have had an insufficient response to a previous treatment	• 1st SYK inhibitor to treat thrombocytopenia in chronic ITP • Multiple other agents for chronic ITP, but only one other pharmacy benefit agent (Promactra), a thrombopoietin • Indicated in patients with chronic ITP who have had an insufficient response to a previous treatment • FIT 1 & 2 trials showed statistically and clinically significant benefits over placebo in a discrete (and small) subset of patients • Responders declare themselves early with a robust and sustained response • Significant adverse effects exist; however, in this treatment-refractory population, for responsive patients, benefits may outweigh risks	• UF • Do not add to EMMPI list
hydroxyurea tablets (Siklos)	Hematological Agents: Sickle Cell Anemia Agents	• hydroxyurea (generics) • l-glutamine (Endari)	Reduce the frequency of painful crises caused from sickle cell anemia and to reduce need for blood transfusions in pediatric patients ≥ 2 years of age, with recurrent moderate to severe painful crises	• New formulation of hydroxyurea specifically approved for sickle cell disease in pediatric patients for which it was given orphan drug designation • Other hydroxyurea formulations have been used off-label in pediatric populations with sickle cell disease • Hydroxyurea is routinely recommended in clinical practice guidelines for sickle cell disease • New strength of hydroxyurea (1000 mg tablet has 3 score lines allowing dosing in 250 mg increments; 100 mg tablet not scored); tablets can be dissolved in water for administration • Other hydroxyurea formulations are used in the oncology setting, including treatment of chronic myelocytic leukemia • Siklos has little to no clinical benefit relative to other hydroxyurea UF formulations	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
levonorgestrel/ ethinyl estradiol/ ferrous (Balcoltra)	Contraceptive Agents: Monophasics with 20 mcg EE	• Lessina • Loestrin FE	Prevention of pregnancy	• Levonorgestrel-containing combined oral contraceptive (COC) drug with iron-containing inert pills, which as stated in the package insert, "do not provide any therapeutic purpose." • Indications, efficacy, and safety comparable to multiple COCs on the formulary • No compelling advantage over existing COCs available on the BCF and UF	• NF • Do not add to EMMPI list
lofexidine (Lucemyra)	Narcotic Analgesics and Combinations	• clonidine 0.1 mg	Mitigation of abrupt opioid withdrawal symptoms	• 1st drug FDA-approved to treat opioid withdrawal symptoms, but clonidine is widely used off label for this purpose • Only placebo-controlled trials available; lofexidine is statistically superior to placebo at day 7 • Lofexidine has been approved in Europe since 1992 and has been indirectly compared to clonidine with similar efficacy but with claims of fewer side effects • An FDA clinical reviewer stated that there is no basis for claiming safety advantages of lofexidine over clonidine • No advantages over current therapies for managing symptoms of opioid withdrawal	• NF • Do not add to EMMPI list
oxycodone IR (Roxybond)	Narcotic Analgesics and Combinations	• oxycodone IR • morphine IR • OxyContin	Pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	• 10th narcotic abuse deterrent formulation (ADF) and 1st short-acting (IR) abuse deterrent agent marketed • Bioequivalent to oxycodone; no additional efficacy studies conducted • Associated with lower "drug liking" and "take drug again" scores • CPGs do not recommend for or against ADFs • ICER committee voted there was insufficient information to recommend Roxybond • Provides little to no clinical benefit relative to other oxycodone formulations or other narcotic analgesics	• NF • Do not add to EMMPI list
pegvaliase-pqpz injection (Palynziq)	Metabolic Agents Miscellaneous	• sapropterin (Kuvan 100 mg tab and 500 mg powder)	Reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations > 600 micromol/L on existing management	• Novel agent approved for PKU to lower phenylalanine levels in adults with inadequate control on existing therapy • Palynziq replaces the PAL enzyme, which converts the accumulated phenylalanine into excretable byproducts • Reasonably effective in reducing the serum phenylalanine concentrations • Treatment with pegvaliase does not require residual enzyme activity to be effective • Study patients were not required to adhere to a strict phenylalanine-restricted diet • Kuvan was the first agent FDA-approved for PKU, but only 25% to 50% of patients with PAH deficiency are Kuvan-responsive • Contains a boxed warning for the risk of anaphylaxis; only available through a restricted REMS program	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
				• Palynziq has a unique place in therapy for the treatment of PKU, by potentially fulfilling an unmet need in patients with uncontrolled phenylalanine levels who have not adequately responded to dietary restrictions and/or Kuvan therapy	
tolvaptan (Jynarque)	Nephrology Agents Miscellaneous	• tolvaptan (Samsca)	Rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)	• Jynarque is another formulation of tolvaptan, a vasopressin antagonist, approved for rapidly progressing ADPKD • Two published studies showed statistically significant differences in total kidney volume, fewer ADPKD-related events, and slower renal function decline with tolvaptan compared to placebo • While statistically significant in most endpoints, study results were not clinically significant • Safety concerns include risk of liver injury that requires frequent monitoring and a stringent REMS • Most common ADRs leading to discontinuation (15.4%) were aquaretic effects (pollakiuria, polyuria, nocturia) • Few alternatives currently exist for ADPKD; however, it is unclear the exact patient who will benefit from tolvaptan, and long-term benefits have not been established	• UF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Nonformulary During the August 2018 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Do NOT Add to the Mail Order Requirement (Excepted from Mail Order Requirement)
August 2018	**Corticosteroids – Immune Modulators: Atopic Dermatitis** crisaborole (Eucrisa) (maintain on list) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** ▪ amantadine ER (Osmolex ER) ▪ estradiol (Imvexxy)	**HCV DAAs** Limited duration of use (acute use exception applies): ▪ daclatasvir (Daklinza) ▪ simeprevir (Olysio) ▪ sofosbuvir (Sovaldi) ▪ grazoprevir/elbasvir (Zepatier) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** Acute use exception applies: ▪ lofexidine (Lucemyra) Existing exceptions apply: ▪ oxycodone IR (Roxybond), C-II exception ▪ levonorgestrel/ethinyl estradiol/iron (Balcoltra), contraceptive exception

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2018	**Corticosteroids-Immune Modulators: Atopic Dermatitis Subclass**	UF Class Review	BCF ▪ pimecrolimus (Elidel) remains BCF ▪ tacrolimus generic added to the BCF	UF ▪dupilumab injection (Dupixent)	NF ▪ crisaborole (Eucrisa)	Pending signing of the minutes - 2 weeks after signing The effective date is November 21, 2018.	▪ Manual PA criteria applies to all new users for dupilumab (Dupixent) and crisaborole (Eucrisa).	▪ Updates made to the Dupixent PA ▪ Tacrolimus added to the BCF ▪ See Appendix C for PA criteria.
Aug 2018	**Hepatitis C Virus (HCV) Direct-Acting Antivirals Subclass (DAAs)**	UF Class Review Class previously reviewed in Feb 2017, May 2015, Nov 2012; New drug review in Nov 2017	Extended Core Formulary (ECF) No DAA selected ▪peginterferon alfa-2a (Pegasys) Nov 2012 ▪ribavirin 200 mg capsules (generics); excludes RibaPak formulation Nov 2012	UF ▪sofosbuvir/velpatasvir (Epclusa) ▪ledipasvir/sofosbuvir (Harvoni) ▪glecaprevir/ pibrentasvir (Mavyret) ▪paritaprevir/ritonavir/ ombitasvir (Technivie) ▪paritaprevir/ritonavir/ ombitasvir/dasabuvir XR (Viekira XR) ▪paritaprevir/ritonavir/ ombitasvir/dasabuvir Pak (Viekira Pak) ▪sofosbuvir/velpatasvir/ voxilaprevir (Vosevi)	NF ▪ daclatasvir (Daklinza) ▪ simeprevir (Olysio) ▪ sofosbuvir (Sovaldi) ▪ grazoprevir/elbasvir (Zepatier)	Pending signing of the minutes / 60 days The effective date is January 2, 2018.	▪ Manual PA required. ▪ QLs apply; 28-day supply.	▪ Previous requirement for step therapy with Harvoni removed ▪ PA criteria simplified for all the DAAs except Vosevi ▪ Vosevi separate PA form due to unique FDA indication ▪ See Appendix C for PA criteria.

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

Appendix H—Table of Abbreviations

AAD	American Academy of Dermatology
AASLD	American Association for the Study of Liver Diseases
ACTH	adrenocorticotropic hormone
AD	atopic dermatitis
ADF	abuse deterrent formulation
ADHD	Attention Deficit Hyperactivity Disorder
ADPKD	autosomal dominant polycystic kidney disease
ADR	adverse drug reaction
ARB	angiotensin receptor blocker
BCF	Basic Core Formulary
BIA	budget impact analysis
CFR	Code of Federal Regulations
CGRP	calcitonin gene-related peptide
CHF	congestive heart failure
CKD	chronic kidney disease
CLD	chronic liver disease
CM	chronic migraine
CMA	cost minimization analysis
COC	combined oral contraceptive
CPG	Clinical Practice Guidelines
CVA	cerebral vascular accident
DAA	Direct Acting Antivirals drug class
DHA	Defense Health Agency
DMARD	disease-modifying anti-rheumatic drug
DoD	Department of Defense
ECF	Extended Core Formulary
EE	ethinyl estradiol
eGFR	estimated glomerular filtration rate
EM	episodic migraine
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER	extended release
ESRD	end stage renal disease
FDA	U.S. Food and Drug Administration
GnRH	gonadotropin-releasing hormone
GT	genotype
HCTZ	hydrochlorothiazide
HCV	Hepatitis C virus
HFpEF	heart failure with preserved ejection fraction
HTN	hypertension
ICER	Institute for Clinical and Economic Review
IDSA	Infectious Diseases Society of America
IR	immediate release
ISGA	Investigator's Static Global Assessment
ITP	immune thrombocytopenia
IVIG	intravenous immunoglobulin
JAK	Janus kinase

JAMA	Journal of the American Medical Association
JNC	Joint National Committee
mCRPC	metastatic castration-resistant prostate cancer
mHRCSPC	metastatic high-risk castration-sensitive prostate cancer
MEK	
MHS	Military Health System
MI	myocardial infarction
MMD	monthly migraine days
MN	medical necessity
MS	multiple sclerosis
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NF	nonformulary
NSAID	nonsteroidal anti-inflammatory drug
NSCLC	non-small cell lung cancer
NYHA	New York Heart Association
ODT	orally dissolving tablet
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAL	phenylalanine ammonia lyase
PBM	pharmacy benefit manager
PDE-4	phosphodiesterase-4
PE	pulmonary embolism
PERT	Pancreatic Enzymes Replacement Therapy drug class
PKU	phenylketonuria
POS	point of service
PPI	proton pump inhibitor
PSA	prostate-specific antigen
PT	patient
QL	quantity limit
RA	Rheumatoid arthritis
RAAs	Renin Angiotensin Antihypertensive Agents class
RAV	resistance-associated variant
RBC	red blood cell
RCT	randomized controlled trial
REMS	Risk Evaluation and Mitigation Strategies
SQ	subcutaneous
TCI	topical calcineurin inhibitor
TIBs	targeted immunomodulatory biologics
TNF	tumor necrosis factor
UCLA	University of California, Los Angeles
UF	Uniform Formulary
VTE	venous thromboembolism
XR	extended release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2018

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on May 9 and 10, 2018, 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 2018 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the February 2018 DoD P&T Committee meeting on April 24, 2018.

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

A. Pancreatic Enzyme Replacement Therapy (PERT)

Background—The class was most recently reviewed for Uniform Formulary status in February 2014. Since the last review, the drug class name was changed from "Pancreatic Enzyme Products" to "Pancreatic Enzyme Replacement Therapy" (PERT), to align with accepted nomenclature in the clinical literature. The drugs in the class all contain various amounts of lipase, amylase, and protease, and are available under the trade names of Creon, Pancreaze, Pertzye, Ultresa, Viokace, and Zenpep.

The products were reviewed for the FDA-approved indication of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis or other conditions; other uses (e.g., pain relief from pancreatitis) were not reviewed.

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

- Creon, Pancreaze, Ultresa and Zenpep are formulated as capsules containing delayed release enteric-coated microspheres, while Pertzye capsules contain enteric-coated microspheres with a bicarbonate buffer.
- Viokace is an uncoated tablet that is not approved for use in pediatrics; it requires administration with a proton pump inhibitor, to prevent degradation in the stomach.
- Based on a 2016 Cochrane Review in patients with cystic fibrosis, Creon, Pancreaze, Zenpep, Viokace, Ultresa, and Pertzye are effective at improving fat malabsorption in patients with exocrine pancreatic insufficiency, when compared to placebo.
- The 2016 Cochrane review found no difference between Creon and other enteric-coated microsphere products in the endpoints of change in weight, stool frequency, abdominal pain, or fecal fat excretion. Creon was superior to the tablet formulation (Viokace) in only one endpoint, decreasing stool frequency.
- Zenpep has the largest number of dosage strengths available, but multiple capsules of all the formulations can be used to obtain individualized patient dosing. Creon and Zenpep both have higher strengths available. All the products except for Viokace provide dosing for infants.
- Creon has the greatest number of FDA-approved indications and the highest MHS utilization.
- Although Pertzye is the only product with gastrostomy (G)-tube administration information contained in the package insert, instructions are available for G-tube administration with Creon, Viokace, and Zenpep.
- There is a high degree of therapeutic interchangeability among the PERT products, and having one on the formulary is sufficient to meet the needs of MHS patients.

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

- CMA results showed that Creon was the most cost-effective agent in the PERT class.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Creon as formulary and step-preferred, Viokace as UF and non-step-preferred, and Pertzye, Pancreaze,

Ultresa and Zenpep as NF and non-step-preferred demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 1 opposed, 0 abstained, 0 absent) the following, based on clinical and cost effectiveness:
    - UF and step-preferred
        - Creon
    - UF and non-step-preferred
        - Viokace tablet
    - NF and non-step-preferred
        - Pancreaze
        - Pertzye
        - Ultresa
        - Zenpep
    - This recommendation includes step therapy, which requires a trial of Creon prior to use of Viokace and the NF, non-step-preferred PERT drugs in all new and current users.

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

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the non-step-preferred products, requiring a trial of Creon first in all new and current users. Note that PA is not needed for Creon, and the step-therapy requirements will be included in the manual PA. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Pancreaze, Pertzye, Ultresa, and Zenpep. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: TIER 1 COST-SHARE—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) lowering the current tier 2 cost share for Creon to the generic tier 1 cost-share.

    The authority for this recommendation is codified in 32 CFR 199.21(j)(3), which states that "when a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand

pharmaceutical agent being the most cost effective agent for purchase by the Government, the Pharmacy and Therapeutics Committee may also designate that the drug be cost-shared at the generic rate." The objective is to maximize use of Creon in the TRICARE Mail Order pharmacy and Retail Network, given its significantly lower cost relative to the other PERT products. Lowering the cost-share for Creon will provide a greater incentive for beneficiaries to use the most cost effective PERT formulation in the purchased care points of service.

6. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) adding all the PERT products to the EMMPI program. See Appendix F.

7. ***COMMITTEE ACTION: UF, PA, AND TIER 1 COST SHARE 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 in all points of service 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 7, 2018.

B. Growth Stimulating Agents

Background—The Growth Stimulating Agents (GSAs) were last reviewed at the August 2007 DoD P&T Committee meeting. All the products contain recombinant human growth hormone (rhGH, or somatropin). Since the 2007 review, two products (Zorbtive and Tev-Tropin) have been discontinued, and one product, Zomacton has entered the market. There are no generic products in the class.

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

- The products are all bioidentical and equally biopotent to each other.
- Head-to-head trials show equivalency in pharmacokinetic profiles, efficacy, and safety.
- The GSA products all offer 5 and 10 mg dosing options, pen devices, small needle gauges (29-, 30-, and 31-gauge), a needle-guard option, patient support programs, home nurse education, instructional websites, and an emergency hotline number.
- The GSA products differ in terms of their FDA-approved indications; storage requirements (refrigeration vs. room temperature); preservative (benzyl alcohol vs. metacresol vs. phenol); delivery devices, smallest available dosage increment; and reconstitution or device assembly steps required prior to administration. None of these differences impact patient outcomes.

- Advantages of Norditropin FlexPro include that it has the greatest number of FDA-approved indications (seven); it does not require refrigeration or mixing prior to administration; it contains phenol as a preservative; and is administered in a pen device that is convenient and easy to use. It can also deliver small increments in dosage, down to 0.025 mg with the 5 mg pen.
- One advantage of Genotropin is the availability of the low-dose, single-use MiniQuick formulation which can deliver the lowest dosage options for children. However, all the products can deliver low dosages.
- Norditropin FlexPro, Nutropin, Omnitrope, and Saizen are pre-mixed formulations that are convenient for patients.
- Disadvantages of Saizen, Serostim, Zomacton, and Omnitrope include the benzoyl alcohol preservative, which is toxic to neonates and infants. However, alternate formulation options are available for these products.
- Zomacton is the only product available in a needle-free device.
- Overall, the GSA products have a high degree of therapeutic interchangeability, based on Military Health System (MHS) provider opinion, systematic reviews, meta-analyses, and professional treatment guidelines.

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

- CMA results showed that Zomacton, Omnitrope, and Norditropin FlexPro were the most cost-effective products in the growth stimulating agents class.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Norditropin FlexPro as formulary and step-preferred demonstrated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF and step-preferred
        - Norditropin FlexPro
    - UF and non-step-preferred
        - Omnitrope
        - Zomacton
    - NF and non-step-preferred
        - Genotropin and Genotropin MiniQuick
        - Humatrope

        - Nutropin AQ Nuspin
        - Saizen
        - Serostim
    - This recommendation includes step therapy, which requires a trial of Norditropin FlexPro, prior to use of the non-step-preferred GSAs in all new and current users.
    - Note that as part of this recommendation, Norditropin FlexPro will remain the Extended Core Formulary (ECF) GSA product.

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—PA criteria currently apply to the GSAs. The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) updating the current PA criteria for the class to include the updated safety warning for use of a GSA in patients with Prader-Willi syndrome and obstructive sleep apnea, and to require the prescription to be written by the appropriate subspecialist. Additionally the step therapy requirements for a trial of Norditropin FlexPro in all new and current users will be included in the manual PA. Use of the non-step-preferred products is allowed if the patient has a contraindication or has experienced an adverse reaction to Norditropin FlexPro, and then Omnitrope and Zomacton, before moving to NF agents. Prior Authorization will expire in one year . See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Genotropin and Genotropin MiniQuick, Humatrope, Nutropin AQ Nuspin, Saizen and Serostim. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: TIER 1 COST-SHARE—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) lowering the current tier 2 cost share for Norditropin FlexPro to the generic tier 1 cost-share, under the authority previously discussed on pages 3-4.

5. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR GROWTH STIMULATING AGENTS***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) excluding the GSAs from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, due to the clinical requirements of the PA.

6. ***COMMITTEE ACTION: UF, PA, AND TIER 1 COST SHARE IMPLEMENTATION PERIOD—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service 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 7, 2018.

C. Gastrointestinal-2 (GI-2) Agents: Opioid Induced Constipation (OIC) Subclass

Background—The P&T Committee evaluated the peripherally acting mu opioid receptor antagonists (PAMORAs) for opioid induced constipation (OIC). The products are a subclass of the GI-2 Agents; the subclass has not previously been reviewed for formulary status. The drugs in the class include methylnaltrexone (Relistor), naldemedine (Symproic), and naloxegol (Movantik), and are all indicated for treating OIC. Relistor is also available in an injection for treatment of OIC in the palliative care setting

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

- The PAMORAs inhibit the action of opioids in the GI tract, (which decreases constipation), but still maintain the analgesic effects from the mu receptors in the central nervous system.
- According to professional treatment guidelines, scheduled doses of a stimulant laxative, (e.g. bisacodyl/ senna) with or without a stool-softener (e.g. docusate), a high fiber diet, increased fluid intake, moderate exercise and opioid dosage reduction to the minimum effective dose are recommended as first-line options for OIC.
- Limitations to the evidence for efficacy of the OIC drugs include the lack of a validated minimally clinically important difference in study endpoints, the allowance of concomitant or "rescue" laxative doses, and the short duration of the trials (less than 3 months). Additionally, in the trials leading to FDA approval for the OIC drugs, there were differing inclusion and exclusion criteria, especially with regard to intensity of opioid dosing.
- Given the varying efficacy endpoints and lack of head-to-head trials, there is insufficient evidence to conclude that one PAMORA is more effective than another or associated with fewer adverse events.
- There is no long-term safety data available with the OIC drugs. The FDA is requiring cardiovascular outcomes trials (CVOTs) for the PAMORAs to evaluate CV mortality, non-fatal myocardial infarction, and stroke. Results from the CVOTs are pending.
- Advantages of naldemedine (Symproic) include once daily dosing and no need to adjust the dose in patients with renal dysfunction. Symproic is available in one tablet strength, so dose titration is not required. However, disadvantages include rare cases of rash and hypersensitivity reactions reported in the clinical trials leading to FDA approval, and CYP3A4 drug interactions.
- Naloxegol (Movantik) can be crushed and placed down a nasogastric tube and is also dosed once daily. Disadvantages include that study endpoints evaluating the 12.5 mg dosage were not statistically significant in one trial; it requires renal and hepatic dosing adjustment; and has CYP3A4 drug interactions
- Advantages of the methylnaltrexone (Relistor) tablets include the lack of CYP3A4 drug interactions. However, only one phase III trial is available for the oral tablet.
- MHS provider feedback supported use of traditional laxative therapy as first-line therapy for OIC.

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 naldemedine (Symproic) was the most cost-effective OIC drug, followed by naloxegol (Movantik), and methylnaltrexone (Relistor).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating naldemedine (Symproic) and naloxegol (Movantik) as formulary with methylnaltrexone (Relistor) as NF demonstrated significant 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:

    - UF
        - naldemedine (Symproic)
        - naloxegol (Movantik)
    - NF: methylnaltrexone (Relistor) tablets and injection
    - Note that a BCF product was not selected for the OIC drugs; metronidazole remains the GI-2 Agents BCF selection.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***PA criteria currently apply to Relistor and Movantik, which requires a trial of two traditional laxatives and a trial of lubiprostone (Amitiza) prior to use of an OIC drug. For new users of Symproic and Movantik, the P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the requirement for a trial of OTC laxatives, and removing the requirement for a trial of lubiprostone, based on the treatment guidelines from the American Gastroenterological Association where PAMORAs are recommended specifically for laxative-refractory patients.

    The Committee also recommended updating the existing manual PA criteria for Relistor tablets to require a trial of lubiprostone and both Symproic and Movantik, due to the relatively limited amount and low quality evidence available. The PA criteria for Relistor tablets will apply to new and current users. PA is not required for Relistor injection, as this product is limited to the palliative care setting. PA will expire in one year. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updated MN criteria for Relistor tablets and injection. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for Relistor, and adding QLs for Movantik and Symproic. See Appendix D.

5. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR OIC DRUGS***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) excluding the OIC drugs from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, due to the lack of long-term safety data. Existing utilization patterns in the MHS also show high attrition rates with these products.

6. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee agreed that the OIC drugs were not suitable for the EMMPI program, as they have a high rate of medication discontinuation and are not necessarily used as maintenance medications. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) that the agents recommended for NF status, methylnaltrexone (Relistor) tablets and injection, be exempted from the requirement that NF agents be generally available only at mail order.

7. ***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 60-day implementation period in all points of service 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 October 10, 2018.

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

*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 2018 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:
    - apalutamide (Erleada) – Oral Oncologic Agent for Prostate Cancer
    - bictegravir/emtricitabine/tenfovir alafenamide (Biktarvy) – Antiretrovirals for Human Immunodeficiency Virus (HIV)
    - efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi) – Antiretrovirals for HIV
    - efavirenz/lamivudine/tenofovir disoproxil fumarate (Symfi Lo) – Antiretrovirals for HIV
    - ibrutinib tablets (Imbruvica) – Oral Oncologic Agent for mantle cell lymphoma and chronic lymphocytic leukemia, new formulation (note that Imbruvica capsules were already designated as uniform formulary prior to the Innovator Rule established in August 2015)
    - insulin lispro (Admelog) – Short-Acting Insulin for Diabetes Mellitus
    - lamivudine/tenofovir disoproxil fumarate (Cimduo) – Antiretrovirals for Human Immunodeficiency Virus (HIV)
    - netarsudil 0.02% ophthalmic solution (Rhopressa) – Glaucoma Agents
    - tezacaftor/ivacaftor (Symdeko) – Cystic Fibrosis Agents
    - vancomycin oral solution (Firvanq) – Gastrointestinal-2 agents: Miscellaneous for *Clostridium difficile* associated diarrhea or enterocolitis

- NF:
    - clobetasol propionate 0.025% cream (Impoyz) – High Potency Corticosteroids-Immune Modulators for Moderate to Severe Plaque Psoriasis
    - desmopressin nasal spray (Noctiva) – Miscellaneous Endocrine Agent for nocturia due to nocturnal polyuria
    - doxylamine/pyridoxine ER tablets (Bonjesta) – Antiemetic-Antivertigo Agents
    - ertugliflozin (Steglatro) – Non-Insulin Diabetes Drugs – Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor
    - ertugliflozin/metformin (Segluromet) – Non-Insulin Diabetes Drugs –SGLT2 Inhibitor
    - ertugliflozin/sitagliptin (Steglujan) – Non-Insulin Diabetes Drugs – SGLT2 Inhibitor
    - glycopyrrolate inhalation solution (Lonhala Magnair) – Pulmonary-2: Long Acting Muscarinic Agents (LAMAs) for Chronic Obstructive Pulmonary Disease
    - pitavastatin magnesium (Zypitamag) – Antilipidemic-Is (LIP-Is)
    - secnidazole (Solosec) – Miscellaneous Anti-Infective for bacterial vaginosis in adult women

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Impoyz, Noctiva, Bonjesta, Steglatro, Segluromet, Steglujan, Lonhala Magnair, Zypitamag, and Solosec. 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 (see Appendix C for the full criteria):

- Applying the same manual PA criteria for ertugliflozin (Steglatro), ertugliflozin/metformin (Segluromet), and ertugliflozin/sitagliptin (Steglujan) in new and current users, as is currently in place for the other non-step-preferred SGLT2 inhibitors. Patients must first try the step-preferred SGLT2 inhibitor empagliflozin (Jardiance, Glyxambi, Synjardy or Synjardy XR).
- Applying the same step therapy and manual PA criteria to new and current users of pitavastatin magnesium (Zypitamag) as is currently in place for pitavastatin calcium (Livalo). Step therapy for the Antilipidemic I's drug class requires a trial of a generic statin at comparable low-density lipoprotein (LDL) lowering capability.
- Applying manual PA criteria to new and current users of Impoyz cream, Lonhala Magnair inhalation solution, Noctiva nasal spray, and Rhopressa ophthalmic solution.
- Applying manual PA criteria to new users of Bonjesta, Erleada, and Symdeko.
- Applying manual PA criteria to new users of Imbruvica tablets and capsules.

  INTERIM P&T COMMITTEE MEETING—Following the May 2018 P&T Committee meeting, the Committee became aware that Imbruvica capsules would remain on the market. The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) to revise the PA for Imbruvica to require a trial of Imbruvica capsules first in new users, prior to use of the tablets, as shifting patients to the tablet formulation unnecessarily reduces dosage titration options.

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 two weeks after the signing of the minutes in all points of service.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications and feedback from the field. The updated manual PAs outlined below will apply to new users.

    a) **Antiemetic-Antivertigo Agents: doxylamine succinate and pyridoxine hydrochloride ER (Diclegis)—**Diclegis PA criteria were first recommended at the August 2014 DoD P&T Committee Meeting. PA criteria were reviewed and updated to require a trial of both OTC doxylamine and pyridoxine before use of Diclegis.

    b) **Targeted Immunomodulatory Biologics (TIBs): abatacept (Orencia)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Orencia was recently approved by the FDA for treatment of polyarticular Juvenile Idiopathic Arthritis (JIA) in patients two year or older. PA criteria were updated to add the additional indication JIA in pediatric patients.

    c) **Targeted Immunomodulatory Biologics (TIBs): secukinumab (Cosentyx)—** Cosentyx was approved by the FDA in January 2015 for treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Since then, three additional indications were approved by the FDA: psoriatic arthritis, psoriasis of the scalp and most recently ankylosing spondylitis in January 2018. The PA criteria were updated to add the additional FDA indications.

    d) **Oncological Agents: abiraterone acetate (Zytiga)—**In April 2011, the FDA approved Zytiga for use in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer in patients who have received prior chemotherapy containing docetaxel. PA criteria for abiraterone (Zytiga) were recommended at the November 2012 meeting, consistent with the FDA labeling. The FDA has subsequently updated the approved labeling for patients with metastatic high-risk castration-sensitive prostate cancer receiving concomitant prednisone. The PA criteria were updated to add the additional FDA indication, and to require that the patient receive concomitant therapy with a gonadotropin-releasing hormone (GnRH) analog or have had bilateral orchiectomy.

    e) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)/Insulin Combination: insulin glargine/lixisenatide (Xultophy) and insulin degludec/liraglutide (Soliqua)**—Xultophy and Soliqua were reviewed in May 2017, and step therapy and manual PA criteria applied. Insulin glargine (Lantus) is the preferred basal insulin. The GLP1RA class was reviewed in February 2018, and exenatide weekly (Bydureon/BCise) and

dulaglutide (Trulicity) were designated as the preferred products. The PA criteria for Xultopy and Soliqua were updated to include provider acknowledgement of the preferred basal insulin and GLP1RAs.

f) **Parkinson's Disease Drugs: amantadine hydrochloride extended release (Gocovri)**—Gocovri was reviewed as a new drug during the November 2017 P&T Committee meeting, and PA criteria were recommended requiring the patient to have failed and tried amantadine immediate release (IR) 200 mg BID. Since this recommendation, feedback was received from neurologists that patients are not always able to tolerate a 400 mg daily dose of amantadine immediate release (IR). The PA criteria for Gocovri were updated to allow a trial of a lower dose of amantadine IR (300 mg daily in divided doses) to qualify for Gocovri.

g) **Oncological Agents: abemaciclib (Verzenio)**—Verzenio was first reviewed at the November 2017 P&T Committee Meeting and PA criteria were recommended for treatment of metastatic breast cancer. The PA criteria were updated to add the new FDA indication for use in postmenopausal women when used in combination with an aromatase inhibitor (i.e. anastrozole/letrozole) as initial endocrine based therapy.

h) **Targeted Immunomodulatory Biologics (TIBs): apremilast (Otezla)—**The current PA criteria for the TIBs does not allow combination therapy with other TIBs, due to overlapping mechanisms of action and risk of enhanced toxicity. Otezla has a mechanism of action unique to the TIBs; it is a phosphodiesterase-4 (PDE4) inhibitor, an enzyme that breaks down cyclic adenosine monophosphate (cAMP). FDA labeling for Otezla does not specify that it cannot be utilized in combination with other TIB agents, and it has a low risk of immunosuppression. The PA criteria for Otezla were updated to allow use in combination with the other TIBs (e.g., in a patient requiring Humira for treatment of RA and Otezla for treatment of plaque psoriasis), if the provider provides documented evidence as to why combination therapy is required.

i) **Clarification for PA criteria for the Weight Loss Drugs from the November 2017 meeting—**The PA criteria were clarified to state the following: "A trial of phentermine **or a generic product (benzphetamine, diethylpropion, phendimetrazine IR/SR)** is required prior to use of the branded agents, unless the patient has a significant CV disease or other contraindications to a stimulant".

   (1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA***— The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Diclegis, Orencia, Cosentyx, Zytiga, Xultophy, Soliqua, Gocovri, Verzenio and Otezla. All updated PA criteria apply to new users. See Appendix C for full criteria.

B. QLs—QLs were reviewed for three drugs from drug classes where there are existing QLs, including the oncologic agents; starter-pack default quantity limits, and six drugs where QLs are not currently in place.

1. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) QLs for Erleada, Solosec, Imbruvica, Lonhala Magnair starter pack and refill kit, Impoyz, and Saxenda. Additionally, default QLs for starter-pack medications were also recommended. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

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

   - (14 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PAs for Diclegis, Orencia, Cosentyx, Zytiga, Xultophy, Soliqua, Gocovri, Verzenio and Otezla become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.

   - (14 for, 0 opposed, 0 abstained, 2 absent) The QLs for the 6 drugs, weight loss agents and starter-packs listed in section VI, B, above, and in Appendix D become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.

VII. LINE EXTENSIONS

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

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) clarifying the formulary status of the following two products to reflect the current formulary status, and applicable step therapy, PA criteria, MN criteria, and QLs for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

   - Insulins—Short Acting Agents: Insulin lispro injection (Humalog U-100 Junior KwikPen) insulin pen with ½ unit dosing for Type 1 Diabetes Mellitus is designated formulary on the UF, which is the same as lispro (Humalog) insulin, and added to the EMMPI list.

   - Attention Deficit Hyperactivity Disorder-Wakefulness Promoting Agents—Stimulants: Amphetamine ER oral solution (Adzenys ER OS) oral solution is designated as NF, with the same MN criteria as Amphetamine ER orally dissolving tablets (Adzenys ER ODT) tablets. See Appendix B for the MN criteria.

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

See Appendix F for the Mail Order status of medications designated NF during the May 2018 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the May 2018 meeting, including the newly approved drugs affected by the EMMPI, will be effective on the first Wednesday two weeks after the signing of the minutes.

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

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

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

   a) **Add**: Insulin lispro (Admelog) and the glaucoma medication netarsudil (Rhopressa); products in these classes have already been designated as suitable for addition to the EMMPI program.

   b) **Do Not Add:**

   - Ibrutinib (Imbruvica) is an oral oncology drug, only some of which are currently on the EMMPI list, and there is no cost advantage at the TRICARE Mail Order Pharmacy or MTFs relative to the Retail Network.
   - The following products fall into classes not currently required to go to the TRICARE Mail Order Pharmacy (i.e., not on the EMMPI list:
     - the antiretrovirals bictegravir/emtricitabine/TAF (Biktarvy), etavirenz/lamivudine/TDF (Symfi, Symfi Lo), and lamivudine/TDF (Cimduo)
     - the cystic fibrosis medication tezacaftor/ivacaftor (Symdeko)
     - the prostate cancer medication apalutamide (Erleada)
   - Vancomycin oral solution (Firvanq) is intended for acute use.

2. ***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):

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: the antidiabetics ertugliflozin (Steglatro), ertugliflozin/metformin (Segluromet), and

ertugliflozin/sitagliptin (Steglujan); glycopyrrolate inhalation solution (Lonhala Magnair); or pitavastatin magnesium (Zypitamag)

b) **Do Not Add:** The P&T Committee recommended exceptions from the mail order requirement for the following medications: clobetasol propionate (Impoyz), doxylamine/pyridoxine ER (Bonjesta), and secnidazole (Solosec), due to acute/time-limited use; and the nocturnal polyuria agent desmopressin nasal (Noctiva), due to safety concerns and uncertainty about real world persistence.

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

The P&T Committee reviewed four drugs from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; these drugs were not in compliance with FY08 NDAA, Section 703. The law stipulates that if a drug is not compliant with Section 703, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail POS and medical necessity at MTFs. These NF drugs will remain available in the Mail Order POS without pre-authorization.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following products be designated NF on the UF:

- Aurobindo Pharma: armodafinil (*New Drug Application-authorized generic*) 200 mg tablet
- Quinn Pharmaceuticals: mercaptopurine (*NDA-authorized generic*) 50 mg tablet
- Noden Pharma: aliskiren (Tekturna) 150 mg tablet; 300 mg tablet
- Noden Pharma: aliskiren-hydrochlorothiazide (Tekturna HCT) 150-12.5 mg tablet; 150-25 mg tablet; 300-12.5 mg tablet; 300-25 mg tablet

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs of armodafinil, mercaptopurine, Tekturna, and Tekturna HCT:

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.

NOTE: Should the mail order requirement impact availability of a drug, the P&T Committee will allow an exception to the Section 703 rule.

C. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period for the Section 703 non-compliant NDCs of armodafinil, mercaptopurine, Tekturna, and Tekturna HCT; and, 2) DHA send letters to beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is November 7, 2018.

X. ITEMS FOR INFORMATION

A. 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 FY17 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 the www.health.mil website when finalized.

B. UF SUB-WORKING GROUP UPDATE: ALIGNING OVER-THE-COUNTER (OTC) FORMULARIES

The P&T Committee was updated on successful implementation of the first phase of an initiative to transition to a more uniform list of OTC products available across MTFs, and ultimately across the pharmacy benefit. The MTF OTC Test List went into effect for MHS GENESIS sites at 0001 on 29 Mar 2018. This list was designed to test the technical aspects of rejecting "not covered" OTC drugs at MTF GENESIS sites and was intended to have minimal impact on current operations; over the first month, less than 1% of all OTC prescriptions were rejected. The project will now move into Phase 2, with the first OTCs identified for removal from the covered list presented to the DoD P&T Committee at an upcoming meeting. The Committee noted that the form for MTFs to request UF changes (available at https://health.mil/PandT) has been updated to include recommended changes to the MTF OTC List.

XI. ADJOURNMENT

The meeting adjourned at 1500 hours on May 10, 2018. The next meeting will be in August 2018.

Appendix A—Attendance: May 2018 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

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

Appendix F—Mail Order Status of Medications Designated Nonformulary During the May 2018 DoD P&T Committee Meeting

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

8 AUG 18

Date

Appendix A—Attendance: May 2018 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC for Mr. David Bobb	Chief, DHA Pharmacy Operations Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
Col James Jablonski, MC	Air Force, Physician at Large
LTC John Poulin, MC	Army, Physician at Large
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Col Kevin (Wade) Tiller, BSC for Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Gwendolyn Thompson, MSC for COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Benjamin Keller, USCG	Coast Guard, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Kelly Echevarria, PharmD	Department of Veterans Affairs
Voting Members Absent	
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
COL Angela Mysliwiec, MC	TRICARE Regional Office Representative
Nonvoting Members Present	
Mr. Bryan Wheeler	Deputy General Counsel, DHA
Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Lt Col John Oberlin, MC	Air Force, Internal Medicine Physician
CAPT Robert Hayes	Indian Health Service
Ms. Kimberlymae Wood	DHA Contract Operations Division
Ms. Yvette Dluhos	DHA Contract Operations Division
LCDR Ebenezer Aniagyei, MSC	Defense Logistics Agency Troop Support
Sooyun Kim, PharmD	Defense Logistics Agency Troop Support
Mayank Patel	Student, University of the Incarnate Word

Appendix A—Attendance (continued)

Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
David Folmar, PharmD	DHA Formulary Management Branch
LCDR Scott Raisor, BCPS	DHA Formulary Management Branch
LCDR Christina Andrade, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
CPT Zachary Leftwich, MSC	DHA Formulary Management Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Cortney Raymond	DHA Formulary Management Branch Contractor
Robert Conrad, PharmD	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Dave Meade, PharmD, BCPS	DHA Integrated Utilization Branch

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• Pancreaze • Pertzye • Ultresa • Zenpep **Pancreatic Enzyme Replacement Therapy (PERT)**	• Use of formulary agent(s) has resulted in therapeutic failure **Formulary Alternatives:** Creon, Viokace
• Genotropin • Humatrope • Nutropin AQ Nuspin • Saizen • Serostim **Growth Stimulating Agents (GSA)**	• Use of <u>all</u> formulary agents is contraindicated • Patient has experienced significant adverse effects from <u>all</u> formulary agents. **Formulary Alternatives:** Norditropin Flex Pro, Omnitrope, Zomacton
• methylnaltrexone (Relistor) tablet **Gastrointestinal-2 Agents: Opioid Induced Constipation**	• Use of <u>all three</u> agents Amitiza, Movantik and Symproic have resulted in therapeutic failure **Formulary Alternatives:** naloxegol (Movantik), naldemedine (Symproic), lubiprostone (Amitiza)
• methylnaltrexone (Relistor) injection **Gastrointestinal-2 Agents: Opioid Induced Constipation**	• No alternative formulary agent: Patient is receiving palliative care **Formulary Alternatives:** naloxegol (Movantik), naldemedine (Symproic)
• clobetasol propionate 0.025% cream (Impoyz) **High Potency Corticosteroids-Immune Modulators**	• Use of all formulary agents are contraindicated **Formulary Alternatives:** clobetasol propionate 0.5% (Clobex, Olux, Temovate, generics), halobetasol propionate (Halonate, generics), desoximetasone (Topicort, generics), fluocinonide 0.05% (non-Vanos products), betamethasone dipropionate augmented (Diprolene/-AF, generics)
• desmopressin nasal spray (Noctiva) **Miscellaneous Endocrine Agents**	• No alternative formulary agent: Patient is an adult and requires treatment for nocturnal polyuria **Formulary Alternatives**: generic desmopressin nasal, oral desmopressin

Drug / Drug Class	Medical Necessity Criteria
• doxylamine/pyridoxine ER tablets (Bonjesta) **Antiemetic-Antivertigo Agents**	• No alternative formulary agent – patient cannot swallow two tablets separately and must take fixed dose combination product **Formulary Alternatives:** OTC pyridoxine (vitamin B6), OTC doxylamine, metoclopramide, ondansetron
• ertugliflozin (Steglatro) • ertugliflozin/metformin (Segluromet) • ertugliflozin/sitagliptin (Steglujan) **Non-Insulin Diabetes Drugs: SGLT2 Inhibitors**	• The patient has experienced significant adverse effects from empagliflozin-containing products that are not expected to occur with ertugliflozin-containing products **Formulary Alternatives:** empagliflozin-containing product (Jardiance, Glyxambi, Synjardy, Synjardy XR))
• glycopyrrolate inhalation solution (Lonhala Magnair) **Pulmonary-2: Long Acting Muscarinic Agents (LAMAs)**	• Use of all formulary and non formulary agents have resulted in therapeutic failure (Spiriva Respimat/Handihaler, Tudorza Pressair, Incruse Ellipta, Seebri Neohaler) **Formulary Alternatives:** Spiriva Handihaler/Respimat, Incruse Ellipta, Tudorza Pressair **Non Formulary Alternative:** Seebri Neohaler
• pitavastatin magnesium (Zypitamag) **Antilipidemic-Is (LIP-Is)**	• Use of all formulary agents is contraindicated and the patient cannot take pravastatin or rosuvastatin **Formulary Alternatives:** atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin
• secnidazole (Solosec) **Miscellaneous Anti-Infective**	• Use of one oral and at least one vaginal formulary agents have resulted in or are likely to result in therapeutic failure **Formulary Alternatives:** metronidazole tablets, metronidazole vaginal gel, clindamycin cream
• amphetamine ER oral solution (Adzenys ER OS) **Attention Deficit Hyperactivity Disorder (ADHD): Stimulants**	• Use of as least two formulary ADHD stimulants is contraindicated • Patient has experienced significant adverse effects from at least two formulary ADHD stimulants • Use of at least two the formulary ADHD stimulants has resulted in therapeutic failure **Formulary alternatives:** mixed amphetamine salts XR (Adderall XR, generic), methylphenidate ER (Ritalin LA); methylphenidate ER oral suspension (Quillivant XR)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Step-Preferred • Creon **Non-Step-Preferred** • Pancreaze • Pertzye • Ultresa • Viokace • Zenpep **Pancreatic Enzyme Replacement Therapy (PERT)**	Creon is the preferred Pancreatic Enzyme Replacement product; Prior Authorization is not required for Creon. Manual PA criteria apply to all new and current users of Pancreaze, Pertzye, Ultresa, Viokace and Zenpep. All new and current users of a PERT are required to try Creon first, before receiving one of the non-step-preferred products. Manual PA criteria—Pancreaze, Pertzye, Ultresa, Viokace and Zenpep is approved if any of the following criteria are met: • The patient has failed an adequate trial of Creon, defined as at least 2 dose adjustments done over a period of at least 4 weeks OR • The patient is ≤ 2 years old and a sufficient trial of Creon was unsuccessful OR • For Viokace: the patient requires an uncoated tablet due to actual or suspected dissolution issues with enteric coating of Creon Prior authorization does not expire.
Step-Preferred • Norditropin FlexPro **Non-Step-Preferred** • Genotropin • Humatrope • Nutropin AQ Nuspin • Omnitrope • Saizen • Serostim • Zomacton **Growth Stimulating Agents (GSA)**	May 2018 changes are bolded **Norditropin FlexPro is the preferred Growth Stimulating Agent** **All new and current users of the nonformulary, non-step-preferred Growth Stimulating Agents must try Norditropin FlexPro first.** Manual PA Criteria: Norditropin FlexPro, Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim and Zomacton are approved if: • The patient is younger than 18 years of age and has the following indications: o Growth hormone deficiency o Small for Gestational Age o Chronic Renal Insufficiency **associated with growth failure** o Prader-Willi Syndrome **(in patients with a negative sleep study for obstructive sleep apnea)** o Turner Syndrome o Noonan's Syndrome o Short stature homeobox (ShoX) gene mutation • For patients younger than 18 years of age who do not have one of the indications above, document the diagnosis below: _____ • For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment **OR** • The patient is older than 18 years of age and has the following indications: o Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood o HIV/AIDS wasting/cachexia o Short Bowel Syndrome • For patients older than 18 years of age, the prescription is written by **or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist)** AND For Omnitrope and Zomacton: In addition to the above criteria, the following criteria applies to new users of Omnitrope and Zomacton: • The patient has a contraindication to Norditropin FlexPro OR

Drug / Drug Class	Prior Authorization Criteria
	• The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with Omnitrope or Zomacton (e.g. because of different preservative) OR • For Zomacton: the patient prefers a needle free device **AND** <u>For Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, and Serostim</u>: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, and Serostim: • The patient has a contraindication to Norditropin FlexPro AND Omnitrope AND Zomacton OR • The patient has experienced an adverse reaction to Norditropin FlexPro AND Omnitrope AND Zomacton that is not expected with the non-step-preferred product (e.g., because of different preservative) Note that all possible preservative formulations are available between Norditropin FlexPro, Omnitrope, and Zomacton. Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, or Serostim • Use of a Growth Stimulating Agent is not approved for idiopathic short stature, the normal ageing process, obesity, or depression • Use of a Growth Stimulating Agent is not approved for other off-label uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment, etc.) • Concomitant use of multiple Growth Stimulating Agents is not approved Prior authorization expires in one year.
• naloxegol (Movantik) **GI-2 Agents : Opioid Induced Constipation Subclass**	Changes from the May 2018 meeting are in strikethrough; **May 2018 updates are in BOLD.** Manual PA criteria apply to new users of Movantik. <u>Manual PA criteria</u>—Approved if all criteria are met: • The patient is 18 years of age or older with a diagnosis of opioid-induced constipation (OIC) AND • The patient is currently taking an opioid agonist AND • The patient is not on other opioid antagonists (naloxone not including rescue agents**,** naltrexone, etc.) AND • The patient has either failed or not tolerated two or more of the following: o At least one stimulant laxative (sennosides or bisacoldy) AND o At least one osmotic laxative (Miralax, lactulose, or magnesium citrate) AND ~~• Must have failed lubiprostone (Amitiza) AND~~ • The patient does not have a known or suspected gastrointestinal obstruction or is not at increased risk of recurrent obstruction AND • The patient is not currently on strong CYP3A4 inducers inhibitors (e.g., clarithromycin, ketoconazole) Non-FDA-approved uses are not approved. Prior authorization ~~does not expire~~ expires in 1 year. <u>Renewal PA Criteria</u>: Coverage will be approved for an additional year if <u>all</u> of the following apply: • The patient continues to take opioids AND • The patient continues lifestyle modifications including regular use of a stimulant laxative (e.g. bisacodyl, senna), a high fiber diet, increased fluid intake, moderate exercise and opioid dose de-escalation to minimum effective dose AND • The patient is responding in a meaningful manner (e.g. improvement of at least 1 additional spontaneous bowel movement per week over baseline)

Drug / Drug Class	Prior Authorization Criteria
• naldemedine (Symproic) **GI-2 Agents : Opioid Induced Constipation Subclass**	Manual PA criteria apply to new users of Symproic Manual PA criteria—Approved if all criteria are met: • The patient is 18 years of age or older with a diagnosis of opioid-induced constipation (OIC) AND • The patient is currently taking an opioid agonist AND • The patient is not on other opioid antagonists (naloxone not including rescue agents, naltrexone, etc.) AND • The patient has either failed or not tolerated two or more of the following: o At least one stimulant laxative (sennosides or bisacodyl) AND o At least one osmotic laxative (Miralax, lactulose, or magnesium citrate) AND • The patient does not have a known or suspected gastrointestinal obstruction or is not at increased risk of recurrent obstruction AND • The patient is not currently on strong CYP3A4 inducers inhibitors (e.g., clarithromycin, ketoconazole) Non-FDA-approved uses are not approved. Prior authorization expires in 1 year. Renewal PA Criteria: Coverage will be approved for an additional year if all of the following apply: • The patient continues to take opioids AND • The patient continues lifestyle modifications including regular use of a stimulant laxative (e.g. bisacodyl, senna), a high fiber diet, increased fluid intake, moderate exercise and opioid dose de-escalation to minimum effective dose AND • The patient is responding in a meaningful manner (e.g. improvement of at least 1 additional spontaneous bowel movement per week over baseline)
• methylnaltrexone (Relistor) tablets **GI-2 Agents : Opioid Induced Constipation Subclass**	Changes from the May 2018 meeting are in strikethrough; **May 2018 updates are in BOLD.** Manual PA criteria apply to new and current users of Relistor tablets. PA is not required for Relistor injection. Manual PA criteria—Approved if all criteria are met: • The patient is 18 years of age or older with a diagnosis of opioid-induced constipation (OIC) AND • The patient is currently taking an opioid agonist AND • The patient is not on other opioid antagonists (naloxone not including rescue agents, naltrexone, etc.) AND • The patient has either failed or not tolerated two or more of the following: o At least one stimulant laxative (sennosides or bisacodyl) AND o At least one osmotic laxative (Miralax, lactulose, or magnesium citrate) AND • **The patient has tried and failed naloxegol (Movantik) AND** • **The patient has tried and failed naldemedine (Symproic) AND** • The patient has tried and failed lubiprostone (Amitiza) AND • The patient does not have a known or suspected gastrointestinal obstruction or is not at increased risk of recurrent obstruction AND • The patient is not currently on strong CYP3A4 inducers inhibitors (e.g., clarithromycin, ketoconazole) Non-FDA-approved uses are not approved. Prior authorization ~~does not expire~~ expires in 1 year. Renewal PA Criteria: Coverage will be approved for an additional year if all of the following apply: • The patient continues to take opioids AND • The patient continues lifestyle modifications including regular use of a stimulant laxative (e.g. bisacodyl, senna), a high fiber diet, increased fluid intake, moderate exercise and opioid dose de-escalation to minimum effective dose AND • The patient is responding in a meaningful manner (e.g. improvement of at least 1 additional spontaneous bowel movement per week over baseline)

Drug / Drug Class	Prior Authorization Criteria
• apalutamide (Erleada) **Oral Oncologic Agent**	Manual PA criteria apply to all new users of Erleada Manual PA criteria: Erleada is approved if all criteria are met: • The patient has a diagnosis of non-metastatic castration-resistant prostate cancer (as shown by a negative CT scan of abdomen/pelvis and/or negative bone scan) AND • Patients should be co-prescribed gonadotropin-releasing hormone analog therapy concurrently OR patients should have had bilateral orchiectomy AND • Erleada is prescribed by or in consultation with an oncologist or urologist Non-FDA-approved uses are not approved. Prior authorization expires in one year Renewal criteria: Erleada will be continued for another year if: • The patient continues to be free of metastases • No toxicities have developed • The patient has not had disease progression requiring subsequent therapy (such as abiraterone [Zytiga])
• clobetasol propionate 0.025% cream (Impoyz) **High Potency Corticosteroids-Immune Modulators**	Manual PA applies to all new and current users of Impoyz Manual PA criteria: Coverage will be approved if all criteria are met: • Patient has moderate to severe plaque psoriasis AND • Patient is ≥ 18 years old AND • Patient is not a candidate for or has failed phototherapy AND • Contraindications exist to all formulary high-potency topical steroids **OR** • Patient has had an inadequate response to all formulary high-potency topical steroids **OR** • Patient has had an adverse effect to each of the formulary high-potency topical steroids Non-FDA-approved uses are not approved. Prior authorization expires in 30 days. Renewal Criteria: Renewal of therapy will not be allowed
• desmopressin nasal spray (Noctiva) **Endocrine Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Noctiva. Manual PA criteria: Coverage will be approved if all criteria are met: • The patient ≥ 50 years old (only the low dose is allowed for pts >65 years old) • Causes of nocturia have been evaluated, nocturnal polyuria is confirmed with a 24-hour urine collection, and the patient has experienced at least 2 nocturia episodes per night for ≥6 months • The patient is not currently taking any of the following medications: o loop diuretics, thiazide diuretics, systemic or inhaled corticosteroids, lithium, alpha 1-adrenoceptor antagonists, 5-alpha reductase inhibitors (5-ARIs), anticholinergics, antispasmodics, sedative/hypnotic agents, NSAIDs, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), antidepressants, anti-epileptics, opioids, or sodium glucose co-transporter 2 inhibitors (SGLT2s) • The patient has normal sodium level (135-145 meq/L) prior to initiation of therapy; the sodium level is rechecked after one week of therapy, and another sodium level is rechecked after 1 month of therapy • The patient does not have the following conditions: o acute or chronic rhinitis

Drug / Drug Class	Prior Authorization Criteria
	o atrophy of nasal mucosa o renal impairment (eGFR < 50 mL/min) o hyponatremia or history of hyponatremia o polydipsia o nocturnal enuresis o syndrome of inappropriate antidiuretic hormone (SIADH) o congestive heart failure (New York Heart Association Class II-IV) o uncontrolled hypertension or uncontrolled diabetes mellitus Non-FDA-approved uses are not approved. Prior authorization expires in 6 months. Renewal criteria: Coverage will be approved for an additional 6 months if all of the following apply: • Patient has not developed any of the above conditions • Patient is not taking any of the above medications • Patient has shown a reduction in nocturia episodes
• doxylamine succinate and pyridoxine ER tablets (Bonjesta) • doxylamine succinate and pyridoxine tablets (Diclegis) **Antiemetics/Antivertigo Agents**	Manual PA applies to all new users of Bonjesta and Diclegis Manual PA criteria: Bonjesta is approved if ALL criteria are met. • The patient has a diagnosis of nausea and vomiting associated with pregnancy • The patient has tried at least one non-pharmacologic treatment (for example, ginger, acupressure, high protein bedtime snack) and failed to obtain relief of symptoms • The patient has tried OTC doxylamine **and** pyridoxine and failed to obtain relief of symptoms • The provider has considered a change to an alternate anti-emetic (e.g., ondansetron) prior to prescribing Bonjesta or Diclegis Non-FDA-approved uses are not approved. Prior authorization will expire after 9 months.
• glycopyrrolate inhalation solution (Lonhala Magnair) • **Pulmonary-2: Long Acting Muscarinic Agents (LAMAs)**	Manual PA is required for all new and current users of Lonhala Magnair inhalation solution (starter kit and refill kit) Lonhala Magnair is approved if all criteria are met: • The patient has a diagnosis of chronic obstructive pulmonary disease AND • The patient has tried and failed an adequate course of a nebulized Short Acting Muscarinic Antagonist (e.g., ipratropium) AND • The patient has tried and failed an adequate course of Spiriva Respimat AND • The patient has tried and failed an adequate course of therapy at least one of the following dry powder inhalers: Tudorza Pressair, Incruse Ellipta, Spiriva Handihaler, or Seebri Neohaler OR • The patient cannot generate the peak inspiratory flow needed to activate at least one of the following dry powder inhalers: Tudorza Pressair, Incruse Ellipta, Spiriva Handihaler, or Seebri Neohaler Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ertugliflozin (Steglatro) • ertugliflozin/metformin (Segluromet) • ertugliflozin/sitagliptin (Steglujan) **Non-Insulin Diabetes Drugs: SGLT2 Inhibitors**	Manual PA criteria apply to all new and current users of Steglatro, Segluromet, and Steglujan Manual PA criteria—Coverage will be approved if all criteria are met: • For Steglatro: o The patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin AND o The patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, and Synjardy XR) and had an inadequate response or experienced significant adverse events, or have a contraindication to the preferred empagliflozin-containing SGLT2 inhibitor. • For Segluromet: o The patient has had an inadequate response to metformin AND o The patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, and Synjardy XR) and experienced a significant adverse event, that is not expected to occur with the preferred empagliflozin-containing SGLT2 inhibitor. • For Steglujan: o The patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin AND o The patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, and Synjardy XR) and had an inadequate response or experienced significant adverse events, or have a contraindication to the preferred empagliflozin-containing SGLT2 inhibitor. AND o The patient must have had an inadequate response to sitagliptin alone. Non-FDA-approved uses are not approved. Prior authorization does not expire.
• ibrutinib (Imbruvica) tablets and capsules **Oral Oncologic Agents**	Manual PA criteria apply to all new users of Imbruvica tablets and capsules Manual PA criteria—Coverage will be approved if all criteria are met: • Imbruvica capsules are the preferred Department of Defense' preferred formulation for Imbruvica. o **If the prescription is for Imbruvica capsules, please continue to the questions below.** o **If the prescription is for Imbruvica tablets, documentation must be provided as to why the capsule formulation cannot be used, and then continue with the questions below.** ▪ **Why can't the patient take the capsule formulation of Imbruvica:** _____ • The patient is ≥ 18 years old • The patient has laboratory evidence of and pathologic confirmation of 1 of the following: o Mantle Cell Lymphoma o Marginal Zone Lymphoma o Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma with or without 17p deletion o Waldenström's macroglobulinemia o chronic Graft versus Host Disease • Imbruvica is prescribed by or in consultation with a hematologist/oncologist Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• netarsudil 0.02% ophthalmic solution (Rhopressa) **Glaucoma Agents**	Manual PA criteria apply to all new and current users of Rhopressa Manual PA criteria: Rhopressa approved if all criteria are met: • The patient has a diagnosis of ocular hypertension or open-angle glaucoma • The prescription is written by an ophthalmologist or an optometrist • The patient has had a trial of appropriate duration of two different formulary options from different glaucoma drug classes, in combination or separately, and has not reached intraocular pressure target goals as defined by provider. The drug classes include: o prostaglandin analogs (latanoprost or bimatoprost) o beta blockers (Betoptic, Betoptic-S, Ocupress, Betagan, Optipranolol) o alpha 2-adrenergic agonists (brimonidine, apraclonidine) o topical carbonic anhydrase inhibitors (dorzolamide (Trusopt) Non-FDA-approved uses are not approved. PA does not expire
• pitavastatin magnesium (Zypitamag) **Antilipidemic Is (LIP-Is)**	All new and current users of Zypitamag must try a preferred statin at appropriate LDL lowering first. Automated PA criteria • The patient has received a prescription for a preferred agent (generic atorvastatin, simvastatin, pravastatin, fluvastatin, lovastatin, pravastatin or rosuvastatin) targeting similar LDL reduction (LDL lowering between 30% to 50%, LDL lowering <30%) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria—If automated criteria are not met, Zypitamag is approved (e.g., trial of generic statin is NOT required) if: • The patient has tried a preferred statin with similar LDL reduction (moderate or low intensity) and was unable to tolerate it due to adverse effects. • The patient is taking a drug that is metabolized by CYP3A4 is unable to take pravastatin or rosuvastatin PA does not expire.
• tezacaftor/ivacaftor (Symdeko) **Cystic Fibrosis Agents**	Manual PA criteria apply to new users of Symdeko. Manual PA criteria—Symdeko is approved if **ALL** of the following criteria are met: • Symdeko is prescribed for the treatment of cystic fibrosis in patient ages 12 years and older. • The patient meets the following criteria: a. The patient is homozygous for the *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test. OR b. The patient has at least one specific gene mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Symdeko as detected by an FDA-approved CF mutation test. AND c. Please enter the CF-related gene mutation based on FDA-Approved testing. (write in below): _____ • Symdeko is not approved for use in combination with other CFTR modulators (e.g., Orkambi, Kalydeko). Non-FDA-approved uses are not approved. Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• abiraterone acetate (Zytiga) **Oncological Agents**	**May 2018 updates are in BOLD.** Manual PA criteria apply to all new users of Zytiga. Manual PA criteria—Zytiga is approved if **ALL** of the following criteria are met: • Patient has a documented diagnosis of – metastatic castration-resistant prostate cancer (CRPC) OR – **metastatic high-risk castration-sensitive prostate cancer (CSPC)** AND • On concomitant prednisone • Concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog or have had bilateral orchiectomy Non-FDA-approved uses are not approved. Prior authorization does not expire.
• amantadine ER Gocovri) **Parkinson's Disease Drugs**	Changes from the May 2018 meeting are in strikethrough; additionally, **May 2018 updates are in BOLD.** Manual PA criteria apply to all new users of Gocovri. Manual PA Criteria—Gocovri is approved if: • The patient is ≥18 years old AND • Has a diagnosis of Parkinson's Disease AND • Has had therapeutic failure of a trial of amantadine ~~200mg BID~~ **300 mg/day given in divided** doses using immediate release tablets Non-FDA-approved uses are not approved. Prior authorization does not expire.
• Apremilast (Otezla) • **Targeted Immunomodulatory Biologics (TIBs)**	Changes from the May 2018 meeting are in strikethrough; additionally, **May 2018 updates are in BOLD.** Manual PA criteria apply to all new users of Otezla. Manual PA criteria—Coverage will be approved if ALL of the following criteria are met: • **Provider acknowledges: adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent for FDA-approved indications** • Patient has had a contraindication, inadequate response or experienced an adverse reaction to adalimumab (Humira) • Patients ≥ 18 with • Active psoriatic arthritis OR • Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy • ~~Not approved for use in combination with other biologics~~ • ~~Coverage NOT provided for concomitant use with other TIBS (anakinra, etanercept, adalimumab, golimumab, certolizumab, or infliximab)~~ • Will Otezla be prescribed in combination with Actemra, Cimzia, Enbrel, Humira, Kineret, Orencia, Remicade, Rituxan, Simponi, Stelara, or Xeljanz? • **If yes: Fill in the blank write-in referencing literature to support combination and patient will be monitored closely for adverse effects** Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• **Starter Packs for all drug classes**	▪ Quantity per Duration Event (QPDE): 1 pack/fill and no refills allowed)
• apalutamide (Erleada) **Oncologic Agents**	▪ MTF/Mail: 180 tablets/45 days ▪ Retail: 120 tablets/30 days
• clobetasol propionate 0.025% (Impoyz) **Antiviral Agents**	▪ MTF/Mail/Retail: 120 grams/28 days
• glycopyrrolate Nebulizer (Lonhala Magnair) **Pulmonary-2 Agents: Long Acting Muscarinic Antagonists**	▪ MTF/Mail: 3 devices/90-day supply ▪ Retail: 1 device/30-day supply
• glycopyrrolate Nebulizer (Lonhala Magnair Starter Pack) **Pulmonary-2 Agents: Long Acting Muscarinic Antagonists**	▪ Quantity per Duration Event (QPDE): 1 pack/fill and no refills allowed)
• ibrutinib (Imbruvica) tablets **Oncological Agents**	▪ MTF/Mail: 56 tabs/56 days ▪ Retail: 28 tabs/28 days
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• naldemedine (Symproic) • naloxegol (Movantik) **Opioiod Induced Constipation**	▪ MTF/Mail: 60 day supply ▪ Mail: 30 day supply
• methylnaltrexone tabs and injection (Relistor) **Opioiod Induced Constipation**	▪ MTF/Mail: 60 day supply ▪ Mail: 45 day supply
• secnidazole (Solosec) **Anti-Infectives**	▪ MTF: 1 packet per 7 days, no refills ▪ Retail: 1 packet per 7 days, no refills ▪ Note – not appropriate for dispensing at Mail Order, due to acute use

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

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
apalutamide (Erleada)	Oncological Agents: Prostate II	• abiraterone (Zytiga) • enzalutamide (Xtandi)	Non-metastatic castration resistant prostate cancer	• While technically the 1st agent FDA approved for non-metastatic castration resistant prostate cancer, available agents that are UF have data supporting use, with one pending FDA review/approval for this specific indication • National Cancer Comprehensive Network (NCCN) Category 1 recommended for this indication, especially if prostate specific antigen (PSA) doubling time ≤ 10 months • 1st drug approved based on endpoint of metastasis-free survival (length of time tumor did not spread to other parts of the body/death after starting treatment)	• UF • Do not add to EMMPI list
bictegravir/ emtricitabine/ tenofovir alafenamide (Biktarvy)	Antiretrovirals: Combinations	• Tivicay + Descovy • Genvoya • Triumeq • Stribild	HIV-1 treatment in tx-naïve adults or patients stable on current regimen for ≥ 3 mos. w/o hx of tx failure or resistance to individual components	• 8th single tablet regimen (STR) option for HIV treatment • Formulation has bictegravir: a new integrase strand transfer inhibitor (INSTI) • Evaluated in two phase III non-inferiority trials vs Triumeq and vs Tivicay+Descovy • Not studied in patients with chronic kidney disease, viral hepatitis, pregnancy, pediatric, or geriatric populations • Has not been investigated with nucleoside reverse transcriptase inhibitor (NRTI) backbones other than Truvada • Black box warning (BBW): post-treatment acute exacerbation of Hepatitis B • Need more data on efficacy, safety, and resistance to better characterize strengths and weaknesses • Provides an additional first-line option	• UF • Do not add to EMMPI list
clobetasol propionate 0.25% cream (Impoyz)	Corticosteroids-Immune Modulators: High Potency	• clobetasol 0.05% cream • fluocinonide 0.05% cream • betamethasone dipropionate augmented 0.05% cream • desoximetasone 0.25% cream • halobetasol 0.05% cream • diflorasone 0.05% cream • fluocinonide 0.1% cream	Moderate-severe plaque psoriasis	• A new formulation (0.025%) of clobetasol propionate; a high potency steroid • Numerous similar formulary options (28 options on BCF and UF) • Within potency classes (high, medium, low) and vehicle, topical steroids are highly interchangeable • Impoyz is a reduced concentration (0.025% vs 0.05%) indicated for more severe disease (moderate-severe vs mild-moderate) with lower efficacy than comparators (30% vs 50%-100% clearance) • No advantage over existing formulary agents	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
desmopressin nasal spray (Noctiva)	Endocrine agents miscellaneous	• DDAVP Nasal	Nocturia due to nocturnal polyuria	• A new formulation of desmopressin approved in adults for the indication of nocturia due to nocturnal polyuria • Noctiva was evaluated in two 12-week placebo controlled, phase 3 studies • Noctiva was statistically superior to placebo in reducing the average number of nocturic episodes per night from baseline however there was no clinically relevant difference • Significant placebo effect • Significant safety concerns exist including a black box warning for risk of hyponatremia and drug interactions • There is little to no clinical benefit of Noctiva	• NF • Do not add to EMMPI list
doxylamine-pyridoxine ER (Bonjesta)	Antiemetic-Antivertigo Agents	• pyridoxine 25mg OTC • doxylamine 25mg OTC • ondansetron 8mg • Diclegis	Nausea/vomiting in pregnancy for those who do not respond to conservative management	• 2nd available combination pyridoxine and doxylamine product • Same manufacturer and active ingredients as Diclegis, but contains an ER formulation of pyrodoxine • Approved with one bioequivalence study • Both components available over the counter • Use in hyperemesis gravidarum has not been studied • One small head-to-head comparator trial showed ondansetron was more effective • Has little to no clinical benefit relative to similar drugs on the formulary and available OTC	• NF • Do not add to EMMPI list
efavirenz/ lamivudine/ tenofovir disoproxil fumarate (Symfi)	Antiretrovirals: Combinations	• Atripla • Complera	HIV-1 treatment for adult and pediatric patients weighing ≥ 40 kg	• Symfi was evaluated in one phase III non-inferiority active comparator trial • Not studied in geriatric population • Not recommended in moderate/severe hepatic impairment, renal impairment, pregnancy or lactation • BBW: Post treatment acute exacerbation of Hepatitis B • Same ADRs as individual agents combined • Provides an alternative that could be utilized as an single tablet regimen (STR) based upon patient needs/individualization	• UF • Do not add to EMMPI list
efavirenz/ lamivudine/ tenofovir disoproxil fumarate (Symfi Lo)	Antiretrovirals: Combinations	• Atripla • Complera	HIV-1 treatment for adult and pediatric patients weighing ≥ 35 kg	• Same as Symfi except Symfi Lo utilized two studies to provide indirect efficacy results • Provides an alternative that could be utilized as an single tablet regimen (STR) based upon patient needs/individualization	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
ertugliflozin (Steglatro)	Non-insulin diabetes drugs: SGLT2 Inhibitors	• empagliflozin (Jardiance)	To improve glycemic control in adults with T2DM	• Ertugliflozin is the 4th FDA-approved SGLT2 inhibitor • Approved as a fixed dose combination (FDC) with sitagliptin (Steglujan) and as a FDC with metformin (Segluromet) • Ertugliflozin was evaluated in 7 placebo or active controlled clinical trials as monotherapy, in 2-drug, and 3-drug combinations • There are no head to head studies between ertugliflozin and other SGLT2 inhibitors • Clinically relevant differences in A1c were achieved when compared to placebo • Three drug combinations provided greater reduction in A1c compared to two drugs, however there were no clinically relevant differences • Step therapy exists in the SGLT2 inhibitor class requiring a trial of empagliflozin prior to use of other SGLT2 inhibitors • Adds no compelling clinical advantage over existing UF agents	• NF and non-step-preferred • Add to EMMPI list
ertugliflozin/ metformin (Segluromet)	Non-insulin diabetes drugs: SGLT2 Inhibitors	• empagliflozin/ metformin (Synjardy, Synjardy XR)	For pts not adequately controlled on ertugliflozin or metformin, or in pts already treated with both ertugliflozin and metformin	• Same as above for ertrugliflozin • Approved as a fixed dose combination (FDC) with metformin (Segluromet) • Adds no compelling clinical advantage over existing UF agents	• NF and non-step-preferred • Add to EMMPI list
ertugliflozin/ sitagliptin (Steglujan)	Non-insulin diabetes drugs: SGLT2 Inhibitors	empagliflozin (Jardiance) sitagliptin (Januvia) • empagliflozin/ linagliptin (Glyxambi)	T2DM; when treatment with both ertugliflozin and sitagliptin is appropriate	• Same as above for ertrugliflozin • Approved as a fixed dose combination (FDC) with sitagliptin (Steglujan) • Adds no compelling clinical advantage over existing UF agents	• NF and non-step-preferred • Add to EMMPI list
glycopyrrolate inhalation solution (Lonhala Magnair)	Pulm-2: LAMAs	• tiotropium (Spiriva Respimat/ Handihaler) • umeclidinium (Incruze Ellipta) • glycopyrrolate (Seebri Neohaler)	For the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD)	• Lonhala Magnair is the 5th LAMA and the 1st nebulized LAMA • Spiriva Respimat is a soft mist inhaler which does not require inspiratory flow of ≥60 L/min • Lonhala Magnair was superior to placebo in improving FEV 1 and was similar in efficacy to tiotropium (Spiriva Handihaler) • Same active ingredient and similar amount delivered to lungs (14.2mcg vs 13.1mcg) as NF agent Seebri Neohaler	• NF • Add to EMMPI list
ibrutinib tablets (Imbruvica)	Oral Oncological Agents	• acalabrutinib (Calquence)	• Mantle cell lymphoma • Chronic lymphocytic leukemia (CLL) • Small lymphocytic lymphoma (SLL)	• First approved in 2013 as capsules • New formulation of oral tablets • No new studies and no new indications • Ibrutinib is one of two Bruton Tyrosine Kinase Inhibitors with more indications than its comparator	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
			• Waldenström's macroglobulinemia • Marginal zone lymphoma (MZL) • Chronic graft versus host disease (cGVHD)	• Indirect comparison with comparator shows worse adverse event profile • Oncologist concerns regarding requiring patients to transition to once daily dosing when dose titration may be regularly required	
insulin lispro (Admelog)	Insulins: Short-acting agents	• insulin aspart (Novolog) • insulin lispro (Humalog)	To treat diabetes mellitus, Type 1 and 2 in adults and pediatric patients > 3 years	• Admelog is a new formulation of insulin lispro • Admelog was evaluated in 2 open-label active comparator studies with another insulin lispro • Similar efficacy in term of change in A1c levels from baseline treatment groups at the primary endpoint at week 26 • Provides no compelling clinical advantage over existing rapid-acting insulins	• UF • Add to EMMPI list
lamivudine/ tenofovir disoproxil fumarate (Cimduo)	Antiretrovirals: Nucleoside/ Nucleotide Reverse Transcriptase Inhibitor (NRTI)	• Truvada • Combivir • Epzicom	For use in combination with other antiretroviral agents for HIV-1 treatment of adult and pediatric patients weighing ≥ 35 kg	• Cimduo was evaluated in one phase III non-inferiority to provide indirect efficacy results • Not recommended in hepatic impairment, CrCl <50mL/min, or lactating patients • Same ADRs as individual agents combined • BBW: Post treatment acute exacerbation of Hepatitis B • Provides an alternative that could be utilized as a two-NRTI backbone for a three drug regimen based upon patient needs/individualization	• UF • Do not add to EMMPI list
netarsudil 0.02% ophthalmic solution (Rhopressa)	Glaucoma Agents	• latanoprost 0.05% • timolol 0.5%	Reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension	• Rhopressa is a novel ophthalmic agent indicated for elevated IOP in patients with open-angle glaucoma or ocular hypertension • Evaluated in 2 pivotal phase 3 studies; both studies showed Rhopressa lowered IOP by a minimally clinically important difference (MCID) of 5 mmHg difference from baseline; one study demonstrated non-inferiority to timolol 0.05% BID • Dosed once daily • Conjunctival hyperemia incidence is > 50% and is higher than other agents • Limitations include short duration of studies and no combination studies	• UF • Add to EMMPI list
pitavastatin magnesium (Zypitamag)	Antilipidemics-1	• atorvastatin • pravastatin • simvastatin • pitavastatin calcium (Livalo)	Reduce TC, LDL, TG, apolipoprotein B, and increase HDL; for patients with primary hyperlipidemia or mixed hyperlipidemia as an adjunct to diet	• Approved via 505b2 application using clinical data from pitavastatin (Livalo) • Low to moderate intensity (LDL lowering less than 45%) statin with same active ingredient as Livalo, just with a magnesium salt instead of calcium salt. • No cardiovascular outcomes studies have been conducted with any pitavastatin formulation • No clinical benefits over generic, cost effective statins that have proven cardiovascular benefits from outcome studies	• NF and non-step preferred • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
secnidazole (Solosec)	Antiinfectives: Miscellaneous	• metronidazole 500mg tablet • metronidazole vaginal gel • sclindamycin vaginal gel	Bacterial vaginosis in adult women	• Secnidazole is a new antiinfective granted accelerated approval with a QIDP designation indicated for bacterial vaginosis • Current guidelines suggest oral metronidazole, tinidazole cream, metronidazole gel, clindamycin oral and cream • A single 2 gram dose of oral secnidazole has similar safety and efficacy as 14 doses of metronidazole • Disulfiram reaction is a precaution • Cross resistance vs metronidazole possible • Advantage: single 2 gram dose for bacterial vaginosis tx	• NF • Do not add to EMMPI list
tezacaftor/ ivacaftor (Symdeko)	Cystic Fibrosis Agents	• Kalydeco • Orkambi	CF in patients who are ≥12 years who are homozygous for ΔF508 CFTR mutation or other CFTR mutations responsive to drug	• 3rd CFTR modulator on the market approved for CF; 2nd combination formulation • Two phase III RCTs showed statistical superiority over placebo in absolute Δ $ppFEV_1$ from baseline (4-5% improvement from baseline is considered clinically meaningful) • Dosing adjustments recommended w/ moderate to strong CYP3A inhibitors • Offers coverage for both homozygous and heterozygous ΔF508 CFTR mutations • Advantages: Similar clinical profile compared to Orkambi, but with expanded mutation coverage, fewer ADRs, less hepatotoxicity, and fewer drug interactions	• UF • Do not add to EMMPI list
vancomycin HCL oral solution (Firvanq)	Gastrointestinal-2 agents: Miscellaneous	• Fidaxomicin	*C. diff.* associated diarrhea or Enterocolitis caused by *MSSA/MRSA* in adults or pediatric patients	• Firvanq is the first FDA-approved oral vancomycin solution; no compounding required • Oral vancomycin is one of two drugs recommended as 1st line therapy for *C. diff.* infections per updated IDSA 2017 Guidelines • No new studies were submitted for this approval; efficacy based on two previous trials conducted on vancomycin capsules • Advantage: only FDA-approved vancomycin solution	• UF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Nonformulary During the May 2018 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 2018	**Pancreatic Enzyme Replacement Therapies (PERT)†** ▪ Pancreaze ▪ Pertzye ▪ Ultresa ▪ Zenpep **Growth Stimulating Agents (GSA) *††** ▪ Genotropin ▪ Genotropin MiniQuick ▪ Humatrope ▪ Nutropin ▪ Saizen ▪ Serostim **Newly Approved Drugs per 32 CFR 199.21(g)(5)** ▪ ertugliflozin (Steglatro)* ▪ ertugliflozin/metformin (Segluromet)* ▪ ertugliflozin/sitagliptan (Steglujan)* ▪ glycopyrrolate inhaler (Lonhala Magnair)* ▪ pitavastatin magnesium (Zypitamag)*	**GI-2 Agents: Opioid Induced Constipation Agents** High rate of medication discontinuation: ▪ methylnaltrexone (Relistor) tablets and SQ injection **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Acute use exception applies:** ▪ clobetasol propioinate 0.25% cream (Impoyz) ▪ doxylamine/pyridoxine extended release (Bonjesta) ▪ secnidazole (Solosec) **Other:** Uncertainty about real world persistence and safety concerns: ▪ desmopressin nasal (Noctiva)

***Note: class as a whole is on the EMMPI list

† For the PERT class, Creon and Viokace are added to the EMMPI program. See page 4

†† For the GSA class, Norditropin Flex Pro is already on the EMMPI program.

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2018	**Pancreatic Enzyme Replacement Therapy**	UF Class Review Class previously reviewed Feb 2011, Feb 2014	BCF, step preferred ▪Creon	UF, non-step-preferred ▪ Viokace	NF, non-step-preferred ▪ Pancreaze ▪ Pertzye ▪ Ultresa ▪ Zenpep	Pending signing of the minutes / 90 days The effective date is November 7, 2018	▪ Manual PA criteria applies to all new and current users ▪ No PA required for Creon	▪ A trial of Creon is required first in all new and current users ▪ See Appendix C for PA criteria.
May 2018	**Growth Stimulating Agents**	UF Class Review Class previously reviewed in Aug 2007	Extended Core Formulary, step-preferred: ▪Norditropin FlexPro	UF non-step-preferred ▪ Omnitrope ▪ Zomacton	NF non-step-preferred ▪ Genotropin ▪ Humatrope ▪ Nutropin ▪ Saizen ▪ Serostim	Pending signing of the minutes / 90 days The effective date is November 7, 2018	▪ Manual PA criteria applies to all new and current users	▪ Must try Norditropin FlexPro first in all new and current users. Then must use Omnitrope and Zomacton (either order) before moving to NF agents (Genotropin, Humatrope, Nutropin, Saizen, and Serostim) ▪ See Appendix C.

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 2018	**GI-2 Agents Opioid Induced Constipation (OIC) Subclass**	UF Class Review Subclass not reviewed; Class Reviewed Nov 2015	▪BCF: none in the subclass metronidazole is BCF for the GI-2 Agents	▪ naldemedine (Symproic) ▪ naloxegol (Movantik)	▪ methylnaltrexone (Relistor) tablet and injection	Pending signing of the minutes / 60 days The effective date is October 10, 2018	▪ Manual PAs and QLs apply ▪ No PA required for Relistor injection	▪ PA applies: must try two OTC laxatives before use of an OIC drug. ▪ Relistor tabs must try Movantik, Symproic and Amitiza first in new and current users ▪ See Appendix C

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

Appendix H—Table of Abbreviations

A1c	hemoglobin A1c
ADHD	Attention Deficit Hyperactivity Disorder
ADR	adverse drug reaction
AE	adverse event
ARR	absolute risk reduction
BBW	black box warning
BCF	Basic Core Formulary
BIA	budget impact analysis
BPA	blanket purchase agreement
CF	cystic fibrosis
CFR	Code of Federal Regulations
CFTR	cystic fibrosis transmembrane conductance regulator
CLL	chronic lymphocytic leukemia
CMA	cost minimization analysis
COPD	chronic obstructive pulmonary disease
CrCl	creatinine clearance
CV	cardiovascular
CVOTs	cardiovascular outcomes trials
DAPA	Distribution and Pricing Agreement
DHA	Defense Health Agency
DoD	Department of Defense
DPI	dry powder inhaler
DR	delayed release
ECF	Extended Core Formulary
EHR	electronic health record
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FDC	fixed-dose combination
FEV1	forced expiratory volume in one second
FY	Fiscal Year
G-tube	gastrostomy tube
GI	gastrointestinal
GLP1RA	glucagon-like peptide-1 receptor agonist
GH	growth hormone
GSA	Growth Stimulating Agents drug class
IOP	intraocular pressure
IR	immediate release
IV	intravenous
JIA	Juvenile Idiopathic Arthritis
LAMA	Long-Acting Muscarinic Antagonist
LIP-Is	Antilipidemic Is drug class
MCID	minimally clinically relevant difference
MCL	mantle cell lymphoma
MHS	Military Health System
MN	medical necessity

MTF	Military Treatment Facility
NCCN	National Comprehensive Cancer Network
NDAA	National Defense Authorization Act
NF	nonformulary
NNT	number needed to treat
ODT	orally dissolving tablet
OIC	opioid induced constipation
OS	oral solution
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PAMORA	peripherally acting mu opioid receptor antagonists
PDE-4	phosphodiesterase-4
PERT	Pancreatic Enzyme Replacement Therapy drug class
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PSA	prostate-specific antigen
PT	patient
QPDE	quantity per duration event
REMS	Risk Evaluation and Mitigation Strategies
rhGH	recombinant human growth hormone
SC/SQ	subcutaneous
SGLT2	sodium glucose co-transporter 2 inhibitor
SL	sublingual
STR	single tablet regimen
T2DM	type 2 diabetes mellitus
TEN	Toxic Epidermal Necrolysis Syndrome
TIBs	targeted immunomodulatory biologics
TX	treatment
UF	Uniform Formulary
VA	U.S. Department of Veterans Affairs
XR/SR	extended/sustained release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2018

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 7 and 8, 2018, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2017 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2017 DoD P&T Committee meeting on January 31, 2018.

2. **Clarification to the November 2017 Quantity Limits at the Military Treatment Facilities (MTFs):** Quantity limits are defined as any quantity restriction, including quantity limits, collective limits and day supply limits. Additionally, unless otherwise directed by the DoD P&T Committee, quantity restrictions at the MTFs are to be established the same way as in the Mail Order.

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

A. Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) Subclass

Background—The GLP1RAs were most recently reviewed in August 2015, with exenatide once weekly (Bydureon) and albiglutide (Tanzeum) selected for UF and step-preferred status,

with all the other GLP1RAs designated as NF and non step-preferred. Since the last review, two new products have been approved, an exenatide once weekly autoinjector (Bydureon BCise), and semaglutide (Ozempic). The GLP1RA combinations with insulin were not included in this review.

Voluntary market discontinuation of Tanzeum is expected in August 2018. The purpose of this review is to select a second step-preferred UF agent to replace the formulary position currently held by Tanzeum.

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

- Metformin remains the first-line treatment in all patients with type 2 diabetes mellitus (T2DM) unless there are contraindications.
- The new Bydureon BCise autoinjector formulation is easier to self-administer than the Bydureon pen. It is comparable to Bydureon in lowering A1c.
- When used as monotherapy or in combination with other oral agents, the GLP1RAs decrease hemoglobin A1c (A1c) on average approximately 1% to 2% from baseline. Overall, differences in A1c between the GLP1RAs are not clinically relevant.
    - However, in one study (SUSTAIN-3), semaglutide (Ozempic) was statistically and clinically superior to exenatide once weekly (Bydureon) in glycemic control, as semaglutide lowered A1c by 1.5% from baseline compared to 0.9% with exenatide. Limitations to the SUSTAIN-3 study include its open label, active comparator design; it was not designed to show superiority.
    - In the open-label, active comparator SUSTAIN-7 study, semaglutide was statistically superior to dulaglutide (Trulicity) in glycemic control, as it reduced A1c by 1.5-1.8% from baseline compared to 1.1-1.4% with dulaglutide. However, the differences in change in A1c between semaglutide and dulaglutide were not considered clinically relevant, as the change in A1c between the two drugs was less than 0.5%.
- Patients are likely to experience weight loss with use of any GLP1RA.
- Cardiovascular outcomes trials (CVOTs) evaluating the effects on endpoints, including CV mortality, non-fatal myocardial infarction, and stroke, have been completed with four of the products: liraglutide (Victoza) in the LEADER trial, Ozempic in SUSTAIN-6, Bydureon in the EXSCEL trial, and lixisenatide (Adlyxin) in the ELIXA trial. Trials are currently ongoing with dulaglutide (Trulicity) in the REWIND trial and Tanzeum in the HARMONY-OUTCOME trial.
- Liraglutide (Victoza) is the only GLP1RA that has an additional indication to reduce CV risk in patients with established CV disease, based on the LEADER trial. However, given the differences in patient populations in the CVOTs, it is difficult to directly compare one GLP1RA to another in terms of CV benefit.

- In the four CVOTs, the association of GLP1RAs with retinopathy has been a concern, however this was a secondary outcome, and the trials were underpowered to adequately assess worsening retinopathy. Additional studies are needed to definitively determine the long-term effects of GLP1RAs on diabetic retinopathy.
- Gastrointestinal (GI) effects of nausea, vomiting, and diarrhea are the most commonly reported adverse effects with the class. The incidence of nausea varies based on dosing, with higher doses resulting in more nausea. Bydureon has the lowest incidence of nausea at 14%, compared to Ozempic (16-20%), Trulicity (12-21%), Victoza (23%), Adlyxin (29%), and exenatide twice daily (Byetta) (35%).
- Victoza, Adlyxin, and Ozempic have an advantage in offering a smaller needle size for patient convenience. One disadvantage of Bydureon and Bydureon BCise is the larger needle size.
- Bydureon, Bydureon BCise, Trulicity, and Ozempic, have the advantage of once weekly dosing, while Victoza and Adlyxin are dosed once daily, and Byetta is dosed twice daily. Potential advantages of Bydureon and Bydureon BCise include that they are the only GLP1RAs that do not require dosage titration.
- Trulicity, Victoza, and Ozempic require no dose adjustment in renal insufficiency.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the GLP1RAs. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that exenatide once weekly (Bydureon and Bydureon BCise) were the most cost-effective agents, followed by dulaglutide (Trulicity), exenatide twice daily (Byetta), semaglutide (Ozempic), liraglutide (Victoza), and lixisenatide (Adlyxin).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating exenatide (Bydureon and Bydureon BCise) and dulaglutide (Trulicity) as formulary and step-preferred, with exenatide twice daily (Byetta), semaglutide (Ozempic), liraglutide (Victoza), and lixisenatide (Adlyxin) as NF 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 (15 for, 0 opposed, 0 abstained, 1 absent) the following:

    - UF and step-preferred
        - exenatide once weekly (Bydureon and Bydureon BCise)
        - dulaglutide (Trulicity)

    - NF and non step-preferred

- albiglutide (Tanzeum)
- exenatide twice daily (Byetta)
- liraglutide (Victoza)
- lixisenatide (Adlyxin)
- semaglutide (Ozempic)

- This recommendation includes step therapy which requires a trial of exenatide once weekly (Bydureon or Bydureon BCise) and dulaglutide (Trulicity) prior to use of the NF, non step-preferred GLP1RA drugs in all new and current users.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) maintaining exenatide once weekly (Bydureon) and adding exenatide once weekly autoinjector (Bydureon BCise) to the BCF.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION (PA) CRITERIA***—PA criteria currently apply to the GLP1RAs subclass. Currently, a trial of metformin or a sulfonylurea is required prior to use of a GLP1RA, and use of the step-preferred GLP1RAs are also required prior to the non step-preferred products. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the requirement for a trial of a sulfonylurea, and maintaining the metformin step, based on the treatment guidelines from several diabetes associations where metformin is preferred due to its positive effects on glycemic control, safe adverse effect profile, and minimal cost. Additionally sulfonylureas are no longer considered first line therapy for diabetes. The Committee also recommended updating the existing manual PA criteria so that new and current GLP1RA users must try the step-preferred products, Bydureon or Bydureon BCise and Trulicity, prior to using Tanzeum, Byetta, Victoza, Adlyxin, or Ozempic. Use of the non step-preferred products is allowed if the patient has had an inadequate response to the step-preferred GLP1RAs. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Tanzeum, Byetta, Adlyxin, Victoza, and Ozempic. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) quantity limits for liraglutide (Victoza) to limit use to the FDA-labeled indication for diabetes mellitus. See Appendix D.

6. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) adding semaglutide (Ozempic) to the EMMPI program, as

the other GLP1RAs are currently on the EMMPI list. See Appendix F.

7. ***COMMITTEE ACTION: UF, and PA IMPLEMENTATION PERIOD***
The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 90-day implementation period in all points of service 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 July 25, 2018.

B. Anti-Inflammatory Immunomodulatory Ophthalmics: Ophthalmic Immunomodulatory Agents Subclass

Background—Cyclosporine 0.05% ophthalmic emulsion (Restasis) and lifitegrast 5% ophthalmic solution (Xiidra) are the two products in this subclass, which are both approved to treat dry eye disease. Prior authorization criteria currently apply to both drugs.

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

- Ocular surface inflammation and damage are characteristic of moderate to severe dry eye disease. Restasis and Xiidra are both approved for dry eye disease, but their mechanisms of action differ.
- Both drugs are dosed twice daily. Xiidra's onset of action can occur as soon as two weeks following initiation of therapy, however peak effect will not likely occur until after 12 weeks of therapy. In contrast, Restasis' onset of action may take up to six months. Over-the-counter (OTC) ocular lubricants can be used concomitantly with both Restasis and Xiidra.
- Both Restasis and Xiidra in individual placebo-vehicle controlled trials have shown reductions in signs and symptoms of dry eye disease using different endpoints. There are no head-to-head trials between Restasis and Xiidra. It is difficult to determine the clinical relevance of these changes, and dry eye disease is a progressive condition that waxes and wanes. Recent treatment guidelines for dry eye disease do not favor one product over another (American Academy of Ophthalmology 2017; Dry Eye Workshop II 2017).
- There are no published studies evaluating efficacy when patients are switched from one product to another.
- While the clinical studies that led to FDA approval had low patient dropout rates, most trials were of short duration. An analysis of MHS prescription claims showed that approximately 70% of patients fill prescriptions for less than six months of therapy.
- The safety profiles of Restasis and Xiidra are most commonly associated with ocular burning and stinging. Lifitegrast causes dysgeusia in 16% of patients. There are no apparent serious concerns.
- There is a moderate degree of therapeutic interchangeability with Restasis and Xiidra, as there is a variable response to these drugs in practice. To meet the needs of DoD

beneficiaries, at least one ophthalmic immunomodulatory agent is needed to treat the majority of patients with dry eye syndrome.

Relative Cost-Effectiveness Analysis and Conclusion—CMA, and BIA were performed. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA showed that Restasis and Xiidra were cost effective in the various formulary scenarios.
- BIAs with corresponding sensitivity analyses were performed on all formulary scenarios.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following, based on clinical and cost effectiveness:
    - UF:
        - cyclosporine 0.05% ophthalmic emulsion (Restasis)
        - lifitegrast 5% ophthalmic solution (Xiidra)
    - NF: None
    - Note that a BCF product was not selected for the subclass. The BCF drugs will remain Pred Forte and Pred Mild in the Anti-Inflammatory Immunomodulatory Ophthalmic Agents class.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) revising the existing manual PA criteria for both Restasis and Xiidra. The drugs must be prescribed by an ophthalmologist or optometrist, the diagnosis of dry eye disease must be documented, and a trial of two OTC ocular lubricants is now required. The revised PA criteria will apply to new patients and existing users who have not filled a prescription for Restasis or Xiidra in the past 120 days. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR OPHTHALMIC IMMUNOMODULATORY DRUGS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) excluding Restasis and Xiidra from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy, due to the MHS claims analysis showing 70% of patients do not continuously fill prescriptions beyond six months.

C. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday after a 90-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is July 25, 2018.

D. Osteoporosis Drugs*:* Parathyroid Hormone (PTH) Analogs

Background—The P&T Committee evaluated the PTH analogs for treatment of osteoporosis; this subclass has not previously been reviewed for formulary status, although the full class was reviewed in 2008. The subclass consists of two injectable products, teriparatide (Forteo) and abaloparatide (Tymlos), which are both approved for the treatment (and not for the prevention) of osteoporosis in postmenopausal women at high risk for fracture.

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

- Both abaloparatide (Tymlos) and teriparatide (Forteo) have potential benefit in reducing fracture risk in high-risk patients or those with a history of fragility fractures, regardless of whether they were treated with bisphosphonates or not.
- With regard to fracture risk reduction, both Tymlos and Forteo have comparable efficacy for vertebral and non-vertebral fracture risk reduction in patients at high risk for fractures, compared to placebo. A 2016 trial (ACTIVE) reported the risk difference of new vertebral fractures with abaloparatide versus placebo was 3.6%, with a number needed to treat (NNT) of 28, compared to a risk difference of 3.4% with teriparatide versus placebo (NNT 29).
- In terms of changes in bone mineral density, both Tymlos and Forteo produced a statistically significant increase in bone mineral density at 18 months compared to placebo at the hip, femoral neck, and lumbar spine (ACTIVE trial).
- Both PTH analogs have similar adverse drug reaction profiles. Both drugs are limited to cumulative lifetime use of two years based on findings of osteosarcoma associated with use of teriparatide in rodent studies. However, a 2017 meta-analysis from the Institute for Clinical and Economic Review reported extensive real world clinical experience with teriparatide (Forteo) in postmenopausal women without identification of any new adverse events.
- In terms of other factors, Tymlos does not require refrigeration, while Forteo must be kept refrigerated. Forteo has additional indications for men with high fracture risk and for treatment of glucocorticoid-induced osteoporosis in patients at high risk for fracture.
- There is a high degree of interchangeability between Forteo and Tymlos.

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 Forteo was the more cost-effective PTH analog, followed by Tymlos.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating Forteo as formulary and step-preferred, with Tymlos as NF and non step-preferred demonstrated the largest estimated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF and step-preferred: teriparatide (Forteo)
    - NF and non step-preferred: abaloparatide (Tymlos)
    - This recommendation includes step therapy, which requires a trial of teriparatide in new patients, prior to use of abaloparatide.
    - Note that a BCF product was not selected for the Parathyroid Hormone Analogs Subclass

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for new users of Forteo and Tymlos, consistent with the package labeling for indications and safety. Additionally, the step therapy requirements will be included in the manual PA. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Tymlos. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) QLs for Forteo and Tymlos. See Appendix D.

5. ***COMMITTEE ACTION: UF, AND PA IMPLEMENTATION PERIOD—*** The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 0 absent) an effective date of the first Wednesday after a 60-day implementation period in all points of service. Based on the P&T Committee's recommendation, the effective date is June 27, 2018.

D. Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones (ACTH)

Background—The P&T Committee evaluated the ACTH subclass, which is comprised of injectable corticotropin. Injectable corticotropin has been commercially available since 1952, but now is only marketed as a proprietary product, H.P. Acthar Gel. This is the first formulary review of the subclass, but manual PA criteria have applied to H.P. Acthar Gel since December 2013.

H.P. Acthar Gel is a highly purified natural product of adrenocorticotropin derived from porcine pituitary gland. H. P. Acthar gel carries FDA indications for treatment of infantile spasms (West Syndrome) and treatment of exacerbations of multiple sclerosis (MS). The label also states that H.P. Acthar Gel "may" be used for a wide variety of other disorders, but does not explicitly state that it is indicated for those disorders. This language is in the context of the drug's initial approval in 1952, prior to the higher standards demonstrating clinical

effectiveness mandated by the Kefauver-Harris Amendment of the Food Drug and Cosmetic Act in 1962.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) the following for H.P. Acthar Gel:

- Infantile Spasms
  - Optimal treatment of infantile spasms involves early hormonal therapy.
  - Evidence supports both glucocorticoid-dependent as well as glucocorticoid-independent pathways in the treatment of infantile spasms.
  - A comprehensive review of the evidence in infantile spasms suggests that the clinical effectiveness of high-dose oral corticosteroids (e.g., prednisone) is non-inferior to that of ACTH. Evidence also supports that some patients refractory to high-dose oral corticosteroids will respond to ACTH.
  - Trial evidence is supported by numerous Level 1 systematic reviews and meta-analyses with low to moderate quality evidence.
  - The most common adverse effects of ACTH in infantile spasms leading to intervention, dose-reduction, or discontinuation include infection and irritability. The adverse effects are typically transitory in relation to treatment duration.
- MS Exacerbation
  - Professional treatment guidelines clearly and unanimously define the standard of care for treating MS exacerbations with intravenous (IV) methylprednisolone.
  - A comprehensive review of the evidence in MS suggests that the clinical effectiveness of high-dose oral corticosteroids is equivalent to or superior to that of ACTH.
  - A 2013 Cochrane review concluded that onset of treatment in an MS exacerbation is irrelevant to the exacerbation outcome. The evidence is insufficient to determine the impact of hormonal therapies on future exacerbation prevention and is also insufficient to determine the impact of hormonal therapies on long-term disability.
  - There is limited evidence to delineate adverse event profiles between ACTH and methylprednisolone. Head-to-head clinical trials have shown that the adverse reactions with ACTH and methylprednisolone are equivalent. Methylprednisolone is associated with a higher propensity for GI and psychiatric effects, while ACTH has a higher propensity for causing weight gain and edema.
  - Clinical trial evidence is supported by numerous Level 1 systematic reviews and meta-analyses with low to moderate quality evidence.
- Other Uses

  A comprehensive review of the evidence for all of the disease states where H.P. Acthar Gel "may" be used failed to identify well-controlled studies of clinically meaningful endpoints that substantively determined H.P. Acthar Gel's efficacy, maximum-tolerated dose, toxicity, and safety as compared with standard means of treatment. Therefore, the evidence for H.P. Acthar Gel failed to establish clinical effectiveness for those

conditions. H.P. Acthar Gel is unsupported by the literature in the following conditions:

- Rheumatologic disorders: systemic lupus erythematosus, inflammatory myopathies (including dermatomyositis and polymyositis), psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, and ankylosing spondylitis
- Dermatologic diseases: erythema multiforme (of any severity), Stevens-Johnson syndrome, and Toxic Epidermal Necrolysis (TEN) syndrome
- Allergic states: serum sickness
- Ophthalmic diseases: severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, birdshot choroiditis, chorioretinitis, anterior segment inflammation, scleritis, conjunctivitis, and Opsoclonus Myoclonus syndrome
- Respiratory diseases: sarcoidosis
- Nephrotic syndromes, including focal segmental glomerulosclerosis (FSGS), idiopathic membranous nephropathy, IgA nephropathy, membranoproliferative glomerulonephritis (MPGN), and monoclonal diffuse proliferative glomerulonephritis, and any other non-nephrotic edematous state
- Other neurologic disease: amyotrophic lateral sclerosis (ALS), MS (not related to exacerbation of MS), optic neuritis (not related to exacerbation of MS), and neurosarcoidosis
- Any other indication outside of the medically necessary indications of infantile spasms and MS exacerbation

Relative Cost-Effectiveness Analysis and Conclusion—CMA was performed. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 2 absent) that H.P. Acthar Gel was significantly more costly than its clinical comparators.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) the following, based on clinical and cost effectiveness:
    - UF: injectable corticotropin (H.P. Acthar Gel)
    - NF: None
    - Note that a BCF product was not selected for the Adrenocorticotropic Hormones Subclass.
2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for new and current users of H.P. Acthar Gel for treatment of infantile spasms (West Syndrome) in infants less than 24 months of age who are unresponsive to

high-dose steroids. Manual PA criteria are also recommended for new and current users of H.P. Acthar Gel with MS exacerbation who have failed or who are intolerant to an adequate trial of IV or oral corticosteroids. PA renewal will be allowed for infantile spasms; however, PA review will be required for each occurrence of MS exacerbation.

H.P. Acthar Gel is not approved for use of any other condition outside of infantile spasms or MS exacerbation. H.P. Acthar Gel's efficacy for the other indications listed above in the clinical effectiveness conclusion has not been established and/or remains unproven. Experimental and investigational use of H.P. Acthar Gel for these other conditions is not medically necessary and is therefore excluded from TRICARE coverage. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) quantity limits for H.P. Acthar Gel. See Appendix D.

4. ***COMMITTEE ACTION: UF AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday after a 60-day implementation period in all points of service 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 June 27, 2018.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Part 1: 16 for, 0 opposed, 0 abstained, 0 absent; Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly-approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly-approved drugs reviewed at the February 2018 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 (Part 1: 15 for, 0 opposed, 1 abstained, 0 absent; Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
    - acalabrutinib (Calquence) – Oral Oncologic Agent for Mantle Cell Lymphoma
    - benznidazole – Miscellaneous Anti-Infective for Chagas Disease
    - dolutegravir/rilpivirine (Juluca) – Antiretrovirals for Human Immunodeficiency Virus (HIV)
    - emicizumab-kxwh (Hemlibra) – Antihemophilic Factors

- letermovir (Prevymis) Antivirals

- NF:
  - coagulation factor IX, recombinant (Rebinyn) – Antihemophilic Factors
  - dapagliflozin/saxagliptin (Qtern) – Non-Insulin Diabetes Drugs – Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor
  - fluticasone propionate 93 mcg nasal spray (Xhance) – Nasal Allergy Drugs – Corticosteroids
  - house dust mite allergen extract (Odactra) – Immunological Agents Miscellaneous: Oral Agents
  - latanoprostene bunod ophthalmic solution (Vyzulta) – Glaucoma Drugs
  - minocycline ER (Ximino) – Antibiotics: Tetracyclines
  - sodium picosulfate/magnesium oxide/anhydrous citric acid (Clenpiq) – Laxatives-Cathartics-Stool Softeners
  - spironolactone 25 mg/5 mL oral suspension (CaroSpir) – Diuretics

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (Part 1: 15 for, 0 opposed, 1 abstained, 0 absent; Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Rebinyn, Qtern, Xhance, Odactra, Vyzulta, Ximino, Clenpiq, and CaroSpir. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (Part 1: 15 for, 0 opposed, 1 abstained, 0 absent; Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Applying the same manual PA criteria for dapagliflozin/saxagliptin (Qtern) in new and current users, as is currently in place for the other non step-preferred SGLT2 inhibitors and dipeptidyl peptidase-4 (DPP-4) inhibitors. Patients must first try the step-preferred SGLT2 inhibitor empagliflozin (Jardiance).
- Applying the same manual PA criteria for minocycline ER (Ximino) in new and current users, as is currently in place for the other non step-preferred tetracyclines. Patients must first try formulary step-preferred agents.
- Applying manual PA criteria to new users of Odactra, Hemlibra, and Calquence, and for new users of CaroSpir who are over 12 years old.
- Applying manual PA criteria to new and current users of Xhance and Vyzulta.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (Part 1: 15 for, 0 opposed, 1 abstained, 0 absent;

Part 2: 15 for, 0 opposed, 0 abstained, 1 absent) an effective date upon the first Wednesday two weeks after the signing of the minutes in all points of service.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

a) **Corticosteroids-Immune Modulator Agents—Corticosteroid Subclass: Prednisone Delayed Release (Rayos)**

Rayos is a branded formulation of delayed release (DR) prednisone that has the same indications as immediate release (IR) prednisone, which was approved in 1955. It is dosed once daily, similar to IR prednisone, and has the same safety profile. Cost-effective generic formulations of prednisone and other glucocorticoids are available on the UF without PA required.

(1) ***COMMITTEE ACTION: PREDNISONE DR (RAYOS) MANUAL PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) manual PA criteria for Rayos due to the significant cost differences and lack of clinically compelling benefits between Rayos and generic prednisone. New and current users of Rayos are required to try generic prednisone IR and a second corticosteroid first. See Appendix C for the full criteria.

b) **Antivirals: Acyclovir/Hydrocortisone 5%/1% Cream (Xerese), Penciclovir 1% Cream (Denavir), and Acyclovir 50 mg buccal tablet (Sitavig)**

The committee reviewed three treatments for herpes labialis (cold sores). Xerese is a branded combination of acyclovir/hydrocortisone cream that has an equivalent efficacy and safety profile as the separate ingredients applied individually. Denavir is a branded penciclovir 1% cream that is indicated for treatment of recurrent cold sores, while Sitavig is a buccal tablet formulation of acyclovir. Cost-effective generic formulations of acyclovir cream and the oral antiviral agents (e.g., acyclovir, valacyclovir) used for treating herpes labialis are available on the UF without PA required.

(1) ***COMMITTEE ACTION: XERESE, DENAVIR, AND SITAVIG MANUAL PA CRITERIA***—The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) manual PA criteria for Xerese, Denavir, and Sitavig due to the significant cost differences and lack of clinically compelling benefits compared with generic topical and oral antivirals. New and current users of these products are required to try generic acyclovir cream and oral antiviral agents first. See Appendix C for the full criteria.

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

    a) **Targeted Immunomodulatory Biologics (TIBs): Tofacitinib (Xeljanz/Xeljanz XR) and Ixekizumab Injection (Taltz)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. Xeljanz was originally approved for treating rheumatoid arthritis, while Taltz was originally approved for plaque psoriasis and was reviewed as a new drug in May 2016. PA criteria were updated to add the additional indication for active psoriatic arthritis in adults for Xeljanz, Xeljanz XR, and Taltz.

    b) **GI-2 Miscellaneous Agents: Plecanatide (Trulance)**—Trulance was reviewed as a new drug in May 2017 and indicated for chronic idiopathic constipation, with manual PA criteria recommended. The PA criteria were updated to add the additional FDA indication for treatment of irritable bowel syndrome with constipation (IBS-C), with the requirement for a trial of linaclotide (Linzess) before approval of plecanatide for IBS-C.

    c) **Female Hypoactive Sexual Desire Disorder Agents: Flibanserin (Addyi)**—Addyi was reviewed in November 2015 with manual PA criteria recommended. The PA criteria were updated to add an expiration date of three months, with renewal PA criteria ensuring efficacy and safety.

    d) **Antidepressants and Non-Opioid Pain Syndrome Agents: Pregabalin (Lyrica) PA and MN Criteria**—Step therapy and manual PA criteria have applied to Lyrica since it was originally reviewed for formulary placement in November 2011, with the most recent update occurring in May 2017. The additional indication for treatment of neuropathic pain associated with spinal cord injury after a trial of gabapentin and duloxetine was added to the PA criteria. The MN criteria for Lyrica were also updated to reflect the PA requirement of a trial of gabapentin and duloxetine.

    e) **Acne Agents—Topical Acne and Rosacea Agents: Dapsone Gel 5% and 7.5% (Aczone) MN Criteria**—Aczone and topical acne agents were reviewed in August 2016 and manual PA criteria updated in August 2017 to reflect the labeled indication of both male and female patients. The MN criteria for Aczone 7.5% were updated to also reflect the labeled indication of both genders.

    f) **Antibiotics: Tetracyclines—**The PA criteria for the tetracyclines, which were originally reviewed in February 2017, was updated to include renewal criteria, with an expiration date of 365 days.

(1) ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) updates to the manual PA criteria for Xeljanz, Xeljanz XR, Taltz, Trulance, Addyi, and Lyrica; updated PA renewal criteria for the tetracyclines; and updates to the MN criteria for Lyrica and Aczone. All updated criteria apply to new users of these agents. See Appendices B and C for the full criteria.

B. QLs—QLs were reviewed for three drugs from drug classes where there are existing QLs, including the oncologic agents, antiemetics, nasal steroids, and five new drugs where QLs are not currently in place.

1. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (11 for, 0 opposed, 0 abstained, 5 absent) QLs for Calquence, Stelara, Xhance, Sitavig, Hemlibra, Neulasta, Emend, and Prevymis. See Appendix D for the QLs.

C. Naloxone Removal of Refill Limitations—When the Committee reviewed the narcotic antagonists in August 2016, no refills were allowed (i.e., a new prescription was required for every fill) in order to ensure the patient would be seen by the provider after an opioid overdose. Subsequently, the MHS Pain Management Working Group (MHS PMWG) reviewed this requirement and noted the widespread availability of naloxone from most pharmacies (based on state laws) allows for dispensing of naloxone without a prescription. The MHS PMWG is now requesting to allow refills for naloxone.

1. ***COMMITTEE ACTION: NALOXONE REFILL LIMITATIONS—***The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) removing the "no refill" limits currently in place for all naloxone formulations. Refills will be allowed as noted on the prescription.

D. PA, MN, QLs, and Removal of Naloxone Refill Limitations Implementation Periods

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

   - (11 for, 0 opposed, 0 abstained, 5 absent) The new manual PA for Rayos, Xerese, Denavir, and Sitavig become effective on the first Wednesday after a 90-day implementation period in all points of service. Additionally, the P&T Committee recommended DHA send letters to the beneficiaries affected by this decision. Based on the P&T Committee's recommendation, the effective date is July 25, 2018.
   - (12 for, 0 opposed, 0 abstained, 4 absent) Updates to the current PAs for Taltz, Xeljanz/Xeljanz XR, Addyi, Trulance, and Lyrica; the MN criteria for Aczone and Lyrica; and the renewal criteria for the tetracyclines become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.

- (11 for, 0 opposed, 0 abstained, 5 absent) The QLs for the 14 drugs listed in section VI, B, above, and in Appendix D become effective on the first Wednesday two weeks after the signing of the minutes in all points of service.
- (14 for, 0 opposed, 0 abstained, 4 absent): Removal of the "no refill" limitations for all naloxone formulations become effective on the first Wednesday two weeks after signing of the minutes in all points of service.

VII. BRAND OVER GENERIC AUTHORIZATION FOR SILDENAFIL TABLETS (VIAGRA)

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Viagra product is more cost effective than the AB-rated generic formulations for sildenafil, which were launched in December 2017. The manufacturer of Viagra has offered a Distribution and Pricing Agreement (DAPA). Therefore, the branded Viagra product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Viagra. The "brand over generic" requirement for Viagra will be removed administratively when it is no longer cost effective compared to the AB-rated generics.

A. ***COMMITTEE ACTION: VIAGRA BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA—***The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) implementing the requirement to prefer the branded Viagra product over generic formulations. Manual PA criteria are required for generic sildenafil in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Viagra product cannot be used. (See Appendix C.)

B. ***COMMITTEE ACTION: VIAGRA BRAND COPAYMENT CHANGE—***The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) that the brand (Tier 2) formulary cost share for Viagra in the TRICARE Mail Order Pharmacy and the TRICARE Retail Network Pharmacy be lowered to the generic (Tier 1) formulary cost share.

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

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

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for five product line extensions ("follow-on products") by the original manufacturer. The line extensions have the same FDA indications

and pricing as the "parent" drug and retain the same formulary and copayment status as the "parent" drug.

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) clarifying the formulary status of the following five products to reflect the current formulary status, and applicable step therapy, PA criteria, MN criteria, and QLs for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- Pulmonary Arterial Hypertension Agents—Endothelin Receptor Agonists: Bosentan (Tracleer) 32.5 mg tablet for solution is designated formulary on the UF, which is the same as bosentan (Tracleer) 62.5 mg and 125 mg tablets.

- Pulmonary-1 Agents—Inhaled Corticosteroids: The new beclomethasone dipropionate HFA (QVAR RediHaler) inhaler is designated as NF, non step-preferred and requires manual PA, which is the same as the QVAR parent agent. Additionally, QLs will also apply. See Section VI, B, above, on page 15, and Appendix D for the QLs.

- Antidepressants and Non-Opioid Pain Syndrome Agents: Pregabalin extended release (Lyrica CR) is designated NF, non step-preferred with the same MN and PA criteria as the pregabalin (Lyrica) parent agent. (See Section VI, A, 2d above, on page 14, Appendix B for updated Lyrica MN criteria, and Appendix C for updated Lyrica PA criteria.)

- Oncologic Agents for Non-Small Cell Lung Cancer: Brigatinib (Alunbrig Initiation Pack) is designated as formulary, similar to Alunbrig.

- Anticoagulant Agents—Oral Anticoagulant Subclass: Apixaban (Eliquis Initiation Pack) initiation pack is designated as formulary on the UF, similar to the Eliquis parent agent.

- GI-2 Miscellaneous Agents: Linaclotide (Linzess) 72 mcg tablet is designated formulary on the UF, similar to Linzess 145 mcg.

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

See Appendix F for the mail order status of medications designated NF during the February 2018 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed below pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the nonformulary to mail requirement. The implementation date for all EMMPI recommendations from the February 2018 meeting, including the newly-approved drugs

affected by the EMMPI, will be effective on the first Wednesday two weeks after the signing of the minutes.

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

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

   The P&T Committee recommended (Day 1 AM: 15 for, 0 opposed, 1 abstained, 0 absent; Day 1 PM: 15 for, 0 opposed, 0 abstained, 1 absent):

   a) **Add**: None

   b) **Do Not Add:**

   - Juluca (HIV medication); not currently required to go to Mail Order (i.e., not on the EMMPI list)
   - Prevymis (for cytomegalovirus infection) and benznidazole (Chagas disease); due to limited treatment duration
   - Hemlibra and Calquence, since it is not feasible or unclear if feasible to provide via mail order

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

   The P&T Committee recommended (Day 1 AM: 15 for, 0 opposed, 1 abstained, 0 absent; Day 1 PM: 15 for, 0 opposed, 0 abstained, 1 absent):

   a) **Add:** The P&T Committee found no reason to exempt the following drugs from the mail order requirement: Vyzulta, Qtern, Odactra, and CaroSpir.

   b) **Do Not Add:** The previously established exception from the mail order requirement for acute use agents applies to Rebinyn and Clenpiq. The following agents may not be feasible to provide through mail order and should be excepted pending further information: fluticasone propionate 93 mcg nasal spray (Xhance) and minocycline ER capsules (Ximino).

B. Status of Other Medications on the EMMPI List

1. ***COMMITTEE ACTION: ADDITION OF AGENTS TO EMMPI LIST***—The P&T Committee recommended (12 for, 0 opposed, 0 abstained, 4 absent) to add flibanserin (Addyi) to the EMMPI list.

X. ITEMS FOR INFORMATION

A. New MHS Pharmacy Copayments

The Committee was briefed on the new MHS pharmacy copayments that were implemented on February 1, 2018. Refer to https://www.tricare.mil/pharmacycosts for the new copayments.

B. Second Annual Review of Newly-Approved Drugs

The Committee was briefed on the utilization and cost trends for the newly-approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. A total of 113 drugs were evaluated, with 56 remaining as NF, and 57 designated as UF. Updates on the metrics for the newly-approved drugs will be presented periodically at upcoming P&T Committee meetings.

XI. ADJOURNMENT

The meeting adjourned at 1400 hours on February 8, 2018. The next meeting will be in May 2018.

Appendix A—Attendance: February 2018 DoD P&T Committee Meeting

Appendix B—Table of Medical Necessity Criteria

Appendix C—Table of Prior Authorization Criteria

Appendix D—Table of Quantity Limits

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

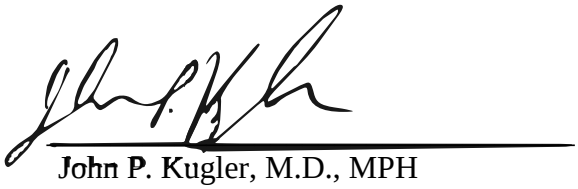
Appendix F—Mail Order Status of Medications Designated Nonformulary During the February 2018 DoD P&T Committee Meeting

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

Appendix H—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

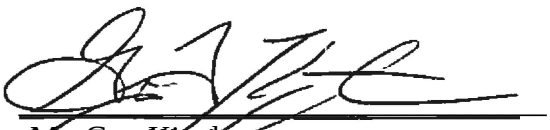
The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:



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

24 APR 2018
Date

Appendix A—Attendance: February 2018 P&T Committee Meeting

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner for Mr. David Bobb	Chief, DHA Pharmacy Operations Branch
CAPT Edward VonBerg, MSC	Chief, DHA Formulary Management Branch (Recorder)
Col James Jablonski, MC	Air Force, Physician at Large
LTC John Poulin, MC	Army, Physician at Large
CAPT Shaun Carstairs, MC	Navy, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
MAJ Rosco Gore, MC	Army, Internal Medicine Physician
LTC Ruben Salinas, MC	Army, Family Medicine Physician
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
COL Kevin Roberts, MSC	Army, Pharmacy Officer
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
CAPT Thinh Ha, MSC	Navy, Pharmacy Officer
Mr. Joe Canzolino	Department of Veterans Affairs
Col Angela Mysliwiec	TRICARE Regional Office Representative
Voting Members Absent	
LCDR Carey Welsh, MC	Navy, Pediatrics Representative
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Nonvoting Members Present	
Ms. Leigh Bradley (SES)	General Counsel, DHA
Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
CAPT Robert Hayes	Indian Health Service
Ms. Yvette Dluhos	DHA Contract Operations Division
Capt Kevin Bourne	Defense Logistics Agency Troop Support
Mr. Jason Wray	Defense Logistics Agency Troop Support

Appendix A—Attendance (continued)

Others Present	
Lt Col Ronald Khoury, MC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
David Folmar, PharmD	DHA Formulary Management Branch
LCDR Scott Raisor	DHA Formulary Management Branch
LCDR Christina Andrade, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Aparna Raizada, MSC	DHA Formulary Management Branch
CPT Zachary Leftwich, MSC	DHA Formulary Management Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Robert Conrad, PharmD	DHA Operations Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Brian Beck, PharmD	DHA Purchased Care Branch
Rukshar Banu	Student, University of Incarnate Word

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• albiglutide (Tanzeum) • exenatide twice daily (Byetta) • liraglutide (Victoza) • lixisenatide (Adlyxin) • semaglutide (Ozempic) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	• Use of <u>both</u> formulary agents (Bydureon/Bydureon BCise and Trulicity) have resulted in significant adverse effects that are not expected to occur with use of the non-preferred products **Formulary Alternatives:** exenatide once weekly (Bydureon and Bydureon BCise), dulaglutide (Trulicity)
• abaloparatide subcutaneous injection (Tymlos) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	• The patient has experienced significant adverse effects from formulary agent • No alternative formulary agent: the patient cannot comply with refrigeration requirement for the formulary alternative **Formulary Alternatives:** teriparatide (Forteo)
• coagulation factor IX, recombinant (Rebinyn) **Antihemophilic Factors**	• Use of the formulary products is contraindicated and treatment with other antihemophilic factors is not clinically appropriate • The patient has experienced adverse effects from the formulary antihemophilic factors **Formulary Alternatives:** Idelvion, Alprolix
• dapagliflozin/saxagliptin (Qtern) **Non-Insulin Diabetes Drugs: SGLT2 Inhibitors**	• The patient has experienced significant adverse effects from empagliflozin that is not expected to occur with dapagliflozin **Formulary Alternatives:** sitagliptin (Januvia, Janumet, Janumet XR); empagliflozin (Jardiance, Glyxambi, Synjardy, Synjardy XR)
• fluticasone propionate 93 mcg nasal spray (Xhance) **Nasal Allergy Drugs: Corticosteroids**	• Use of at least two formulary and nonformulary nasal allergy drugs has resulted in therapeutic failure **Formulary Alternatives:** azelastine 137 mg nasal inhaler, flunisolide, fluticasone propionate 50 mcg nasal inhaler (generic Flonase), mometasone (generic Nasonex), beclomethasone (Beconase AQ)
• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	• At least two formulary agents, including a nasal steroid, AND either a nasal antihistamine, oral antihistamine, or leukotriene receptor antagonist has resulted in therapeutic failure • No alternative formulary agent – the patient has allergic rhinitis and allergic asthma and has persistent asthma exacerbations despite use of inhaled corticosteroids, and their asthma is controlled (defined as an FEV1 >70%) **Formulary alternatives:** fluticasone propionate 50 mcg nasal inhaler (generic Flonase), azelastine 137mcg nasal inhaler, cetirizine, loratadine, montelukast

Drug / Drug Class	Medical Necessity Criteria
• latanoprostene bunod ophthalmic solution (Vyzulta) **Glaucoma Agents:**	• The patient has experienced significant adverse effects from two formulary agents **Formulary Alternatives:** latanoprost (generic Xalatan), bimatoprost (generic 0.03% Lumigan)
• minocycline ER (Ximino) **Antibiotics: Tetracyclines**	• The patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic minocycline immediate release products **Formulary alternatives:** minocycline IR 50 mg or 100 mg
• sodium picosulfate/magnesium oxide/anhydrous citric acid (Clenpiq) **Laxatives-Cathartics-Stool Softeners**	• No alternative formulary agent – the patient requires a sodium picosulfate/Mg oxide/citric acid bowel prep formulation and cannot comply with the mixing requirement for PrePopik **Formulary alternatives:** PrePopik
• spironolactone 25 mg/5 mL oral suspension (CaroSpir) **Diuretics**	• No alternative formulary agent – the patient requires an aldosterone blocker/potassium-sparing diuretic and cannot take tablets **Formulary alternatives:** spironolactone, eplerenone, amiloride, HCTZ/triamterene, amiloride/HCTZ, spironolactone/HCTZ
• pregabalin (Lyrica) • pregabalin ER (Lyrica CR) **Antidepressants and Non-Opioid Pain Syndrome Agents**	**Changes from the February 2018 meeting are in BOLD** • Use of **both** formulary agents **(gabapentin and duloxetine)** have resulted in therapeutic failure **Formulary Alternatives:** gabapentin and duloxetine
• dapsone 7.5% gel (Aczone) **Acne Agents: Topical Acne and Rosacea Agents**	**Changes from the February 2018 meeting are in BOLD** • Patient ~~**is an adult female with**~~ **has** inflammatory acne who has tried AND failed or experienced significant adverse effects from at least three formulary agents, including combination therapy with clindamycin and benzoyl peroxide **Formulary Alternatives:** adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and sulfacetamide sodium/sulfur lotion

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Step-Preferred • exenatide once weekly (Bydureon/Bydureon BCise) • dulaglutide (Trulicity) **Non Step-Preferred** • albiglutide (Tanzeum) • exenatide twice daily (Byetta) • liraglutide (Victoza) • lixisenatide (Adlyxin) • semaglutide (Ozempic) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	Changes from the February 2018 meeting are in strikethrough; additionally, Trulicity has replaced Tanzeum as the second step-preferred GLP1RA. All new users of a GLP1RA 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. The requirement to try a sulfonylurea is now removed. Additionally, Bydureon/Bydureon BCise and Trulicity are now the preferred agents in the GLP1RA subclass. New and current users of the non step-prefrred products, Tanzeum, Byetta, Victoza, Adlyxin, and Ozempic, must try Bydureon/Bydureon BCise and Trulicity first. Manual PA criteria—Bydureon/Bydureon BCise, Trulicity, Tanzeum, Byetta, Victoza, Adlyxin, or Ozempic is approved (i.e., a trial of metformin ~~or SU~~ is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus. • The patient has experienced any of the following issues on metformin: o impaired renal function precluding treatment with metformin o history of lactic acidosis • ~~The patient has experienced any of the following issues on a SU:~~ o ~~hypoglycemia requiring medical treatment~~ • The patient has had inadequate response to metformin ~~or a SU~~ • The patient has a contraindication to metformin ~~or a SU~~ AND In addition to the above criteria regarding metformin ~~and SU~~, the following PA criteria would apply specifically to new and current users of Tanzeum, Byetta, Victoza, Adlyxin, and Ozempic: • The patient has had an inadequate response to Bydureon/Bydureon BCise and Trulicity. Off-label uses are not approved. Prior Authorization does not expire.
• cyclosporine 0.05% ophthalmic emulsion (Restasis) • lifitegrast 5% ophthalmic solution (Xiidra) **Anti-Inflammatory Immunomodulatory Ophthalmics: Ophthalmic Immunomodulatory Agents Subclass**	**February 2018 updates are in BOLD** **PA criteria apply to all new and current users of Restasis or Xiidra. A new user is defined as a patient who has not filled a prescription for Restasis or Xiidra in the past 120 days.** • **If there is no Restasis or Xiidra prescription in the past 120 days, a manual PA is required.** Manual PA criteria: Coverage is approved if all the criteria are met: • **The drug is prescribed by an ophthalmologist or optometrist AND** • The patient is ≥ 18 years old AND • **A diagnosis of Moderate to Severe Dry Eye Disease is supported by both of the criteria below:** o **Positive symptomology screening for moderate to severe dry eye disease from an appropriate measure AND** o **At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) AND** • **Patient must try and fail the following:** o **At least 1 month of one ocular lubricant used at optimal dosing and**

Drug / Drug Class	Prior Authorization Criteria
	frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc], polyvinyl alcohol [Liquitears, Refresh Classic, etc], or wetting agents [Systame, Lacrilube} o **Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol, etc.) AND** • Concomitant use of Restasis and Xiidra is NOT allowed. • Restasis is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) Off-label uses for Xiidra are not approved. Off-label uses for Restasis, other than those listed above, are not approved. PA expires in 365 days. **Renewal Criteria: Coverage will be approved indefinitely if all criteria are met:** • **The drug is prescribed by an ophthalmologist or optometrist.** • **The patient must have documented improvement in ocular discomfort.** • **The patient must have documented improvement in signs of dry eye disease.**
• teriparatide (Forteo) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	Manual PA criteria apply to new users of Forteo. Manual PA criteria—Forteo is approved if **ALL** of the following criteria are met: • The patient is ≥ 18 years old • The drug is prescribed for treatment of osteoporosis, and not for prevention of osteoporosis. • The patient has one of the following diagnoses: o Patient is a postmenopausal female with osteoporosis, OR o The patient is male with primary or hypogonadal osteoporosis, OR o The patient has osteoporosis associated with sustained systemic glucocorticoid therapy (e.g., > 6 months use of >7.5mg/day prednisone or equivalent) AND • Patient has one of the following: o The patient is at high risk for fracture, defined as one of the following: ▪ history of osteoporotic fracture ▪ multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) ▪ documented bone mineral density (BMD) T-score of -2.5 or worse ▪ has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • Cumulative treatment with Forteo will not exceed 24 months during the patient's lifetime AND • Patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton) Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. Prior Authorization may not be renewed.

Drug / Drug Class	Prior Authorization Criteria
• abaloparatide (Tymlos) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	Manual PA criteria apply to new users of Tymlos. Manual PA criteria—Tymlos is approved if **ALL** of the following criteria are met: • The drug is prescribed for treatment of osteoporosis, and not for prevention of osteoporosis. • The patient is a postmenopausal female with osteoporosis at high risk for fracture as defined by one of the following: o history of osteoporotic fracture o multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) o documented bone mineral density (BMD) T-score of -2.5 or worse o has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • Cumulative treatment with Tymlos will not exceed 24 months during the patient's lifetime AND • The patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton) AND • **The patient cannot comply with the refrigeration requirement for Forteo.** Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. Prior Authorization may not be renewed.
• injectable corticotropin (H.P. Acthar Gel) **Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones (ACTH)**	Note: the provider may call ESI to expedite prior authorization review Manual PA criteria apply to all new and current users of H.P. Acthar Gel. Manual PA criteria—H.P. Acthar Gel PA will be approved if all of the following criteria are met for either treatment of infantile spasms or treatment of exacerbation in patients with multiple sclerosis. 1) Infantile Spasms (West Syndrome): • The patient is < 24 months old AND • The patient is diagnosed with infantile spasms with electroencephalogram-confirmed hypsarrhythmia AND • The patient has tried a 2-week course of high-dose (40-60 mg/day) prednisone/prednisolone for any episode of infantile spasms and has failed therapy as evidenced by continued signs/symptoms of either spasms or hypsarrhythmia on EEG AND • H.P. Acthar Gel is prescribed by or in consultation with a pediatric neurologist with expertise in the management of infantile spasm. Prior Authorization expires in 30 days. Renewal Criteria: Coverage will be approved for an additional 365 days for infantile spasms if all criteria are met: • The patient is < 24 months old AND • The patient has demonstrated a clinical response to H.P. Acthar Gel as defined by cessation of both previous characteristic spasms AND hypsarrhythmia on EEG within 2 weeks of starting H.P. Acthar Gel AND • The patient has not previously demonstrated intolerance to H.P. Acthar Gel,

Drug / Drug Class	Prior Authorization Criteria
	defined as the patient requiring discontinuation of H.P. Acthar Gel therapy. 2) Multiple Sclerosis Exacerbation: • The patient is an adult older than 18 years of age diagnosed with multiple sclerosis AND • The patient is diagnosed with an exacerbation of multiple sclerosis OR optic neuritis as a specific exacerbation of multiple sclerosis AND • The patient has failed or is intolerant to an adequate trial of IV/PO corticosteroids (e.g., 1000 mg methylprednisolone IV x 5-14 days OR oral equivalent) for the present exacerbation. o Note that anticipated hypercortisolism and other non-emergent side effects (e.g., non-emergent hyperglycemia, weight gain, non-urgent/emergent hypertension, edema, paresthesias, insomnia, constipation, diarrhea, hyperphagia, anorexia, nasal/sinus congestion, acne, and menstrual irregularities, etc.) do not meet the threshold for authorization of this PA. Similarly, if the patient has had emergent or life-threatening adverse effects to high-dose corticosteroids, H.P. Acthar gel is contraindicated. AND • H.P. Acthar Gel is prescribed by or in consultation with a neurologist. Prior Authorization expires in 30 days. PA Renewal is not authorized for multiple sclerosis exacerbation. 3) Other uses: PA will be not be approved for any condition other than infantile spasms in infants less than 24 months of age or MS exacerbation, including, but not limited to the following: optic neuritis not related to MS exacerbation, Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, Ankylosing Spondylitis, Dermatomyositis, Polymyositis, Juvenile Idiopathic Arthritis, Erythema Multiforme (any severity), Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis Syndrome, Serum Sickness, Keratitis, Iritis, Iridocyclitis, Uveitis, Choroiditis, Birdshot choroiditis, Chorioretinitis, anterior segment inflammation, Nephrotic Syndrome including focal segmental glomerulosclerosis (FSGS), idiopathic membranous nephropathy, IgA nephropathy, membranoproliferative glomerulonephritis (MPGN), and monoclonal diffuse proliferative glomerulonephritis, non-nephrotic edematous states, sarcoidosis, gout, scleritis, or conjunctivitis.
• acalabrutinib (Calquence) **Oncological Agents**	Manual PA criteria apply to all new users of Calquence. <u>Manual PA criteria</u>—Coverage will be approved if all criteria are met: • The patient is ≥ 18 years AND • The patient has pathologically confirmed mantle cell lymphoma, with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 AND • The patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec Off-label uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• dapagliflozin/saxagliptin (Qtern) **Non-Insulin Diabetes Drugs: SGLT2 Inhibitors**	Manual PA criteria apply to all new and current users of Qtern. Manual PA criteria—Coverage will be approved if all criteria are met: • The patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin AND • The patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, and Synjardy XR) and had an inadequate response or experienced significant adverse events, or have a contraindication to empagliflozin AND • The patient must have tried one of the preferred DPP-4 inhibitors (Januvia, Janumet, and Janumet XR) and had inadequate response or experienced significant adverse events, or have a contraindication to sitagliptin. Off-label uses are not approved. Prior authorization does not expire.
• emicizumab-kxwh (Hemlibra) **Antihemophilic Factors**	Manual PA criteria apply to all new users of Hemlibra. Manual PA criteria—Coverage will be approved if all criteria are met: • The patient must have a documented diagnosis of Hemophilia A AND • The patient must have a history of a high titer of factor VIII inhibitor (greater than or equal to 5 Bethesda units per mL) AND • The patient must NOT have been treated within the last 12 months for thromboembolic disease, or have current signs of, thromboembolic disease AND • Hemlibra must be prescribed by or in consultation with a hematologist. Off-label uses are not approved. Prior authorization does not expire.
• fluticasone propionate 93 mcg nasal spray (Xhance) **Nasal Allergy Agents: Corticosteroids**	Manual PA criteria apply to all new and current users of Xhance. Manual PA criteria—Coverage will be approved if all criteria are met: • Patient has nasal polyps AND • Patient must have tried and failed at least two of the following: azelastine 137 mcg nasal spray (generic Astelin), flunisolide nasal spray, fluticasone propionate 50 mcg nasal spray (generic Flonase), or ipratropium nasal spray (Atrovent nasal spray) AND • Patient has tried and failed mometasone (Nasonex) OR beclomethasone (Beconase) Off-label uses are not approved. Prior authorization does not expire.
• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	Manual PA criteria apply to all new users of Odactra. Manual PA criteria—Coverage will be approved if all criteria are met: • Odactra is prescribed by an allergist/immunologist AND • The patient is between the ages of 18 and 65 years AND • The patient has a diagnosis of house dust mite (HDM) allergic rhinitis confirmed with either a positive skin test or an *in vitro* test for pollen-specific for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites AND o The patient's symptoms of allergic rhinitis have not been controlled with a nasal corticosteroid (e.g., fluticasone) AND at least one of the following: oral antihistamine, nasal antihistamines, or a leukotriene receptor antagonist (montelukast) OR o The patient has a diagnosis of HDM-related allergic rhinitis and allergic asthma that has not responded to an adequate trial of inhaled steroids, and the patient's FEV1 >70% AND • The patient has received the first dose in the office setting and was observed for

Drug / Drug Class	Prior Authorization Criteria
	30 minutes with no allergic reactions noted AND • The patient has a prescription for self-administered SC epinephrine AND • The patient does not have a history of severe local allergic reaction to sublingual immunotherapy AND • Patient is not receiving co-administered SC immunotherapy AND • Patient does not have severe, uncontrolled, unstable asthma Other off-label uses other than allergic asthma are not approved. PA expires in 6 months. Renewal Criteria: Coverage will be approved indefinitely if the patient has responded positively to treatment and is not receiving co-administered SC immunotherapy and does not have severe, uncontrolled, unstable asthma.
• latanoprostene bunod ophthalmic solution (Vyzulta) **Glaucoma Agents:**	Manual PA criteria apply to all new and current users of Vyzulta. Manual PA criteria—Coverage will be approved if all criteria are met: • Patient must have a diagnosis of open angle glaucoma OR ocular hypertension • Patient is ≥16 years old • Patient has tried and failed at least two ophthalmic prostaglandin glaucoma agents (e.g., latanoprost, bimatoprost) Off-label uses are not approved. Prior authorization does not expire.
• minocycline ER (Ximino) **Antibiotics: Tetracyclines**	PA criteria apply to all new and current users of Ximino. Automated PA Criteria: • Patient has filled a prescription for one generic IR doxycycline (either the hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) AND one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 days Manual PA Criteria—If automated PA criteria are not met, Ximino is allowed if: • The patient has acne with inflammatory lesions AND • The patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events Off-label uses are not approved. Prior authorization expires in 365 days. Renewal criteria: Ximino will be approved for an additional 365 days, if: • The patient's therapy has been re-evaluated within the last 12 months • The patient is tolerating treatment and there continues to be a medical need for the medication • The patient has disease stabilization or improvement in disease while on therapy
• spironolactone 25 mg/5 mL oral suspension (CaroSpir) **Diuretics**	Manual PA criteria apply to all new users of CaroSpir who are over 12 years old. Manual PA criteria—Coverage will be approved if all criteria are met: • The patient has heart failure, hypertension or edema from cirrhosis AND • The provider must write in why the patient requires CaroSpir and cannot take an aldosterone blocker / potassium-sparing diuretic in a tablet formulation o Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience Non-FDA approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• prednisone delayed release (Rayos) **Corticosteroids-Immune Modulators: Corticosteroids Subclass**	Manual PA criteria apply to all new and current users of Rayos. Note that PA is not required for generic prednisone; providers are encouraged to consider changing the prescription to generic prednisone. Manual PA criteria—Coverage for Rayos will be approved if: • The provider writes in why the patient requires delayed release prednisone and why patient cannot take immediate release prednisone • Acceptable responses are approved if ALL of the criteria are met: o The patient has a diagnosis of rheumatoid arthritis AND o The patient medical history includes trial and failure of both: ▪ generic prednisone AND ▪ at least one generic oral corticosteroid (e.g., dexamethasone, methylprednisolone, etc.) Off-label uses are not approved. Prior Authorization does not expire.
• acyclovir/ hydrocortisone 5%/1% cream (Xerese) **Antivirals**	Note: DoD Formulary products include topical or oral antiviral agents. Consider alternate agents first, such as acyclovir oral/topical or valacyclovir oral tablets. This PA is only approved for treatment of immunocompetent patients 6 years and older with recurrent herpes labialis (not approved for prophylaxis). Manual PA criteria apply to all new and current users of Xerese. Manual PA criteria—Coverage for Xerese is approved if: • The provider writes in why the patient requires Xerese and why they cannot take oral antivirals or cannot use acyclovir 5% cream and hydrocortisone 1% cream separately. • Acceptable responses are approved if ALL of the criteria are met: o Tried and failed topical acyclovir 5% cream and hydrocortisone 1% cream separately AND o Treatment failure of one of the following: oral acyclovir, valacyclovir, or famciclovir Off-label uses are not approved. Prior Authorization does not expire.
• penciclovir cream 1% (Denavir) • acyclovir 50mg buccal tablet (Sitavig) **Antivirals**	Note: DoD Formulary products include topical or oral antiviral agents. Consider alternate agents first, such as acyclovir oral/topical or valacyclovir oral tablets. This PA is only approved for treatment of immunocompetent patients 12 years and older with recurrent herpes labialis (not approved for prophylaxis). Manual PA criteria apply to all new and current users of Denavir or Sitavig. Manual PA criteria—Coverage for Denavir or Sitavig is approved if: • The provider writes in why the patient requires Denavir or Sitavig and why they cannot take oral antivirals or cannot use acyclovir 5% cream. • Acceptable responses are approved if ALL of the criteria are met: o Tried and failed topical acyclovir 5% cream AND o Treatment failure of one of the following: oral acyclovir, valacyclovir, or famciclovir Off-label uses are not approved. Prior Authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• plecanatide (Trulance) **GI-2 Miscellaneous Drugs**	**Changes from February 2018 meeting are in BOLD and will apply to new 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 **OR IBS-C** AND 3. Patient does not have gastrointestinal obstruction AND **4.** Patient has failed or is intolerant to linaclotide (Linzess) **AND ONE OF THE FOLLOWING:** **1. If started on Linzess 145 mcg and intolerant due to diarrhea, must have trialed 72 mcg strength OR** **2. If started on Linzess 72 mcg and inadequate response, must try and have failed 145 mcg strength AND** 5. Dual therapy with another guanylate cyclase-C agonist is not allowed. Off-label uses are not approved. PA expires in one year. Renewal PA criteria 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.
• flibanserin (Addyi) **Female Hypoactive Sexual Desire Disorder Agents—Mixed Serotonin Agonist/Antagonists**	**Changes from the February 2018 meeting are in BOLD and apply to new and current users of Addy.** Manual PA criteria apply to all new and current users of Addyi. Manual PA criteria—Coverage for Addyi is approved if: • The drug is prescribed for a premenopausal female with HSDD not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance AND • The patient does not have current alcohol use • The patient does not have hepatic impairment (Child-Pugh score ≥6) • The patient is not receiving concomitant therapy with a moderate or strong CYP3A4 inhibitor (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil) AND • The prescription is written by a provider who is certified/enrolled in the flibanserin REMS program. • Note that contraindications to the use of flibanserin include concurrent alcohol, moderate or strong CYP3A4 inhibitors, and hepatic impairment **Off label uses are not approved.** **~~PA does not expire~~ PA expires after three months.** **Renewal PA criteria:** PA will be approved indefinitely if the patient continues to exhibit clinical benefit, continues to be premenopausal, and continues to abstain from alcohol.

• pregabalin (Lyrica) • pregabalin ER (Lyrica CR) **Antidepressants and Non-Opioid Pain Syndrome Agents**	**Changes from the February 2018 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 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, fibromyalgia **or neuropathic pain associated with spinal cord injury)** 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 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 **Off-label uses are not approved.** PA does not expire.
• All non step-preferred tetracyclines, including: • minocycline ER 45 mg, 90 mg, 135 mg ER (generics) • minocycline DR 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg (Solodyn) • minocycline ER capsule 45mg, 90mg, 135mg (Ximino) **Antibiotics: Tetracyclines**	**Changes from February 2018 meeting are in BOLD** **Renewal PA criteria apply to both new and current users of non-preferred tetracycline oral agents.** PA expires in 365 days. **Renewal PA criteria: PA will be renewed for an additional 365 days if the following:** • **Patient's therapy has been re-evaluated within the last 12 months** • **Patient is tolerating treatment and there continues to be a medical need for the medication** • **Patient has disease stabilization or improvement in disease while on therapy**
• sildenafil generic for Viagra **Phosphodiesterase-5 (PDE-5) Inhibitors**	Manual PA criteria apply to all new users of generic Viagra. Note that brand Viagra is the preferred phosphodiesterase-5 inhibitor product in the DoD. Manual PA Criteria—Coverage for generic Viagra is approved if the following criteria is met: • The provider has provided patient-specific justification as to why the brand Viagra product cannot be used. • Acceptable reasons include the following, which have occurred or are likely to occur with the branded Viagra product: allergy to the branded Viagra; contraindication; sub-therapeutic response; physical restriction (e.g., swallowing issues); and brand availability issues

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• liraglutide (Victoza) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	▪ MTF/Mail: 9 pens/90-day supply ▪ Retail: 3 pens/30-day supply
• teriparatide (Forteo) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	▪ MTF/Mail: 3 prefilled pens/84-day supply ▪ Retail: 1 prefilled pen/28-day supply
• abaloparatide (Tymlos) **Osteoporosis Drugs: Parathyroid Hormone Analogs**	▪ MTF/Mail: 3 prefilled pens/90-day supply ▪ Retail: 1 prefilled pen/30-day supply
• injectable corticotropin (H.P. Acthar Gel) **Corticosteroids-Immune Modulators: Adrenocorticotropic Hormones**	▪ MTF/Mail/Retail: 14-day supply
• acalabrutinib (Calquence) **Oncologic Agents**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs)**	Note: revised from default TIB agent rules, Nov 2017 meeting ▪ MTF/Mail/Retail: 56-day supply
• fluticasone propionate (Xhance) **Nasal Allergy Drugs**	▪ MTF/Mail: 3 bottles/90-day supply ▪ Retail: 1 bottle/30-day supply
• acyclovir buccal tablet (Sitavig) **Antiviral Agents**	▪ MTF/Mail/Retail: 2 tablets/28-day supply
• emicizumab-kxwh (Hemlibra) **Antihemophilic Factors**	▪ MTF/Mail: 60-day supply ▪ Retail: 30-day supply
• pegfilgrastim (Neulasta) **White Blood Cell Stimulants:**	Note: revised from July 2004 meeting ▪ MTF/Mail: 8 syringes/56-day supply ▪ Retail : 4 syringes/28-day supply
• aprepitant (Emend) **Antiemetic/Antivertigo Agents**	Note: revised from July 2004 meeting ▪ MTF/Mail: 16 capsules/56-day supply ▪ Retail: 8 capsules/28-day supply
▪ letermovir (Prevymis) **Antiviral Agents**	▪ MTF/Mail/Retail: 30-day supply

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

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
acalabrutinib (Calquence)	Oncological Agents	Imbruvica	100 mg capsules; 100 mg every 12 hrs	Adult patients with Mantle Cell Lymphoma (MCL) who have received at least one prior therapy	Serious: hemorrhage, infections, Afib, secondary primary malignancies, headache, diarrhea, bruising, fatigue, myalgia	• **Provides 2nd, more selective Bruton Tyrosine Kinase inhibitor for treatment of MCL** • Possibly less associated toxicity given less off-target effects • Accelerated approval based on overall response rates (ORR) and pending additional studies to verify benefit • Being studied as 1st line treatment for MCL in combination with rituximab
benznidazole	Anti-Infectives: Miscellaneous	None	12.5mg and 100mg oral tablets; dosed by weight	Pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by *Trypanosoma cruzi*	AEs are common. abdominal pain, nausea, vomiting, rash, decreased appetite, headache, and increased transaminases	• **First FDA-approved medication for Chagas Disease**; Orphan drug designation • Available since 1971 for investigational drug use by the Centers for Disease Control • One other investigational agent, Nifurtimox, has been available outside the U.S. since 1965 • **Significant risk for mild and severe AEs** • Definition of clinical 'cure' and clinical infection remains controversial
coagulation factor IX, recombinant (Rebinyn)	Antihemophilic Factors	• Alprolix • Idelvion	Age, weight, indication based dosing; 500, 1000, 2000 IU per vial	Adults and children with hemophilia B for 1) On-demand treatment and control of bleeding episodes; 2) Perioperative management of bleeding	Most common: itching/site reactions, few serious events; monitor for embolism/thrombosis, hypersensitivity; neutralizing antibodies	• **Provides 3rd extended half-life factor IX, achieved through pegylation** • For on-demand and perioperative use, but not indicated for routine prophylaxis or immune tolerance induction in Hemophilia B • Indication for routine prophylaxis blocked by exclusivity by another product; not assessed by FDA for that potential and likely off-label use • Concerns regarding long-term use in children given pegylation products depositing in choroid plexus and potential neurocognitive effects/development
dolutegravir/ rilpivirine (Juluca)	Antiretrovirals	• Complera • Triumeq • Tivicay plus Truvada • Atripla	dolutegravir 50mg/ rilpivirine 25mg tablets; one tablet a day	HIV To replace current antiretroviral regimen in virologically suppressed patients who are on a stable antiretroviral regimen for at least 6 months	Most common: nasopharyngitis, headache, upper respiratory tract infection, diarrhea, back pain	• Provides 4th single tablet regimen (STR) option for HIV • **First 2-drug combination (vs 3-drug) for HIV** • Both ingredients with established efficacy and safety profiles and generally well tolerated • Rilpivirine requires an acidic environment for absorption • **Anticipated place in therapy: for patients virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen for >6 months with no history of treatment failure or resistance**

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
emicizumab-kxwh (Hemlibra)	Antihemophilic Factors	• FEIBA • Novo-Seven RT • Obizur • High dose factors	Load: 3 mg/kg SubQ qwk for 4 wks, Maintenance: 1.5 mg/kg q wk;30 mg, 60 mg, 105 mg, 150 mg vials	Routine prophylaxis to prevent or reduce the frequency of bleeding episode in adult and pediatric patients with hemophilia A with factor VIII inhibitors	Serious: thrombotic microangiopathy, thromboembolism; injection site reactions, headache, arthralgia, pyrexia, diarrhea, myalgia	• **Provides 1st factor IXa and factor X-directed bispecific humanized monoclonal antibody that acts to replace factor VIII** • **Significant advance in therapy**
fluticasone propionate 93 mcg nasal spray (Xhance)	Nasal Allergy Drugs: Corticosteroids	• fluticasone propionate (Flonase) • mometasone (Nasonex)	nasal spray	For the treatment of nasal polyps in patients 18 years of age or older	Similar to others in class: epistaxis, septal ulceration, sinusitis, headache	• Xhance is only indicated for nasal polyps for adults ≥18; is not approved for allergic rhinitis • Contains the same active ingredient as Flonase but has a different indication • Mometasone is another product indicated for nasal polyps • **No compelling advantage over existing UF agents**
house dust mite (HDM) allergen extract (Odactra)	Immunological Agents — Miscellaneous: Oral Agents	Nasal Allergy Drugs • fluticasone propionate (Flonase) • flunisolide (Nasarel), generic • azelastine 137 mg (Astelin), • generic ipratropium (Atrovent) • montelukast	10 mg SL tablets QD dosing year round	Adults age 18-65 as immunotherapy for HDM-induced allergic rhinitis, with or without conjunctivitis	• Black box warning for anaphylaxis and severe laryngopharyngeal restriction • Itching of the nose/ears • Swelling of the mouth, lips, tongue • Ulceration/sores in the mouth	• **1st sublingual immunotherapy (SLIT) for HDM allergy-related allergic rhinitis/conjunctivitis** • Diagnosis must be confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae or Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts • 1st dose must be administered by health care professional with experience in allergy/allergic reactions • Need co-prescription with injectable epinephrine • Moderately effective in reducing symptoms of HDM-related allergic rhinitis • **In patients with HDM-related allergic asthma, Odactra may reduce the risk of asthma exacerbations and is recommended in the GINA 2017 asthma guidelines as an add-on to ICS therapy (off-label use)**
latanoprostene bunod ophthalmic solution (Vyzulta)	Glaucoma Agents	• latanoprost (Xalatan) • bimatoprost (Lumigan)	ophthalmic solution	For the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension	Mild • Conjunctival hyperemia 6% • Eye irritation 3% • Instillation pain 2%	• Latanoprostene bunod is metabolized to latanoprost and nitric oxide (NO); both products suggested to decrease intraocular pressure (IOP) • Unclear if dual mechanism of action improves efficacy over other ophthalmic prostaglandins • **Studies used clinically inferior comparators in phase 3 trials** • **No compelling advantage over existing UF agents**

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
letermovir (Prevymis)	Antivirals	• ganciclovir • valganciclovir	240 mg, 480 mg tablets; 240mg/12mL, 480/24mL vial for injection; Dosing: 480mg daily x 100 days	Prophylaxis of cytomegalovirus (CMV) infection and treatment in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)	Generally mild: • Diarrhea • Nausea • Fever	• **New antiviral indicated for prophylaxis and treatment of CMV infection in adults undergoing a HSCT** • Well-established generic competitors with increased adverse events profile • Letermovir has important drug-drug interactions that must be assessed before initiation of therapy • Overall, letermovir was well tolerated, with a minimal safety issues • **For centers that use CMV prophylaxis in high-risk patients, letermovir would be favored over other agents**
minocycline ER capsules (Ximino)	Antibiotics: Tetracyclines	• minocycline generic • minocycline ER generic • Solodyn ER	minocycline ER 45mg, 90mg, 135mg capsules	Inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older	≥1%: Generally mild: • Headache • Fatigue • Dizziness • Pruritus	• No new studies were submitted to the FDA for this product • No studies of added benefit in acne vulgaris of treatment by capsule vs tablet were performed • **No compelling advantage over existing UF agents**
dapagliflozin/ saxagliptin (Qtern)	Non-Insulin Diabetes Drugs: SGLT2 Inhibitors	SGLT2s • canagliflozin • dapagliflozin • **empagliflozin** DPP4s • alogliptin • linagliptin • saxagliptin • **sitagliptin**	dapagliflozin 10mg/ saxagliptin 5 mg oral tablet	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus with inadequate control with dapagliflozin or who are on the combo already	>10%: URTIs 1-10%: HA, dyslipidemia, hypoglycemia, diarrhea, UTI, localized fungal infections, back pain, arthralgia, renal insufficiency	• **Fixed-dose combination (FDC) of dapagliflozin and saxagliptin** • Evaluated in 1 trial showing the 2 drug combination reduced A1c more than a single agent but without a clinically significant difference between groups • **Contains 2 nonformulary and non step-preferred agents** • **Aside from providing a FDC, adds no compelling clinical advantage over existing UF agents**
semaglutide (Ozempic)	Non-Insulin Diabetes Drugs: GLP1RAs	• exenatide once weekly • exenatide twice daily • liraglutide • albiglutide • lixisenatide • dulaglutide	SubQ injectable • Pre-filled multi-dose pen • Strengths: 0.25mg, 0.5mg, 1mg	Adjunct to diabetes and exercise in type 2 diabetes mellitus	Black box warning: risk of thyroid C-cell tumors (like most in the class) ≥5%: nausea, vomiting, diarrhea, constipation, abdominal pain	• **7th approved GLP1RA and the 4th once weekly formulation** • Compared head-to-head with Bydureon and Trulicity • No clinically relevant difference in A1c or other secondary endpoints • **Step therapy change after Feb 2018 meeting will require a trial of Bydureon/BCise and Trulicity firs,t before use of non step- preferred agents**

Generic (Trade)	UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary
sodium picosulfate; magnesium oxide; anhydrous citric acid (Clenpiq)	Laxatives-Cathartics-Stool Softeners	• GoLytely • OsmoPrep • Prepopik	Split-dose method: one dose evening before procedure; one dose morning of procedure 2 bottles of 160 mL each	Osmotic laxative indicated for cleansing the colon in adults prior to colonoscopy	Contraindicated if severe renal dysfunction (creatinine clearance <30 mL/min) abdominal pain and bloating, dehydration, hypermagnesemia, hyponatremia, N/V/D, proctalgia, rash, itching, seizures	• **Same ingredients as Prepopik, but is pre-mixed oral solution vs powder** • Does not require mixing with water – ready to drink • Mechanism combines a stimulant effect (sodium picosulfate) to increase motility with, hyperosmotic effect (magnesium oxide and citric acid) to induce diarrhea • More tolerable than PEG-containing regimens (GoLytely) • Disadvantages include the risk of electrolyte disturbances; has not been as well studied as PEG-containing regimens, and higher cost compared to magnesium-containing regimens • **No clinical advantages over other bowel prep products other than it is a low volume pre-mixed bowel prep**
spironolactone oral suspension (CaroSpir)	Diuretics	• spironolactone tabs • amiloride • amiloride/ HCTZ • spironolactone/ HCTZ • triamterene/ HCTZ	25 mg/5 mL oral suspension; 118 mL and 473 mL bottles; banana flavored	• hypertension (add on therapy) • heart failure • edema caused by cirrhosis	• hyperkalemia • fluid/electrolyte imbalance • worsening renal function • gynecomastia	• Aldosterone receptor blocker, potassium-sparing diuretic • No clinical trial data – 505b(2) pathway approval • Package insert states “not therapeutically equivalent to Aldactone” • Limited to doses <100 mg due to pharmacokinetic profile; may cause unexpectedly high spironolactone levels • Convenience formulation for a commercially-prepared product • No pediatric indications • **No compelling advantages over existing UF agents**

Appendix F—Mail Order Status of Medications Designated Nonformulary During the February 2018 DoD P&T Committee Meeting

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Excepted from Mail Order Requirement (Do NOT Add)
Feb 2018	**Non-Insulin Diabetes Drugs: GLP1RAs** (Note: the class as a whole is on the EMMPI list) ▪ semaglutide (Ozempic) **Newly-Approved Drugs per 32 CFR 199.21(g)(5)** ▪ latanoprostene bunod ophthalmic solution (Vyzulta) ▪ dapagliflozin/saxagliptin (Qtern) ▪ house dust mite allergen extract sublingual tablets (Odactra) ▪ spironolactone oral suspension (CaroSpir) **Other** ▪ flibanserin (Addyi)	**Newly-Approved Drugs per 32 CFR 199.21(g)(5)** **Acute use exception applies:** ▪ coagulation factor IX, recombinant (Rebinyn) ▪ sodium picosulfate/magnesium oxide/anhydrous citric acid (Clenpiq) **Other: Feasibility exception applies (unavailable at mail order):** ▪ fluticasone propionate 93 mcg nasal spray (Xhance) ▪ minocycline ER capsules (Ximino)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2018	**Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RA) Subclass**	UF Class Review Class previously reviewed Nov 2010 Nov 2012 Aug 2015	BCF Step-Preferred ▪ exenatide once weekly injection (Bydureon) ▪ exenatide once weekly autoinjector (Bydureon BCise)	UF Step-Preferred ▪ dulaglutide (Trulicity)	NF Non Step-Preferred ▪ albiglutide (Tanzeum) ▪ exenatide twice daily (Byetta) ▪ liraglutide (Victoza) ▪ lixisenatide (Adlyxin) ▪ semaglutide (Ozempic)	Pending signing of the minutes / 90 days The effective date is July 25, 2018	Manual PA criteria required for all new and current users of a GLP1RA	▪ Must try metformin first in all new users of any GLP1RA unless a contraindication exists ▪ Must try Bydureon/BCise and Trulicity first before use of a nonformulary, non step-preferred GLP1RA ▪ Tanzeum market D/C in Aug 2018 ▪ See Appendix C
Feb 2018	**Anti-Inflammatory Immuno-modulatory Ophthalmic Drugs: Ophthalmic Immuno-modulatory Subclass**	UF Class review Class previously reviewed Feb 2016	▪ BCF: none in subclass ▪ prednisolone ophthalmic suspension is BCF (Pred Mild, Pred Forte)	UF ▪ cyclosporine 0.05% ophthalmic emulsion (Restasis) ▪ lifitegrast 5% ophthalmic solution (Xiidra)	None	Pending signing of the minutes / 90 days The effective date is July 25, 2018	Manual PA criteria applies to all new patients defined as not having filled Xiidra or Restasis in the last 120 days	▪ A trial of two different artificial tears products required first ▪ See Appendix C

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2018	**Osteoporosis Drugs: Parathyroid Hormone Analogs Subclass**	UF Class Review Subclass not reviewed; Class Reviewed June 2013	▪BCF: none in the subclass ▪alendronate is BCF for the bisphos-phonates	<u>UF and Step-Preferred</u> ▪ teriparatide injection (Forteo)	<u>NF Non Step-Preferred</u> ▪ abaloparatide injection (Tymlos)	Pending signing of the minutes / 60 days The effective date is June 27, 2018	Manual PA and QL apply	▪ A trial of Forteo is required in all new Tymlos patients ▪ See Appendix C
Feb 2018	**Cortico-steroids-Immune Modulators: Adreno-corticotropic Subclass**	UF Class Review Not previously reviewed	▪BCF: none in the subclass ▪prednisone and prednisolone are on the BCF	<u>UF</u> ▪ repository corticotropin injection (H.P. Acthar Gel)	Not Applicable	Pending signing of the minutes / 60 days The effective date is June 27, 2018	PA and QLs apply	▪ Prior Authorization applies for infantile spasms and multiple sclerosis exacerbation; other uses not covered ▪ See Appendix C

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

Appendix H—Table of Abbreviations

A1c	hemoglobin A1c
ACTH	adrenocorticotropic hormones
ADR	adverse drug reaction
AE	adverse event
Afib	atrial fibrillation
AKC	atopic keratoconjunctivitis
ALS	amyotrophic lateral sclerosis
ARR	absolute risk reduction
BCF	Basic Core Formulary
BIA	budget impact analysis
BMD	bone mineral density
BPA	blanket purchase agreement
CFR	Code of Federal Regulations
CIC	chronic idiopathic constipation
CMA	cost minimization analysis
CMV	cytomegalovirus
CVD	cardiovascular disease
CVOTs	cardiovascular outcomes trials
DAPA	Distribution and Pricing Agreement
DHA	Defense Health Agency
DoD	Department of Defense
DPP-4	dipeptidyl peptidase-4 inhibitor
DR	delayed release
ECF	Extended Core Formulary
EEG	electroencephalography
EHR	electronic health record
EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ER/LA	extended release/long acting
FDA	U.S. Food and Drug Administration
FDC	fixed-dose combination
FEV1	forced expiratory volume in one second
FSGS	focal segmental glomerulosclerosis
FY	Fiscal Year
GI	gastrointestinal
GINA	Global Initiative for Asthma
GLP1RA	glucagon-like peptide-1 receptor agonist
GvHD	graft versus host disease
HA	heachche
HCTZ	hydrochlorothiazide
HDM	house dust mite
HIV	human immunodeficiency virus
HSDD	hypoactive sexual desire disorder
HSCT	hematopoietic stem cell transplant
IBS-C	irritable bowel syndrome – constipation predominant
ICER	Institute for Clinical and Economic Review

IOP	intraocular pressure
IR	immediate release
IV	intravenous
MCL	mantle cell lymphoma
MHS	Military Health System
MHS PMWG	Military Health System Pain Management Work Group
MI	myocardial infarction
MN	medical necessity
MPGN	membranoproliferative glomerulonephritis
MS	multiple sclerosis
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NF	nonformulary
NNT	number needed to treat
NO	nitric oxide
NSCLC	non-small cell lung cancer
ORR	overall response rates
OTC	over-the-counter
P&T	Pharmacy and Therapeutics
PA	prior authorization
PDE-5	phosphodiesterase-5
POD	Defense Health Agency Pharmacy Operations Division
POS	point of service
PT	patient
PTH	parathyroid hormone
QLs	quantity limits
REMS	Risk Evaluation and Mitigation Strategies
SC/SQ	subcutaneous
SGLT2	sodium glucose co-transporter 2 inhibitor
SL	sublingual
SLIT	sublingual immunotherapy
STR	single table regimen
T2DM	type 2 diabetes mellitus
TEN	Toxic Epidermal Necrolysis Syndrome
TIBs	targeted immunomodulatory biologics
TX	treatment
UF	Uniform Formulary
URTI	upper respiratory tract infection
UTI	urinary tract infection
VA	U.S. Department of Veterans Affairs
VKC	vernal keratoconjunctivitis
XR/SR	extended/sustained release