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

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

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** For Genotropin, Humatrope, Nutropin AQ Nuspin, Saizen, and Serostim: 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. 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 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. 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
• 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