DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

November 2019

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on November 6 and 7, 2019, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of August 2019 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the August 2019 DoD P&T Committee meeting on October 30, 2019.

2. **Clarification of Previous Minutes**

   a) **May 2019 Meeting—Proton Pump Inhibitors (PPIs) Alternate Dosage Forms PA criteria:** Existing step therapy for the PPI Alternative Dosage forms requires a trial of the step-preferred tablets/capsules first. The new PA criteria removes the alternative dosage forms from the tablets/capsules step therapy. Patients receiving Prevacid ODT or Zegerid packets will have a manual PA and must try all of UF step-preferred alternative dosage forms first.

   b) **August 2019 Meeting—Pulmonary Arterial Hypertension (PAH) Nitric Oxide PA criteria:** At the meeting, tadalafil 20 mg (Adcirca, Alyq, generics) for PAH was designated as non-step-preferred, however prior to implementation in October 23, 2019 cost-effective generics to tadalafil entered the market. The manual PA requiring sildenafil 20 mg before tadalafil 20 mg was not implemented. Tadalafil 20 mg will now be step-preferred along with sildenafil 20 mg for patients receiving Adempas. This does not apply to the tadalafil 20 mg formulation (Cialis) for erectile dysfunction.

   c) **August 2019 Meeting—Pulmonary Arterial Hypertension (PAH) Adempas PA clarification:** Adempas is the only nitric oxide inhibitor approved for chronic thromboembolic pulmonary hypertension (CTEPH). The Adempas PA criteria was clarified so that the intent was that patients with CTEPH are not required to try a PDE-5 inhibitor first.

   d) **August 2019 Meeting—Pulmonary Arterial Hypertension (PAH) sildenafil BCF clarification:** The BCF listing for sildenafil for PAH only applies to generic sildenafil, not the brand Revatio formulation.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. All uniform formulary (UF), basic core formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018. Medical necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a non-formulary (NF) medication.

Non-formulary 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. Phosphodiesterase-5 (PDE-5) Inhibitors:

Background—The P&T Committee evaluated the relative clinical effectiveness of the PDE-5 inhibitors, which include avanafil (Stendra), sildenafil (Viagra), tadalafil (Cialis), vardenafil oral disintegrating tablet (ODT) (Staxyn), and vardenafil tablets (Levitra). Generic formulations are marketed for all the products, except for Stendra. All the PDE-5 inhibitors are indicated to treat erectile dysfunction (ED) on an as needed basis. Tadalafil is the only PDE-5 inhibitor approved for daily use in addition to as needed use for ED, and is also approved for treating benign prostatic hyperplasia (BPH).

The class was most recently reviewed in November 2011. Sildenafil is currently UF and step-preferred, with the remaining PDE-5 inhibitors designated as NF and non-step-preferred. Prior Authorization (PA) is not required for men over the age of 40 years for erectile dysfunction (ED); however PA is required in men younger than 40 years for ED, for men of all ages for the FDA-approved indication of BPH, and for off-label uses (post-prostatectomy and Raynaud's phenomena). Use of the PDE-5 inhibitors for PAH is not a focus of this review.

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

Erectile Dysfunction (ED)

- There were no major updates to the November 2011 conclusion that there is a high degree of therapeutic interchangeability for the PDE-5 inhibitors for treating ED.
- The 2018 American Urological Association (AUA) guidelines support PDE-5 inhibitors as first-line therapy for ED and state there are no major differences in efficacy between the drugs.
- Two recent network meta-analyses also support that there are no significant differences in efficacy between the PDE-5 inhibitors for ED. Sildenafil was

associated with the highest efficacy compared to placebo, but head-to-head comparisons between the individual PDE-5 inhibitors have not been studied. (Chen 2015, Corona 2016)

- Based on meta-analysis findings, vardenafil is associated with the highest reporting of adverse events followed by sildenafil and tadalafil. (Chen 2015)

BPH

- A 2018 Cochrane review evaluated the effects of the PDE-5 inhibitors compared to placebo, and the alpha blockers and 5-alpha reductase inhibitors on urinary symptoms of BPH. When compared to the alpha blockers, the PDE-5 inhibitors probably provide similar improvement in urinary symptoms, based on moderate-quality evidence.

Off-label uses

- Post-prostatectomy: A Cochrane review in 2018 supports PDE-5 inhibitor use to preserve erectile function post-prostatectomy, but did not provide conclusive evidence of a preferred agent or dosing regimen (i.e., daily vs. on-demand). The authors acknowledge that tadalafil is the only PDE-5 inhibitor indicated for daily use and the most studied agent for daily dosing.
- Raynaud's phenomenon: There are no guidelines for treating this condition. According to the 2017 European Society of Vascular Medicine consensus statement, no specific agent is recommended, but sildenafil and tadalafil are the most studied PDE-5 inhibitors.

Individual PDE-5 characteristics

- Sildenafil (Viagra) was the first PDE-5 inhibitor marketed and has a long history of use. It has the highest MHS utilization of all the PDE-5 inhibitors. Generic formulations of sildenafil were launched in December 2017, and there are at least nine generic manufacturers available as of November 2019.
- Tadalafil (Cialis) advantages include its indication for BPH in addition to ED, approval for daily dosing and on-demand dosing, and a long half-life of 17 hours. Multiple generic formulations of tadalafil are marketed (17 as of November 2019).
- Vardenafil is available in both a film-coated tablet (Levitra) and ODT (Staxyn). The ODT theoretically provides a convenience to the patient, but there are no studies supporting this**.** Disadvantages of vardenafil include low MHS utilization, and limited generic availability.
- Avanafil (Stendra) was the fourth PDE-5 inhibitor to enter the market. Although it has the fastest onset of action of 15 minutes, this has not translated into increased efficacy over the other PDE-5 inhibitors. There is limited published data with avanafil, compared to the other products. One meta-analysis reported a statistically significant lower number of adverse events compared to the other PDE-5 inhibitors (Corona 2016); however this has not correlated with increased efficacy or a lower discontinuation rate. Generic formulations are not expected before 2023.

- Input from MHS providers support Tier 4 status for multiple PDE-5 inhibitors, as long as both a short-acting and long-acting product is available.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the PDE-5 inhibitors. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic sildenafil and generic tadalafil were the most cost effective PDE-5 inhibitors, followed by vardenafil tablet (Levitra, generic), vardenafil ODT (Staxyn, generic), and avanafil (Stendra), which were substantially less cost effective.
- BIA was performed to evaluate the potential impact of designating selected PDE-5 inhibitors as formulary, NF, or Tier 4 on the UF. The BIA results showed that designating generic sildenafil as UF and step-preferred, generic tadalafil as UF and non-step-preferred, with vardenafil ODT (Staxyn, generics), vardenafil tablet (Levitra, generics), avanafil (Stendra), and branded Viagra and branded Cialis as Tier 4 demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: PDE-5 INHIBITOR UF/TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

   - UF and step-preferred
     - sildenafil (generic Viagra only)
   - UF and non-step-preferred
     - tadalafil (generic Cialis only) *moves from NF to UF status*
   - NF - none

   This recommendation includes step therapy in new users, which requires a trial of generic sildenafil before generic tadalafil.

   - Tier 4/Not Covered
     - avanafil (Stendra)
     - vardenafil ODT (Staxyn, generics)
     - vardenafil tablets (Levitra, generics)
     - brand Viagra
     - brand Cialis

   When considering the PDE-5 inhibitor candidates for Tier 4/not covered status, the P&T Committee considered the information outlined in the interim rule, Section 702(b)(10) of the NDAA 2018 published on December 11, 2018, and found at: https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms.

   For the five PDE-5 inhibitors recommended for Tier 4/Not Covered status, the P&T Committee concluded they provide very little to no additional

clinical effectiveness relative to the other PDE-5 inhibitors. Overall, the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the formulary PDE-5 inhibitors. Formulary alternatives include generic sildenafil and generic tadalafil. See Appendix H.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining generic sildenafil on the BCF. Note that this recommendation does not apply to brand Viagra.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA—***Automated step therapy requirements currently apply to the class for ED, requiring a trial of sildenafil (Viagra) first. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing the automation, and requiring manual PA criteria for generic sildenafil and generic tadalafil. The manual PA will continue to require a trial of generic sildenafil prior to generic tadalafil for ED in new users. The age and gender edit for males 40 years and older will continue to apply. PA will continue to be required for ED in males younger than age 40 years and for the off-label uses. Minor updates were made to the PA criteria. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMIT (QL) RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) increasing the QLs for sildenafil and tadalafil for treatment of ED to 10 tablets per 30 days in the Retail Network and 30 tablets per 90 days at the MTFs and Mail Order. Note that this is a collective quantity limit. See Appendix D.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NF TO MAIL REQUIREMENTS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing generic sildenafil and generic tadalafil from the Select Maintenance Drug list. Note that avanafil (Stendra), vardenafil ODT (Staxyn, generics), vardenafil tablet (Levitra, generics), branded Viagra and branded Cialis will be removed from the list when Tier 4/not covered status is implemented.

6. ***COMMITTEE ACTION: UF/TIER 4/NOT COVERED, PA, MN, QL AND EMMPI PROGRAM IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) 1) An effective date of the first Wednesday 120 days after signing of the P&T minutes at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/not covered recommendations at 30 and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is June 3, 2020.

B. Insulins: Rapid-Acting Insulins (RAIs) Subclass

Background—The RAIs have not been previously reviewed for formulary status. Insulin aspart (Novolog) has been BCF since 2003, prior to implementation of the UF Rule in 2005. Insulin lispro (Humalog) and insulin glulisine (Apidra) have not been previously reviewed and have been UF "by default" since their approval. Two products were reviewed as innovators: insulin aspart plus niacinamide (Fiasp) was made NF in November 2017 and inhaled insulin (Afrezza) was made NF in February 2016; both Fiasp and Afrezza require PA.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- There were no major updates to the P&T clinical conclusions from 2003 that showed there are no clinically relevant differences between insulin aspart (Novolog) and lispro (Humalog) in lowering hemoglobin A1c.
- Numerous clinical practice guidelines are available (e.g., American Diabetes Association, American Association of Clinical Endocrinologists, American College of Endocrinology) and none give preference to one RAI over another.
- Although there are subtle differences between RAIs with regard to pharmacokinetic profiles in terms of onset and duration of action, clinical efficacy appears similar between the products.
- Insulin aspart (Novolog) is the current BCF RAI and is approved for use in insulin pumps and in children as young as 2 years of age. Other advantages include that it is available in all dosage forms (pen, vials, and cartridges), and has the majority of the market share in the MHS (>60%).
- Insulin lispro (Humalog) advantages include a long history of use in the MHS, approval for insulin pumps and in pediatric patients down to age 3 years, and availability in all dosage forms (pen, vials, and cartridges). Humalog is second in utilization in the MHS (30%).
- Insulin glulisine (Apidra) was the third FDA-approved RAI. It may be used in insulin pumps and in pediatric patients down to 4 years. Disadvantages of Apidra compared to insulin aspart or lispro include a greater susceptibility to precipitation and catheter occlusions during continuous subcutaneous insulin infusion (CSII), and the association with significantly elevated hypoglycemia rates. It has very low utilization in the MHS (<1%).
- Fiasp is a new formulation of insulin aspart that contains niacinamide, a form of vitamin B3. Although Fiasp has a faster onset of action, the change in pharmacokinetic profile did not show a clinically significant difference in A1c or post-prandial blood glucose compared to Novolog. Fiasp recently gained FDA approval for use in pumps, but was not approved in pediatrics at the time of the review. It has similar adverse effects to Novolog with slightly higher rates of hypoglycemia, upper respiratory infections, and nasopharyngitis.
- Admelog is a new formulation of insulin lispro that did not show a clinically significant difference in A1c or post-prandial blood glucose versus the active

comparator Humalog. It is approved for use in pumps and in pediatrics down to age 3 years.

- Afrezza is the only inhaled insulin. Although it is approved for use in adults, it lacks pediatric labeling, has very low utilization in the MHS, and is the only RAI with a black box warning regarding bronchospasm in patients with asthma or COPD. Despite the unique drug delivery system, Afrezza has numerous limitations including contraindications and warnings. As with all the RAIs, Afrezza requires concomitant basal insulin injections, which negates a potential advantage in patients with needle phobia. Overall, Afrezza offers no clinically compelling advantage over other RAIs.
- With regard to adverse events, there was no new data to change the 2003 conclusion that there is no evidence of a difference in the number, type or severity of adverse reactions between insulin aspart or lispro.
- In a retrospective claims analysis comparing insulin aspart and lispro, there were no significant differences in the percentage of patients experiencing a hypoglycemic event or new or worsening diabetes complications. Additionally, there were no significant differences in emergency department visits between any of the products or device (e.g., vial, pen, cartridge) comparisons.
- With regard to special populations, two systematic reviews found that RAIs were safe in pregnancy, pediatric patients, and in patients with diabetic ketoacidosis (DKA). No preferences were given regarding use of one RAI over another.
- With regard to devices, the RAI pens are the most widely used dosage form in the MHS, followed by vials, then cartridges.
- Overall, with the exception of inhaled insulin (Afrezza), there is a high degree of interchangeability among the RAIs.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the RAIs. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results for the RAIs showed the following products ranked from most cost effective to least cost effective as follows: insulin aspart (Novolog), insulin lispro (Humalog and authorized generic insulin lispro), insulin lispro (Admelog), insulin glulisine (Apidra), insulin aspart with niacinamide (Fiasp), and inhaled insulin (Afrezza), respectively.
- BIA was performed to evaluate the potential impact of designating selected insulins as formulary, NF or Tier 4 on the UF. BIA results showed that designating insulin aspart (Novolog) and insulin lispro (Humalog and authorized generic insulin lispro) as UF and step-preferred, and insulin lispro (Admelog), insulin glulisine (Apidra), insulin aspart with niacinamide (Fiasp), and inhaled insulin (Afrezza) as NF and non-step-preferred demonstrated the most cost avoidance for the MHS.

1. ***COMMITTEE ACTION: RAI UF/TIER 4/NOT COVERED RECOMMENDATION—***

A) The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF and step-preferred
  - insulin aspart (Novolog)
  - insulin lispro (Humalog and authorized generic insulin lispro)
- NF and non-step-preferred
  - insulin lispro (Admelog) *(moves from UF to NF)*
  - insulin glulisine (Apidra) *(moves from UF to NF)*
  - inhaled insulin (Afrezza)

- This recommendation includes step therapy (automated PA), which requires a trial of insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) prior to use of the NF, non-step-preferred RAIs in all new and current users.

B) The P&T Committee recommended (9 for, 7 opposed, 0 abstained, 1 absent) the following:

- Tier 4/Not Covered
  - insulin aspart plus niacinamide (Fiasp)

  The P&T Committee concluded that Fiasp provides very little to no additional clinical effectiveness relative to the other RAIs. Overall, the P&T Committee felt that the needs of TRICARE beneficiaries can be met by the other RAIs. The formulary alternatives include Novolog, Humalog, and authorized generic insulin lispro. See Appendix H.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) maintaining insulin aspart pen, cartridge and vials (Novolog Flexpen, Novolog Flextouch, and Novolog vial) on the BCF.

3. ***COMMITTEE ACTION: AUTOMATED PA (STEP THERAPY) and MANUAL PA CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) automated PA and manual PA criteria for all new and current users of the non-step-preferred RAIs, insulin lispro (Admelog) and insulin glulisine (Apidra). A trial of Novolog and either Humalog or authorized generic insulin lispro will be required first,

unless the patient is using an insulin pump/CSII and is stabilized on Admelog or Apidra, or if they have tried and failed the step-preferred insulins.

Existing manual PA criteria apply to inhaled insulin (Afrezza). The P&T Committee recommend updating the manual PA criteria requiring the patient to have tried and failed Novolog and Humalog or authorized generic insulin lispro in all new and current users. Note that Afrezza will not be included in the automated step therapy criteria. See Appendix C for the full criteria

4. ***COMMITTEE ACTION: REMOVAL OF AUTHORIZED GENERIC INSULIN LISPRO MANUAL PA CRITERIA—***The authorized generic insulin lispro entered the market in April 2019, and manual PA criteria requiring a trial of Humalog first was implemented in May 2019. The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing the manual PA on authorized generic lispro, as it is no longer cost advantageous.

5. ***COMMITTEE ACTION: MN CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Admelog, Apidra, and Afrezza. See Appendix B for the full criteria.

6. ***COMMITTEE ACTION: EMMPI REQUIREMENTS—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) maintaining the RAIs on the EMMPI program, and adding inhaled insulin (Afrezza) to the EMMPI program, as there is no reason to exempt Afrezza from the NF to mail requirement. Additionally, insulin lispro (Admelog) was removed from the EMMPI list since there is no cost advantage to including it on the program. See Appendix F.

7. ***COMMITTEE ACTION: SAFETY NET/RAPID RESPONSE PROGRAM—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) adding the RAIs to the Safety Net/Rapid Response Program managed by Express Scripts. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.

8. ***COMMITTEE ACTION: UF, TIER 4/NOT COVERED, PA, MN, AND EMMPI PROGRAM IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday after a 150-day implementation period, and no earlier than July 1, 2020 in all points of service and, 2) DHA send letters to beneficiaries who are affected by the UF/Tier 4 and PA. Patients affected by the Tier 4 recommendation will receive letters at 90, 60 and 30 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is July 1st 2020.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed for groups 1 and 2: (16 for, 0 opposed, 0 abstained, 1 absent); and group 3: (17 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 November 2019 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF RECOMMENDATION*—**The P&T Committee recommended for groups 1 and 2: (16 for, 0 opposed, 0 abstained, 1 absent); and group 3: (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
    - bremelanotide injection (Vyleesi) – Miscellaneous gynecological agent for Hypoactive Sexual Desire Disorder (HSDD)
    - darolutamide (Nubeqa) – Oral oncologic agent for non-metastatic castration-resistant prostate cancer (nmCRPC)
    - entrectinib (Rozlytrek) – Oral oncologic agent for lung cancer
    - fedratinib (Inrebic) – Oral oncologic agent for myelofibrosis
    - glucagon injection (Gvoke Hypopen and Pre-filled Syringe) – Binders-Chelators-Antidotes-Overdose Agent for severe hypoglycemia
    - glucagon nasal spray (Baqsimi) – Binders-Chelators-Antidotes-Overdose Agent for severe hypoglycemia
    - lamivudine/tenofovir disoproxil fumarate (Temixys) – Antiretroviral combination for human immunodeficiency virus (HIV)
    - midazolam nasal spray (Nayzilam) – Anticonvulsants-antimania agent for seizures
    - pexidartinib (Turalio) – Oral oncologic agent for tenosynovial giant cell tumors
    - segesterone acetate/ethinyl estradiol vaginal ring (Annovera) – Miscellaneous contraceptive agent
    - selinexor (Xpovio) – Oral oncologic agent for relapsing remitting multiple myeloma
    - semaglutide oral tablet (Rybelsus) – Oral glucagon-like peptide-1 receptor agonist for type 2 diabetes mellitus in adults
    - tiopronin extended-release (Thiola EC) – Miscellaneous urinary agent for cystinuria

- NF:
    - amlodipine oral suspension (Katerzia) – Calcium channel blocking agent in an oral suspension for hypertension
    - duloxetine extended-release (Drizalma Sprinkle) – Antidepressants and non-opioid pain syndrome, serotonin-norepinephrine reuptake inhibitors (SNRIs)
    - istradefylline (Nourianz) – Parkinson's agent for off episodes
    - lefamulin (Xenleta) – Antibiotic for community acquired bacterial pneumonia (CABP)
    - pitolisant (Wakix) – Sleep disorders: wakefulness promoting agent for narcolepsy
    - upadacitinib (Rinvoq) – Targeted Immunomodulatory Biologic (TIB) for rheumatoid arthritis
- Tier 4/Not Covered:
    - formoterol/aclidinium inhaler (Duaklir Pressair) – Pulmonary-2 Agent for Chronic Obstructive Pulmonary Disease (COPD)
        - Duaklir Pressair was recommended for Tier 4 status as it has little to no additional clinical effectiveness relative to similar long-acting muscarinic antagonist/long-acting beta agonist (LAMA/LABA) combination drugs; and the needs of TRICARE beneficiaries are met by alternative agents.
            - Formulary LAMA/LABA alternatives to Duaklir Pressair are umeclidinium/vilanterol (Anoro Ellipta), and tiotropium/olodaterol (Stiolto Respimat), and the non-formulary alternatives include glycopyrrolate/indacaterol (Utibron Neohaler), and glycopyrrolate/formoterol (Bevespi Aerosphere). (See Appendix H.)
    - sumatriptan nasal spray (Tosymra) – Migraine agents, triptans
        - Tosymra was recommended for Tier 4 status as it has little to no additional clinical effectiveness relative to similar nasal triptan migraine agents; and the needs of TRICARE beneficiaries are met by alternative agents.
            - Formulary alternatives to sumatriptan nasal (Tosymra) are sumatriptan nasal spray (Imitrex, generics), and zolmitriptan nasal spray (Zomig); and the NF alternative is sumatriptan nasal powder (Onzetra Xsail). (See Appendix H.)
    - tegaserod (Zelnorm) – Gastrointestinal-2 agent for constipation-predominant irritable bowel syndrome (IBS-C)
        - Zelnorm was recommended for Tier 4 status as it has no clinical benefit relative to other agents approved for IBS-C and has significant safety concerns relative to other IBS-C drugs including

cardiovascular and suicidality risks; and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives to Zelnorm include linaclotide (Linzess), plecanatide (Trulance), and lubiprostone (Amitiza), and the nonformulary alternative is pruclaopride (Motegrity). (See Appendix H.)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended for groups 1 and 2: (16 for, 0 opposed, 0 abstained, 1 absent); and group 3: (17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Drizalma Sprinkle, Katerzia, Nourianz, Rinvoq, Wakix and Xenleta. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended for groups1 and 2: (16 for, 0 opposed, 0 abstained, 1 absent); and group 3: (17 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Applying manual PA criteria to new and current users of Drizalma Sprinkle, Nourianz, Rybelsus, Vyleesi, and Wakix.
- Applying manual PA criteria to new users of Inrebic, Nubeqa, Rozlytrek, Thiola EC, Turalio, and Xpovio.
- TIBs: Applying the same manual PA criteria in new users of Rinvoq that are currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally, for Rinvoq a trial of tofacitinib (Xeljanz) or baricitinib (Olumiant) is required if the patient cannot be treated with Humira.

D. ***COMMITTEE ACTION: UF/TIER 4/NOT COVERED, PA AND MN IMPLEMENTATION PERIOD—***The P&T Committee recommended for groups1 and 2: (16 for, 0 opposed, 0 abstained, 1 absent); and group 3: (17 for, 0 opposed, 0 abstained, 0 absent) the following:

- **New Drugs Recommended for UF or NF Status:** An effective date upon the first Wednesday two weeks after signing of the minutes in all points of service, on February 19, 2020.
- **New Drugs Recommended for Tier 4 Status Duaklir Pressair, Tosymra, and Zelnorm:** 1) An effective date of the first Wednesday after a 120-day implementation period at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is June 3, 2020.

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

a) NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5): Skeletal Muscle Relaxants and Combinations— Chlorzoxazone 375 mg and 750 mg (Lorzone, generics)

Chlorzoxazone 375 mg and 750 mg are new strengths approved via the Abbreviated New Drug Application (ANDA) pathway and thus do not qualify for review by the DoD P&T Committee under the innovator program. Chlorzoxazone 500 mg is a scored tablet and produced by several manufacturers. Skeletal muscle relaxants are not considered first-line therapy for musculoskeletal conditions. Cost-effective generic formulations of chlorzoxazone 500 mg and multiple comparable muscle relaxants (e.g., cyclobenzaprine, methocarbamol) are available on the UF without PA required. PA criteria also apply to the chlorzoxazone 250 mg strength, from the November 2018 meeting.

COMMITTEE ACTION: SKELETAL MUSCLE RELAXANTS AND COMBINATIONS CHLORZOXAZONE 375 MG AND 750 MG TABLETS (LORZONE, GENERICS) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for chlorzoxazone 375 mg and 750 mg (Lorzone, generics) in new and current users, due to significant cost differences compared with splitting the 500 mg tablets or using other generic muscle relaxants. See Appendix C for the full criteria.

b) Anesthetic Agents: Local— Lidocaine-Tetracaine 7%-7% topical cream (Pliaglis, generics)

This combination topical anesthetic cream is an authorized generic of Pliaglis and is approved for use prior to superficial dermatological procedures, including dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal. Prior to 2018, this product was restricted to use in the clinic setting by health care professionals. However, the "Not for Home Use" restriction was removed, as the manufacturer submitted a study supporting patient self-use. Numerous cost-effective topical anesthetics (e.g., lidocaine 4% cream, lidocaine 5% cream/ointment, and lidocaine-prilocaine 2.5%-2.5% cream) are available that a patient could apply prior to a procedure.

COMMITTEE ACTION:. LIDOCAINE-TETRACAINE 7%-7% TOPICAL CREAM (PLIAGLIS, GENERICS) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users, due to availability of several cost-effective therapeutic alternatives. Patients

younger than age 12 years are not required to complete a PA form. See Appendix C for the full criteria.

c) Parkinson's Agents: rotigotine (Neupro) patch

The P&T Committee has not previously reviewed the Parkinson's disease drug class. Rotigotine (Neupro) patch was marketed in 2012, and was designated as UF prior to the establishment of the Innovator Rule in August 2015. Although rotigotine is the only non-oral dopamine agonist, Parkinson's disease guidelines do not give a preference for any one agent over another. Cost effective generic formulations of oral pramipexole and ropinirole are available.

COMMITTEE ACTION: ROTIGOTINE (NEUPRO) PATCH MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users, requiring use of an oral dopamine agonist first, unless the patient has swallowing difficulties. See Appendix C for the full criteria

d) Oral Oncologic Agents: venetoclax (Venclexta) and idelalisib (Zydelig)

PA criteria have not previously been required for the chronic lymphocytic leukemia (CLL) drugs, Venclexta and Zydelig. However, PA criteria is in place for several other oncological drugs used to treat CLL.

COMMITTEE ACTION: VENETOCLAX (VENCLEXTA) AND IDELALISIB (ZYDELIG) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for these two products in new users in order to ensure prescribing in accordance with FDA-approved indications or National Comprehensive Cancer Network (NCCN) Guideline-endorsed off-label indications.

e) Miscellaneous Urinary Agents: tiopronin IR (Thiola) —PA criteria were recommended for the IR formulation of tiopronin, since PA criteria were placed for the newly approved drug Thiola EC, in new users, to be implemented the first Wednesday two weeks after signing of the minutes, along with the PA for the new drug Thiola EC.

2. Updated Manual PA Criteria, Step Therapy, and MN Criteria—Updates to the manual PA criteria, step therapy, and MN criteria for several drugs were recommended due to a variety of reasons, including expanded FDA indications, new NCCN guideline recommendations, clinical trial data, standardization with existing PAs for the drug class, changes due to FDA safety announcements and boxed warnings, and age indications. The updated PAs, step therapy, and MN criteria outlined below will apply to new users. See Appendix B for the MN criteria and Appendix C for the PA criteria.

a) Updated Criteria for reasons other than new FDA Indications, NCCN Guideline Updates, or Age Ranges

- **Pulmonary-1 Agents: Combinations: budesonide/formoterol (Symbicort) AND mometasone/formoterol (Dulera)—**Manual PA criteria for Symbicort and Dulera were originally recommended in February 2014, requiring a trial of fluticasone/salmeterol (Advair) first. Recently the Global Initiative for Asthma (GINA) 2019 evidence-based strategy was updated, and states that combination low-dose inhaled corticosteroid (ICS)-formoterol used as needed is now the preferred reliever ("rescue use") for asthma control and reducing exacerbations in adults and adolescents 12 years and older with mild asthma. Short-acting beta agonists (SABAs) are now listed as an "other reliever option" and are no longer the preferred rescue treatment in adults and adolescents with mild asthma. This new approach was based on two studies that used a combination budesonide-formoterol inhaler (SYGMA 1 and SYGMA2, *New England Journal of Medicine May 2018*).

  Limitations to this recommendation include that the two supporting studies were industry funded, and used an active comparator (terbutaline Turbuhaler) that is not available in the U.S. Additionally, the budesonide-formoterol inhaler evaluated in the trials was a dry powder inhaler, while the commercially available U.S. product is a pressurized metered-dose inhaler (Symbicort), and the study design was changed from a superiority trial to a non-inferiority trial. The study results also show that this method is not as effective at decreasing asthma symptoms. Note that the new GINA recommendations apply to patients with symptoms occurring less than twice a month, and with no exacerbation risk (Step 1 in the algorithm). GINA also does not recommend use of ICS-formoterol as the reliever for patients taking combination ICS-long-acting beta agonist (LABA) medications with a different LABA. For these patients, their as-needed reliever inhaler should be SABA. The GINA strategy is a global group, and this approach has not been universally accepted by U.S. researchers/thought leaders (e.g., Up to Date).

  Provider feedback was mixed and not overwhelmingly supportive of the GINA recommendation, given the available data. Manual PA criteria for both Symbicort and Dulera were updated to allow use in patients with mild asthma who require rescue therapy with an ICS-formoterol combination, without requiring a trial of Advair first. The MN criteria for both Symbicort and Dulera where updated accordingly for rescue use.

- **Targeted Immunomodulatory Biologics (TIBs): certolizumab (Cimzia)—**Manual PA criteria for Cimzia were most recently reviewed at the May 2019 P&T Committee meeting after Cimzia was granted FDA-approval for adults with non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. The Cimzia and Humira PA criteria were updated to allow for the indication of nr-axSpA but still require the use

of adalimumab (Humira) prior to use of Cimzia. This recommendation was based on the Assessment of Spondylo Arthritis International Society (ASAS)/European League against Rheumatism (EULAR) guidelines and clinical trial data.

The implementation of the Humira step requirement was delayed in light of additional information that was not available at the May 2019 P&T meeting. The fact that the manufacturer for Humira sought FDA-approval for this indication and was denied in 2009-2013 had not been presented to the Committee in May 2019. The additional information presented at this meeting included the FDA's review of both Cimzia and Humira for nr-axSpA, the high degree of difficulty of actually diagnosing this disease, and provider feedback. The P&T Committee recommended maintaining the requirement for Humira prior to Cimzia for nr-axSpA after evaluating this additional information. The Cimzia PA criteria from the May 2019 P&T Committee meeting requiring use of Humira first in patients with nr-axSpA will now be implemented. (See May 2019 P&T Committee meeting minutes for full criteria.)

- **TIBs: Janus Kinase (JAK) inhibitors tofacitinib (Xeljanz, Xeljanz XR) and baricitinib (Olumiant)—**The FDA has issued several safety alerts for Xeljanz and Xeljanz XR for pulmonary embolism and death with certain doses, most recently in July 2019. The Xeljanz/Xeljanz XR PA criteria were updated to ensure the provider is aware of the July 2019 FDA safety announcement and boxed warning, and to ensure patients do not have a history of thromboembolic disease.

  Olumiant PA criteria were recommended in August 2018, and suggested using Xeljanz prior to Olumiant, since at that time Xeljanz did not contain a boxed warning for thrombosis. This comment will be removed from the Olumiant PA, as Xeljanz/Xeljanz XR now have the warning mentioned above.

  For Xeljanz/Xeljanz XR and Olumiant, additional requirements for absolute neutrophil count (ANC) and absolute lymphocyte count (ALC) monitoring were also added, consistent with the package inserts. The PAs will also allow concomitant use with Otezla, if the provider includes supporting literature for combination use.

- **Oncological Agents: Prostate Cancer CYP-17 Inhibitors: abiraterone acetate (Zytiga, generics)—**Manual PA criteria for Zytiga were recommended when the CYP-17 Inhibitor subclass was reviewed at the February 2019 P&T Committee meeting. Step therapy requiring a trial of abiraterone acetate micronized (Yonsa) first was required. Furthermore, an additional step required Zytiga generic 250 mg prior to Zytiga brand 500 mg, as the 500 mg branded formulation did not have generic equivalents and provided no clinical benefit at a significantly higher cost.

As of October 2019, the blended monthly cost of generic abiraterone acetate 250 mg is now comparable to the step-preferred Yonsa formulation. The step requiring Yonsa before Zytiga generic 250 mg will be removed. The abiraterone acetate (Zytiga) brand 500 mg PA form will still require use of Yonsa or the 250 mg generics first.

- **Hematological Agents: Platelets: avatrombopag (Doptelet)**—Manual PA criteria for Doptelet were first recommended in August 2018 for thrombocytopenia associated with chronic liver disease in patients who are scheduled to undergo a procedure with at least a moderate bleeding risk. Manual PA criteria were later updated in February 2019 to require a trial of Mulpleta first. Mulpleta has the same indication as Doptelet for pre-procedure use, has less complex dosing and was less expensive when the PA was firs placed. There has been a significant price reduction in Doptelet and manual PA criteria were updated to remove the requirement that Mulpleta be used prior to Doptelet in thrombocytopenia associated with chronic liver disease.

- **Acne Agents: Topical Acne and Rosacea: ivermectin (Soolantra) AND brimonidine (Mirvaso) MN Criteria**—MN criteria for Soolantra and Mirvaso have applied since the Topical Acne and Rosacea agents were reviewed in August 2016. The current MN criteria include specific diagnoses for both Soolantra and Mirvaso that allow access to these NF medications without requiring use of the formulary alternatives first. The MN criteria were updated, to align the MN form with the intent of the Committee's recommendations for step therapy from the August 2016 meeting.

b) New FDA-Approved Indications, NCCN Guideline Updates, or Age Ranges

- **TIBs: ixekizumab (Taltz)—**For plaque psoriasis, Taltz currently requires a trial of adalimumab (Humira), secukinumab (Cosentyx) and ustekinumab (Stelara). Taltz is now approved for treating active ankylosing spondylitis (AS) in adult patients, and the new indication was added to the criteria. Note that for AS, a trial of adalimumab (Humira) and secukinumab (Cosentyx) are required first; however a trial of ustekinumab (Stelara) is not required as it is not FDA-approved for use in AS.

- **TIBs: ustekinumab (Stelara)—**Manual PA criteria were updated to reflect a new FDA-approved indication for adults with moderately to severely active ulcerative colitis (UC). The requirement to try Humira prior to Stelara for this indication still applies.

- **Cardiovascular Agents Miscellaneous ivabradine (Corlanor)—**Manual PA criteria for Corlanor were updated to reflect a new pediatric indication for treating stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ≥ 6 months and older, who are in sinus rhythm with an elevated heart rate.

- **Hepatitis C Agents: Direct Acting Agents: ledipasvir/sofosbuvir (Harvoni) AND sofosbuvir (Sovaldi)—**Updates were made to the PA criteria for Harvoni and authorized generics of Harvoni to allow use for adult and pediatric patients ≥ 3 years of age with chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6 infection, without cirrhosis or with compensated cirrhosis. Other recent indications were also added to the form, including genotype 1 infection with decompensated cirrhosis, in combination with ribavirin; and genotype 1 or 4 infection in liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin. Manual PA criteria for Sovaldi were updated to reflect a new FDA-approved indication for adults and pediatric patients 3 years of age and older for treatment of chronic HCV genotype 2 or 3 infection, without cirrhosis or with compensated cirrhosis.,

- **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF): nintedanib (Ofev) and pirfenidone (Esbriet)—**The IPF drugs were reviewed for formulary status in May 2017 and step therapy requires a trial of pirfenidone (Esbriet) prior to Ofev. Ofev recently gained an indication to slow the rate of decline in pulmonary function for a rare condition, systemic sclerosis-associated interstitial lung disease (SSc-ILD). Esbriet lacks the indication for SSc-ILD, so it is not required before Ofev in this condition. The new SSc-ILD indication was added to the Ofev PA. The renewal criteria from the May 2017 class review were also updated for clarification for both Ofev and Esbriet.

- **Oncological Agents: Prostate Cancer 2nd-Generation Antiandrogens: apalutamide (Erleada) and enzalutamide (Xtandi)—**Manual PA criteria were updated to reflect the new FDA-approved indication and NCCN guideline update for treatment of metastatic, castration-sensitive prostate cancer (mCSPC). For Erleada, renewal criteria were removed since it is now indicated for use in metastatic disease.

- **Oncologic Agents: acalabrutinib (Calquence), duvelisib (Copiktra), ibrutinib (Imbruvica), larotrectinib (Vitrakvi) capsules and oral solution, lenalidomide (Revlimid)—**Updates to the manual PA criteria for these oncologic agents reflects more detailed safety information, including standardized embryo-fetal toxicity information. New FDA-approved indications or NCCN guideline-supported indications were also updated as summarized below. A synopsis of the changes submitted are summarized below.
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- acalabrutinib (Calquence)—Allow use for NCCN CLL and small lymphocytic lymphoma (SLL) guideline updates for relapsed or refractory disease
- duvelisib (Copiktra)—Allow use in refractory marginal zone lymphoma
- ibrutinib (Imbruvica)—Allow use for mantle cell lymphoma maintenance therapy
- larotrectinib (Vitrakvi) capsules and oral solution—Allow first-line use for neurotropic tropomysin receptor kinase (NTRK) gene fusion positive non-small cell lung cancer (NSCLC)
- lenalidomide (Revlimid)—Allow use for marginal zone lymphoma

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) to implement the PA criteria for Cimzia originally recommended at the May 2019 P&T Committee meeting (the Humira step requirement). The Committee also recommended the updates to the manual PA criteria for Symbicort and Dulera, Xeljanz, Xeljanz XR, Olumiant, Taltz, Stelara, Zytiga, Erleada, Xtandi, Doptelet, Mirvaso, Soolantra, Corlanor, Harvoni, Sovaldi, Ofev, Esbriet, Calquence, Copiktra, Imbruvica, Vitrakvi, and Revlimid. See Appendix C for the full criteria.

B. Quantity Limits

1. **General QLs**: QLs were reviewed for 22 drugs from several classes, including 11 newly approved drugs, (one agent had two different formulations).

2. **Anesthetic Agents: Local—Lidocaine-Tetracaine 7%-7% topical cream (Pliaglis, generics):** Two 30 gram tubes are adequate to treat the full face prior to a procedure. QLs were recommended to decrease waste. QL were also recommended for the Synera patch.

3. **Oral Oncologic Agents: venetoclax (Venclexta) and idelalisib (Zydelig), larotrectinib (Vitrakvi) capsules and oral solution:** QLs were changed to 30-day supply at all points of service for all products due to toxicities, side effects, or FDA-approved dosing, including the specific dosing for Venclexta.

   COMMITTEE ACTION: QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for Nubeqa, Xpovio, Rozlytrek, Turalio, Inrebic, Rinvoq ER, Vyleesi, Baqsimi, Gvoke PFS, Gvoke HypoPen, GlucaGen Hypokit and GlucGen Diagnostic, Glucagon Emergency, Nayzilam, Wakix, Symbicort, Dulera, Lidocaine-

tetracaine 7%-7% cream and Synera patch, Venclexta, Zydelig, and Vitrakvi (tabs and solution). See Appendix D for the QLs.

C. PA, MN, and QLs Implementation Periods

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

    - (16 for, 0 opposed, 0 abstained, 1 absent) The new PAs for chlorzoxazone 375 mg and 750 mg (Lorzone, generics) and lidocaine-tetracaine 7%-7% become effective the first Wednesday 90-days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for chlorzoxazone and lidocaine-tetracaine 7%-7%, topical cream as new and current users will be subject to the PA.

    - (16 for, 0 opposed, 0 abstained, 1 absent)
        - Updates to the current PA criteria for Cimzia in new users will become effective the first Wednesday upon signing of the minutes.
        - Updates to the current PA criteria for abiraterone acetate 250 mg in new users will become effective the first Wednesday 30-days after the signing of the minutes.
        - Updates to the current PA criteria for Xeljanz, Xeljanz XR, Olumiant, Taltz, Stelara, Erleada, Xtandi, Vitrakvi capsule and solution, Calquence, Copiktra, Imbruvica, Revlimid, Doptelet, Ofev, Esbriet, Symbicort, Dulera, Harvoni, Sovaldi, and Corlanor in new users become effective the first Wednesday 60-days after the signing of the minutes.
        - Updates to the current MN criteria for Symbicort, Dulera, Soolantra, and Mirvaso in new users become effective the first Wednesday 60-days after the signing of the minutes.
        - The new PAs for Neupro patch, Venclexta and Zydelig in new users become effective the first Wednesday 90-days after the signing of the minutes

    - (16 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 22 drugs listed in section VI B above, and in Appendix D, become effective on the first Wednesday two weeks after the signing of the minutes at all POS. The one exception is that the new QLs for the PDE-5 inhibitors will occur when the other drug class recommendations are implemented, the first Wednesday 120 days after the signing of the minutes.

VII. LINE EXTENSIONS

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

A. ***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION***— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following two products to reflect the current formulary status and applicable step therapy, PA criteria, MN criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- **Cardiovascular Agents Miscellaneous**—ivabradine (Corlanor) solution is now available. Previously, Corlanor was only available as an oral tablet formulation. The P&T Committee recommended designating the Corlanor solution as UF with the same manual PA requirements as Corlanor oral tablets.

- **Neurological Agents Miscellaneous**—tafamidis (Vyndamax) 61 mg oral capsule is now available. Previously, tafamidis meglumine (Vyndaqel) 80 mg oral capsule was the only available tafamidis product. The P&T Committee recommended designating the Vyndamax as UF with the same manual PA requirements and QLs as Vyndaqel.

VIII. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE MAIL ORDER PROGRAM

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

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

1. ***COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—***The P&T Committee recommended (groups 1 and 2: 16 for, 0 opposed, 0 abstained, 1 absent; group 3: 17 for, 0 opposed, 0 abstained, 0 absent), adding or exempting the drugs listed in Appendix F to/from the EMMPI program for the reasons outlined in the table. See Appendix F.

IX. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFS: OPHTHALMICS

Background—The DoD P&T Committee continued reviewing the OTC drugs on the MHS GENESIS OTC list. For a full description of the background and process details, refer to the May 2019 and August 2019 DoD P&T Committee meeting minutes, found at http://health.mil/PandT.

Factors influencing whether a particular OTC product was retained or removed from the MHS GENESIS OTC List included volume and utilization across multiple MTFs; feedback from MTF providers to include ophthalmology specialty leaders, ophthalmologists, optometrists, primary care providers, the Primary Care Clinical Communities, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

Note: Products are typically maintained on the MHS GENESIS OTC List at generic name/strength/dosage form (GCN) level (meaning that all national drug codes [NDC]) under a given GCN will routinely be added to the list). The P&T recommendations below are intended to be applied at the GCN level, enabling MTFs to purchase and dispense the most cost-effective product within a given GCN. Specific brand names are listed for clarity only.

A. OTC Ophthalmic Antihistamines:

- The only OTC ophthalmic antihistamine available is ketotifen (Zaditor, Alaway, generics), which is currently on the MHS GENESIS OTC List. Multiple legend ophthalmic antihistamines are readily available, including olopatadine 0.1% (Patanol, generics) and 0.7% (Pazeo), by far the two most commonly used products.

- Ketotifen is approved for the temporary relief of eye itching due to allergic conjunctivitis. The May 2017 DoD P&T Committee review of ophthalmic antihistamines concluded that olopatadine may be more effective for this purpose than ketotifen, based on published meta-analyses and clinical practice guidelines; no more recent data are available.

- Ophthalmology leaders and the majority of survey responders agreed ketotifen should be removed from the MHS GENESIS OTC List.

B. OTC Ophthalmic Hypertonic Sodium Chloride:

- This category includes sodium chloride 5% ophthalmic ointment and drops, and 2% drops (Muro-128, generics), which are used for the temporary relief of corneal edema. The 5% ointment and 5% drops are on the MHS GENESIS list and represent the vast majority of use.

- Ophthalmology leaders agreed that hypertonic sodium chloride products are necessary for the treatment of corneal edema.

C. OTC Ophthalmic Vasoconstrictors and Combinations:

- OTC vasoconstrictors and combinations antihistamines include naphazoline/pheniramine 0.025-0.3% (Visine-A, Naphcon-A, generics), which is currently on the OTC MHS GENESIS test list. The other products, naphazoline/pheniramine 0.0268-0.315% (Opcon-A), naphazoline/zinc sulfate/glycerin 0.012-0.25% (Clear Eyes Itchy Eye Relief), and brimonidine 0.025% (Lumify) are not on the list. The only legend ophthalmic vasoconstrictor is phenylephrine, which is used for pupil dilation prior to examinations or surgery and is not an alternative to the OTC products.

- By far the most commonly dispensed OTC product in this class is naphazoline/pheniramine 0.025-0.3% (Visine-A, Naphcon-A). This product is indicated for the temporary relief of itching and redness of the eyes caused by grass, ragweed, pollen, animal dander, and hair. It should not be used for more than 72-hours as overuse leads to more eye redness (rebound effect).

- Ophthalmology leaders agreed that naphazoline/pheniramine is not needed, noting that most eye professionals ask their patients to specifically avoid it. Most survey responders, including ophthalmologists, optometrists and primary care providers, agreed that naphazoline/pheniramine should be removed from the MHS GENESIS OTC list.

D. OTC ARTIFICIAL TEAR PRODUCTS:

- Products in this category are used for temporary relief of burning and irritation due to dry eyes. They are divided into three subcategories: artificial tear products with preservatives, which are packaged in multiuse bottles; preservative-free products packaged in single-use dropperettes; and preservative-free ointments/gels packaged in tubes, intended for overnight use.

- Guidelines for treating dry eye disease recommend artificial tears (preserved products) as Step 1 in the treatment of Dry Eye Disease, along with eyelid hygiene and warm compresses; lipid-containing artificial tears should be considered for patients with meibomian gland disorder (MGD). Step 2 may include non-preserved artificial tears (to minimize preservative-induced toxicity), overnight treatments (ointments/gels), and/or prescription medications for Dry Eye Disease.

- The literature in general indicated that most OTC artificial tear products produce similar symptomatic relief. Relevant clinical guidelines do not differentiate among the various active ingredients included in these products (e.g., carboxymethylcellulose, hypromellose, mineral oil, polyvinyl alcohol, propylene glycol, and mineral oil/petrolatum). Lipids are typically included in these products as inactive ingredients. The lipid-containing products currently being purchased and dispensed by MTFs include Refresh Optive Advanced, Soothe XP, and Systane Balance.

- Ophthalmology leaders suggested including one preserved product (Refresh Tears, Genteal, or Systane); including both Refresh Celluvisc and Refresh Plus as

preservative-free products (with Refresh Celluvisc providing a thicker formulation) for patients who need to avoid preservatives; and including at least one preservative-free overnight product (ointment/gel) for nocturnal lagophthalmos coverage, facial nerve palsies, and other exposure issues. These products are also used after ophthalmic surgeries, including LASIK and cornea replacement.

- A large number of optometrists responding to the survey indicated a need for a lipid-containing product for patients with MGD. Ophthalmology leaders agreed that this was reasonable.

- Multiple survey responders reported frequent product shortages for the overnight products.

1. ***COMMITTEE ACTION: STATUS OF OTC OPHTHALMICS ON THE MHS GENESIS OTC LIST—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) the following: All of the recommendations below are expected to have relatively little impact at current MHS GENESIS site, including the most recent Wave Travis Sites (Travis, Lemoore, Monterey, and Mountain Home), which implemented MHS GENESIS as of September 2019.

    - *OTC Ophthalmic Antihistamines*: remove ketotifen (Zaditor, Alaway, Eye Itch Relief, generics; GCN 92451)
    - *OTC Ophthalmic Hypertonic sodium chloride:* retain sodium chloride 5% ophthalmic ointment and drops (GCNs 31880 and 31923)
    - *OTC Ophthalmic Vasoconstrictors and Combinations:* remove naphazoline/pheniramine 0.025-0.3% (Visine-A, Naphcon-A; GCN 86003)
    - *OTC Artificial Tear Products:* retain the following
        - Preserved (bottle): GCN 37381 – carboxymethylcellulose 0.5% (Refresh Tears, Lubricant Eye Drop)
        - Preservative-free (dropperettes): GCN 98569 – carboxymethylcellulose 1% (Refresh Celluvisc). GCN 37384 – carboxymethylcellulose 0.5% (Refresh Plus, Restore Plus, Lubricating Plus, Lubricant Eye Drops)
        - Overnight treatment GCN 98935 – mineral oil/petrolatum, white ointment 15%-83% (Lubrifresh PM, Artificial Tears)
    - *OTC Artificial Tear Products:* add the following
        - Preservative-free (dropperettes): GCN 34571 – carboxymethylcellulose sodium/glycerin/polysorbate 80/PF (Refresh Optive Advanced, Refresh Optive Mega-3)
        - Overnight treatment: GCN 99250 – mineral oil/petrolatum, white 20%-80% (Retaine PM, Soothe)
    - *OTC Artificial Tear Products:* remove the following

- Preserved (bottle): GCN 37382 – carboxymethylcellulose sodium 0.25% (Thera Tears), GCN 99283 – dextran 70/hypromellose 0.1%-0.3% (Genteal Tears, Natural Balance Tears, Nature's Tears), GCN 33413 – hypromellose 0.3% (Pure & Gentle Eye Drops), GCN 33422 – polyvinyl alcohol 1.4% (Artificial Tears, Liquitears), GCN 19719 – propylene glycol/peg 400 (Systane, Systane Ultra, Lubricant Eye)
- Preservative-free (dropperettes), GCN 87031 – polyvinyl alcohol/povidone/PF 1.4%-0.6% (Refresh Classic)
- Overnight treatment, GCN 27956 – hypromellose gel 0.3% (Genteal Tears Severe, Systane Gel), GCN 99952 – mineral oil/petrolatum, white 3%-94% ointment (Systane, Overnight Lubricating Eye), GCN 99222 – mineral oil/petrolatum, white 42.5%-56.8% ointment (Refresh Lacri-lube), GCN 28068 – mineral oil/petrolatum, white 42.5%-57.3% ointment (Refresh PM)

2. ***COMMITTEE ACTION: IMPLEMENTATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 120-days following signing of the minutes for all of the recommendations noted above. Letters will be sent to patients at MHS GENESIS sites affected by the removal of ketotifen, as it is characterized by recurrent intermittent use. Letters are not required for naphazoline/pheniramine 0.025-0.3% (Visine-A, Naphcon-A) due to the limited duration of use, or for those products recommended to be added or retained on the OTC MHS GENESIS test list. Additionally, letters are not required for the patients currently receiving an artificial tears product, since they can be simply changed to one of the products that will be on the list.

X. ITEMS FOR INFORMATION

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

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

XI. ADJOURNMENT

The meeting adjourned at 1600 hours on November 7, 2019. The next meeting will be in February 2020.

Appendix A—Attendance: November 2019 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits

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:

FIASP DISCUSSION NEEDS TO OCCUR WITH LTG PLACE AND DETAILED IN A SEPARATE MEMO ~~WITHIN~~ NLT MONDAY 10 FEB 20

Mr. Guy Kiyokawa
Deputy Director, DHA
for Ronald J. Place
LTG, MC, USA
Director

3 FEB 20
Date

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

Addendum February 10, 2020

I. UNIFORM FORMULARY DRUG CLASS REVIEWS

Insulins: Rapid-Acting Insulins (RAIs) Subclass: Insulin aspart plus niacinamide (Fiasp) formulary recommendation

The Director, DHA, taking into consideration the clinical and cost effectiveness of the Rapid Acting Insulins directs the following for insulin aspart with niacinamide (Fiasp):

A. COMMITTEE ACTION: UF/TIER 4/NOT COVERED AND IMPLEMENTATION PERIOD RECOMMENDATION—

- Tier 4/Not Covered: insulin aspart plus niacinamide (Fiasp)
- The implementation period will be as follows 1) an effective date of the first Wednesday after a 150-day implementation period, and no earlier than July 1, 2020 in all points of service and, 2) DHA send letters to beneficiaries who are affected by the Tier 4 recommendations, who will receive letters at 90, 60 and 30 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is July 1st 2020

SUBMITTED BY:

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

DECISION ON RECOMMENDATIONS

Mr. Guy Kiyokawa
Deputy Director, DHA
for Ronald J. Place
LTG, MC, USA
Director

11 FEB 2020
Date

MEMO

UNCLASSIFIED 11 Feb 2020

Subject: November 2019 DoD Pharmacy and Therapeutics (P&T) Committee Recommendations for the Rapid Acting Insulins and the Formulary Status for insulin aspart with niacinamide (Fiasp)

1. **Executive Issues:**
   - This provides supporting background information regarding the November 2019 DoD P&T Committee recommendation for Tier 4 status for insulin aspart with niacinamide (Fiasp).
2. **Discussion:**
   - Insulin aspart with niacinamide (Fiasp) is a new rapid acting insulin approved by the FDA in September 2017. Fiasp was originally reviewed as a newly approved drug at the November 2017 P&T Committee meeting, were it was designated with non-formulary (Tier 3) status, with medical necessity and prior authorization criteria required.
   - At the November 2019 P&T Committee meeting, the Committee concluded that Fiasp is a new formulation of insulin aspart (the same active ingredient found in Novolog insulin) with niacinamide added, a form of vitamin B3. Although Fiasp has a faster onset of action than Novolog, there is no clinically significant difference in hemoglobin A1C or post-prandial blood glucose levels. Both Novolog and Fiasp are approved for use in children and in patients using insulin pumps. Compared to Novolog, Fiasp has slightly higher rates of hypoglycemia, upper respiratory tract infection and nasopharyngitis.
   - The cost analysis conducted at the November 2019 P&T meeting found that Fiasp was the 2nd most costly rapid acting insulin.
   - Several primary care providers and endocrinologists were specifically asked their opinion on whether Fiasp should be not covered. Of the primary care providers answering the question, 13 were in favor of Tier 4 status, 27 wanted non-formulary status, and 5 were unsure. For the endocrinologists asked this question, 5 were in favor of Tier 4 status, 19 wanted non-formulary status, 3 were unsure, and zero responders wanted formulary (Tier 2) status.
   - The Committee had access to the full clinical and cost considerations for the recommendation, which the surveyed providers and endocrinologists did not have. The Committee recommended by majority vote Tier 4/Not Covered status for Fiasp, as the drug provides very little to no additional clinical effectiveness relative to the other rapid acting insulins. Overall, the Committee felt that the needs of TRICARE beneficiaries can be met by the other rapid acting insulins.
   - The P&T Committee vote was split, with 9 recommending Tier 4 status, and 7 opposing; there was 1 member absent for the vote.
     - The reasons in favor of Tier 4 status were due to lack of clinical and cost effectiveness and the fact that Fiasp was the 2nd most costly rapid acting insulin. The members requested that 3 letters be sent to impacted beneficiaries instead of the usual 2 letters, to minimize the risk of a patient not being aware of the

recommendation. Several commercial health plans also have Fiasp excluded from formulary coverage.

  - The reasons for the 7 members voting against Tier 4 status centered on the clinical issues of not covering a rapid acting insulin, with the risk of a patient leaving the pharmacy counter without their drug and possible adverse effects; concern that the Beneficiary Advisory Panel would disagree with the recommendation, based on previous comments of the Panel; the fact that there was not unanimous agreement from the endocrinologists that Fiasp should be Tier 4; and that having non-formulary (Tier 3) status with a new stricter Prior Authorization affecting both new and current users (e.g.; "no grandfathering) would essentially accomplish the same thing as Tier 4 status.

- In the past quarter (November 2019 to January 2020), there are 220 patients receiving Fiasp in the MHS, primarily at the TRICARE Mail Order Pharmacy (163), followed by the MTFs (47) and the Retail Pharmacy Network (19 patients).

Appendix A—Attendance: November 2019 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 Division
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder) POD
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Peter Cole, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Celeste Young, MC for CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Capt Matthew Bezzant, MC for Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
COL Rodney Jorstad, BSC for Col Melissa Howard, BSC	Air Force, Pharmacy Officer, Alternate
Kelly Echevarria, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Mark Kogan	Associate General Counsel, DHA
Eugene Moore, PharmD, BCPS , for CDR Eric Parsons, MSC	COR Tricare Pharmacy Program

Appendix A—Attendance (continued)

Guests	
LCDR Kyleigh Hupfl, MSC	DLA Troop support
Ms. Yvette Dluhos	DHA Contracting
LCDR Karsten Smith	Indian Health Service
MAJ Leighcraft Shakes, BSC	Air Force Consultant Guest
COL Stacey Causey, MSC	Army Consultant Guest
CDR Marisol Martinez	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program
Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Dr. Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Dr. Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Dr. Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
MAJ Matthew Krull, MSC	DHA Formulary Management Branch
MAJ Gregory Palmrose, BSC	DHA MTF Management Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Ebony Moore	DHA Formulary Management Branch Contractor
Rupesh Panchal	University of Texas at Austin Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• insulin lispro (Admelog) • insulin glulisine (Apidra) • inhaled insulin (Afrezza) **Insulins: Rapid-Acting Agents**	• Use of insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic insulin lispro) have resulted in therapeutic failure **Formulary alternatives:** insulin aspart (Novolog), insulin lispro (Humalog or authorized generic lispro)
• amlodipine oral suspension (Katerzia) **Calcium Channel Blocking Agents**	• No alternative formulary agent – patient has swallowing difficulties **Formulary Alternatives:** amlodipine, felodipine, nifedipine
• duloxetine extended-release sprinkle (Drizalma Sprinkle) **Antidepressants & Non-Opioid Pain Syndrome Agents: SNRIs**	• No alternative formulary agent: Patient requires duloxetine but cannot swallow duloxetine capsules **Formulary alternatives:** duloxetine capsules, fluoxetine oral syrup/oral solution, citalopram solution, sertraline solution, venlafaxine sprinkle
• istradefylline (Nourianz) **Parkinson's Agents**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • One drug from each of the 3 classes (Dopamine Agonist, MAO-B inhibitor, and COMT Inhibitor) of the formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** pramipexole (Mirapex), ropinirole (Requip), rotigotine (Neupro), rasagiline (Azilect), selegiline (Eldepryl), tolcapone (Tasmar), entacapone (Comtan, Stalevo)
• upadacitinib (Rinvoq) **TIBs**	• Use of formulary agents (Humira, Simponi, Xeljanz, and Olumiant) is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents (Humira, Simponi, Xeljanz, and Olumiant) • Formulary agents (Humira, Simponi, Xeljanz, and Olumiant) resulted in therapeutic failure **Formulary alternatives:** Humira (BCF), Simponi, Otezla, Xeljanz, Olumiant
• pitolisant (Wakix) **Sleep Disorders: Wakefulness Promoting Agents**	• Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure **Formulary Alternatives:** armodafinil, modafinil, methylphenidate, amphetamine
• lefamulin (Xenleta) **Antibiotics**	• Use of a formulary agent from each of the following three classes: macrolides, fluoroquinolones, and beta-lactams is contraindicated • Use of a formulary agent from each of the following three classes: macrolides, fluoroquinolones, and beta-lactams will result or is likely to result in therapeutic failure (e.g., due to local antimicrobial resistance rates) • No alternative formulary agent. Patient has been stable on the Xenleta IV formulation and is transitioning to the oral formulation.

Drug / Drug Class	Medical Necessity Criteria
	Formulary Alternatives: azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, amoxicillin/clavulanate, cefpodoxime, and cefuroxime
• budesonide/formoterol (Symbicort) • mometasone/formoterol (Dulera) **Pulmonary-1 Agents: Combinations**	**Changes from the November 2019 meeting are in BOLD.** • Use of formulary agents (Advair Diskus and Advair HFA) is contraindicated • Patient has experienced significant adverse effects from Advair that is not expected to occur with the non-formulary ICS/LABA medication • Formulary agents (Advair Diskus and Advair HFA) result or are like to result in therapeutic failure • Patient previously responded to non-formulary agent and changing to a formulary agent (Advair Diskus and Advair HFA) would incur unacceptable risk • No alternative formulary agent: o **For Symbicort and Dulera: patient has asthma and requires rescue therapy with an ICS-formoterol combination** o Symbicort: patient requires an MDI because they have decreased inspiratory effort and cannot use a DPI (Advair Diskus) o Breo Ellipta: patient has complicated drug regimen and requires once daily dosing Formulary Alternatives: Advair Diskus and Advair HFA
• ivermectin (Soolantra) AND brimonidine (Mirvaso) • **Acne Agents: Topical Acne and Rosacea**	**Changes from the November 2019 meeting are strikethrough.** • ~~Use of preferred formulary agent is contraindicated OR treatment with other topical rosacea agents is not clinically appropriate~~ ~~• Diagnosis for MIRVASO: Patient has non-transient, persistent facial erythema of rosacea~~ ~~• Diagnosis for SOOLANTRA: Patient has inflammatory lesions (papulopustular) of rosacea caused by *Demodex* mites~~ • Patient has tried AND failed or experienced significant adverse effects from preferred formulary topical rosacea agent AND has tried and failed azelaic acid topical rosacea agent • Formulary Alternatives: metronidazole (cream, gel) and azelaic acid

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• generic sildenafil tablets **Phosphodiesterase-5 Inhibitors**	**November 2019 updates are in strikethrough** Manual PA criteria apply to all new users of generic sildenafil. Note that brand Viagra is not covered by TRICARE. Age and gender edit Coverage approved for treatment of ED if the patient is a male aged 40 years or older Manual PA Criteria: Coverage is approved if the following criteria are met: • Patient is older than 18 years of age AND • Patient is less than 40 years of age and is being treated for ED of organic or mixed organic/psychogenic origin OR • Patient is less than 40 years of age and is being treated for drug -induced ED where the causative drug cannot be altered or discontinued. OR Coverage is approved for the following non-ED uses requiring daily therapy: • Use of generic sildenafil for preservation/restoration of erectile function after prostatectomy. PA expires after one year. OR • Use of generic sildenafil for Raynaud's Phenomenon ~~OR~~ • ~~**Use of sildenafil for pulmonary arterial hypertension (PAH)**~~ Other non-FDA-approved uses are not approved, including use for females for the treatment of sexual dysfunction. Prior Authorization does not expire except as noted above following prostatectomy.

Drug / Drug Class	Prior Authorization Criteria
• generic tadalafil tablets **Phosphodiesterase-5 Inhibitors**	November 2019 updates are in strikethrough Manual PA criteria apply to all new users of generic tadalafil. Note that brand Cialis is not covered by TRICARE. Note that the previous automation for the step therapy has been removed. Manual PA Criteria: Coverage is approved if the following criteria are met: • Patient is older than 18 years of age AND • Patient has tried generic sildenafil and has had an inadequate response or was unable to tolerate treatment due to adverse effects. OR • Treatment with generic sildenafil is contraindicated. OR • Patient is less than 40 of age and is being treated for ED of organic or mixed organic/psychogenic origin. The patient must try generic sildenafil first and is unable to use generic sildenafil due to reasons stated above (inadequate response or adverse events.) OR • Patient is less than 40 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. The patient must try generic sildenafil first and is unable to use generic sildenafil due to reasons stated above (inadequate response or adverse events.) OR • Use of generic tadalafil 2.5 mg or 5 mg for patients with benign prostatic hyperplasia (BPH) or BPH with erectile dysfunction (ED) meeting prior authorization criteria requiring use of an alpha blocker [(tamsulosin (Flomax) or alfuzosin (Uroxatral)] unless there is a contraindication, inadequate response, or intolerable adverse effects with the alpha blocker. Coverage is approved for the following non-ED uses requiring daily therapy: • Patient requires generic tadalafil for preservation/restoration of erectile function after prostatectomy. PA expires 1 year post surgery. • Use of generic tadalafil for Raynaud's Phenomenon ~~OR~~ • ~~**Use of tadalafil for pulmonary arterial hypertension (PAH)**~~ Other non-FDA-approved uses are not approved, including use for females for the treatment of sexual dysfunction. Prior Authorization does not expire except as noted above following prostatectomy.

Drug / Drug Class	Prior Authorization Criteria
• Inhaled insulin (Afrezza) **Insulins: Rapid-Acting Agents**	**Updates from the November 2019 meeting are in bold and strikethrough.** Manual PA criteria apply to all new and current users of Afrezza. Coverage is approved if all the criteria are met for non-smoking patients with either: Type 1 Diabetes Mellitus (diagnosed) • **Patient has tried and failed (defined as a failure to achieve hemoglobin A1c ≤ 7 % in 90 days) with insulin aspart (Novolog)** • **Patient has tried and failed (defined as a failure to achieve hemoglobin A1c ≤ 7 % in 90 days) with insulin lispro (Humalog or authorized generic insulin lispro)** • ~~Failure to achieve hemoglobin A1c ≤ 7 % in 90 days of use of a rapid or short-acting subcutaneous (SC) insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin~~ • Afrezza is used as adjunctive treatment to current basal insulin therapy • Spirometry testing [baseline forced expiratory volume in the first second (FEV_1)] has been performed upon initiation of therapy, with repeated FEV_1 at 6 months after initiation and repeated annually thereafter • Patient does not have a contraindication to Afrezza (e.g. hypoglycemia, chronic lung disease [asthma, chronic obstructive pulmonary disease (COPD)], hypersensitivity to regular human insulin, or any Afrezza excipients) Type 2 Diabetes Mellitus (diagnosed) • **Patient has tried and failed (defined as failure to achieve hemoglobin A1c ≤ 7 % in 90 days) with insulin aspart (Novolog)** • **Patient has tried and failed (defined as failure to achieve hemoglobin A1c ≤ 7 % in 90 days) with insulin lispro (Humalog or authorized generic insulin lispro)** • ~~Failure to achieve hemoglobin A1c ≤ 7 % in 90 days of use of a rapid or short-acting subcutaneous (SC) insulin product or clinically significant adverse effects experienced with SC rapid or short-acting insulin unexpected to occur with inhaled insulin~~ • Patient has had failure of or clinically significant adverse effects to two oral anti-diabetic agents (i.e., sulfonylurea, TZD, DPP-4 inhibitor, or **SGLT2 inhibitor)** if metformin is contraindicated • Spirometry testing [baseline forced expiratory volume in the first second (FEV1)] has been performed upon initiation of therapy, with repeated FEV1 at 6 months after initiation and repeated annually thereafter • Patient does not have a contraindication to Afrezza (e.g. hypoglycemia, chronic lung disease [asthma, chronic obstructive pulmonary disease (COPD)], hypersensitivity to regular human insulin, or any Afrezza excipients) Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• Insulin glulisine (Apidra) • Insulin lispro (Admelog) **Insulins: Rapid-Acting Agents**	Step therapy and manual PA criteria apply to all new and current users of Apidra and Admelog. <u>Automated PA Criteria</u>: The patient has filled a prescription for insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. AND <u>Manual PA Criteria if automated criteria are not met:</u> Note: Novolog, Humalog, and the authorized generic insulin lispro are DoD's preferred rapid acting insulins. If the prescription is for Novolog, Humalog, or the authorized generic insulin lispro, prior authorization is not required. • If automated criteria are not met, Apidra or Admelog is approved if all criteria are met: • Patient has diabetes AND o Patient has tried and failed insulin aspart (Novolog) AND o Patient has tried and failed insulin lispro (Humalog or authorized generic insulin lispro) OR • Patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog) Non-FDA-approved uses are not approved. PA does not expire.
Newly Approved Drug PAs	
• bremelanotide injection (Vyleesi) **Gynecological Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Vyleesi. <u>Manual PA criteria</u>: Vyleesi is approved if all criteria are met: • Patient is ≥ 18 • Patient is a premenopausal woman with a documented diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty • Decreased sexual desire is NOT caused by: o Co-existing medical or psychiatric condition o Problems with the relationship o Effects of a medication or drug substance • Patient has been informed that other treatment options, such as cognitive-behavior therapy, sexual therapy, or couples therapy, may provide benefit without the risk of side effects • Patient does not have uncontrolled hypertension or known cardiovascular disease • Patient has been counseled on the risks of focal hyperpigmentation (skin discoloration) and severe nausea • Patient agrees to use effective contraception while taking Vyleesi Non-FDA approved uses are not approved. PA expires in 3 months <u>Renewal PA criteria:</u> Note that initial TRICARE PA approval is required for renewal<u>.</u> Coverage will be approved indefinitely for continuation of therapy if the patient has had documented improvement in symptoms without serious side effects

Drug / Drug Class	Prior Authorization Criteria
• darolutamide (Nubeqa) **Oncological Agents: Second-Generation Antiandrogens**	Manual PA is required for all new users of Nubeqa. Manual PA Criteria: Nubeqa is approved if all criteria are met: • Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. The patient is required to try Xtandi first. **OR** • Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Nubeqa AND • Patient is ≥ 18 years AND • Drug is prescribed by or in consultation with an oncologist or urologist AND • Patient has diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** • The patient has had a negative CT scan of abdomen/pelvis and/or negative bone scan **AND** • Prostate-specific antigen doubling time (PSADT) is ≤ 10 months **OR** • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly **OR** have had a bilateral orchiectomy Other non-FDA-approved uses are not approved. PA expires in 1 year. Renewal criteria : Note that initial TRICARE PA approval is required for renewal. Nubeqa is approved for 1 year for continuation therapy if all criteria are met: • The patient continues to be metastases-free • The patient has not progressed onto subsequent therapy (such as abiraterone)
• duloxetine delayed-release capsules (Drizalma Sprinkle) **Antidepressants & Non-Opioid Pain Syndrome Agents: SNRIs**	**PA does not apply to patients 12 years of age and younger (age edit)** PA criteria apply to all new and current users of Drizalma Sprinkle older than 12 years of age. Manual PA Criteria: Drizalma Sprinkle is approved if all criteria are met: • Provider must explain why the patient requires duloxetine sprinkle capsules and cannot take alternatives. Non-FDA-approved uses are not approved. PA expires in 1 year Renewal PA criteria: No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.

Drug / Drug Class	Prior Authorization Criteria
• entrectinib (Rozlytrek) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of Rozlytrek. Manual PA Criteria: Rozlytrek will be approved if all criteria are met: • Patient is ≥ 12 years • Drug is prescribed by or in consultation with an oncologist • Patient has a diagnosis of either: o ROS1(+) Metastatic NSCLC or o The patient has a solid tumor that meets all three of the following criteria: ▪ Has a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, and ▪ Is metastatic OR where surgical resection is likely to result in severe morbidity, and ▪ Has no satisfactory alternative treatments OR that has progressed following such treatment(s). • The patient has had a recent evaluation of his/her left ventricle including ejection fraction • The patient does not have decompensated congestive heart failure (CHF) • The patient has had a recent uric acid level evaluated • The provider is aware and has informed the patient of the risk of CHF development and exacerbation, myocarditis, neurotoxicity, fracture risk, hepatotoxicity, hyperuricemia, QT-prolongation, permanent visual impairment, and embryo-fetal toxicity • Female patients will not breastfeed during treatment and for 1 week after cessation of treatment • All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for at least 5 weeks or 3 months after cessation of treatment for females and males, respectively. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.
• fedratinib (Inrebic) **Oncological Agents**	Manual PA is required for all new users of Inrebic. Manual PA Criteria: Inrebic is approved if all criteria are met • Patient is ≥ 18 years • Drug is prescribed by or in consultation with a hematologist/oncologist • Inrebic will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis • Provider acknowledges that serious and fatal encephalopathy including Wernicke's encephalopathy has occurred in patients treated with Inrebic. If thiamine deficiency is expected or confirmed, Inrebic should be discontinued immediately and the patient should receive emergent parenteral thiamine. • The patient does not have vitamin B1 deficiency. • The following labswill be assessed prior to starting fedratinib and periodically while the patient is taking Inrebic: thiamine (Vitamin B1), CBC with platelets, serum creatinine and BUN, hepatic panel and amylase and lipase • Nutritional status will be assessed prior to starting Inrebic and periodically while the patient is taking fedratinib • If the patient is female, she is not pregnant or planning to become pregnant. • Female patients will not breastfeed during treatment and for at least 1 month after discontinuation. • Females of reproductive potential will use effective contraception during treatment and for at least 1 month after discontinuation. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• istradefylline (Nourianz) **Parkinson's Agents**	Manual PA is required for all new and current users of Nourianz. Manual PA Criteria: Nourianz is approved if all criteria are met: • Patient is ≥ 18 years • Patient has a diagnosis of Parkinson's disease • Drug is prescribed by or in consultation with a neurologist • Patient continues to experience wearing off periods, despite optimizing (e.g., increasing dose and daily frequency) carbidopa/levodopa therapy • Patient is currently taking and will continue taking carbidopa-levodopa therapy • Patient must try and fail an adequate trial of at least two drugs from any of the three classes: o Dopamine Agonist: pramipexole (Mirapex), ropinirole (Requip), rotigotine (Neuopro) o MAO-B: rasagiline (Axilect), selegiline (Eldepryl) o COMT: tolcapone (Tasmar), entacapone (Comtan) Non-FDA approved uses are NOT approved, including restless legs syndrome. PA does not expire.
• pexidartinib (Turalio) **Oncological Agents**	Manual PA criteria apply to all new users of Turalio. Manual PA Criteria: Turalio is approved if all criteria are met: • Patient is ≥ 18 • Drug is prescribed by or in consultation with an oncologist • Patient has symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and is not amenable to improvement with surgery and has not progressed on Turalio. • Patient will be monitored for hepatotoxicity • Prescriber is certified with REMS program • Patient is enrolled in REMS program • If the patient is female, she is not pregnant or planning to become pregnant. • Female patients will not breastfeed. • All patients (females AND males) of reproductive potential will use effective contraception during treatment and for 1 month after discontinuation in females and 1 week after discontinuation in males with female partners. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• pitolisant (Wakix) **Sleep Disorders: Wakefulness Promoting Agents**	Manual PA is required for all new and current users of Wakix. <u>Manual PA Criteria:</u> Wakix is approved if all criteria are met: • Patient is ≥ 18 years • Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy • Narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing • Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Patient is not concurrently taking any of the following: o Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • Patient must have tried and failed and had an inadequate response to modafinil • Patient must have tried and failed and had an inadequate response to armodafinil • Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient does not have a history of severe hepatic impairment • Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, cataplexy, obstructive sleep apnea, major depression, ADHD, or shift work disorder). Not approved for use in children, adolescents, or pregnant patients. PA expires in 1 year. <u>Renewal PA criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.
• selinexor (Xpovio) **Oncological Agents: Multiple Myeloma**	Manual PA applies to new users of Xpovio. <u>Manual PA Criteria</u>: Xpovio is approved if all criteria are met: • Age ≥ 18 • Drug is prescribed by or in consultation with an oncologist • Xpovio will be used in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. • Patient will be monitored for cytopenias including anemia, neutropenia, and thrombocytopenia • Patient will be monitored for electrolyte disturbances including hyponatremia and hypokalemia • Patient will be monitored for infection including upper respiratory infection and pneumonia • Patients will be monitored for dizziness and altered mental status • If the patient is female, she is not pregnant or planning to become pregnant. • Female patients will not breastfeed. • All patients (females AND males) of reproductive potential will use effective contraception during treatment and for at least 1 week after discontinuation. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• semaglutide oral tablet (Rybelsus) **Diabetes Non-Insulin: Oral Glucagon-Like Peptide-1 Receptor Agonists**	Manual PA criteria apply to all new and current users of Rybelsus. Manual PA Criteria: Rybelsus will be approved if all criteria are met: • Patient is ≥ 18 • Patient has a documented diagnosis of type 2 diabetes • Patient has tried and had an inadequate response to metformin, or has a contraindication to metformin • Patient must be able to adhere to the administration requirements (take on an empty stomach with no more than 4 oz. of water at least 30 min before the first meal of the day) • Patient does not have a history of pancreatitis • Patient does not have a personal or family history of medullary thyroid carcinoma (MTC) • Patient does not have multiple endocrine neoplasia syndrome type 2 (MEN2) • Patient and provider acknowledge that Rybelsus has not been shown to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease Not approved for use in children or pregnant patients. Non-FDA approved uses are not approved including weight loss (obesity) or type 1 diabetes mellitus. PA does not expire.
• tiopronin immediate-release (Thiola) • tiopronin delayed-release tablets (Thiola EC) **Urinary Agents Miscellaneous**	Manual PA criteria apply to all new users of Thiola and Thiola EC. Manual PA Criteria: Thiola or Thiola EC is approved if all criteria is met: • Patient is ≥ 9 years • Drug is prescribed by or in consultation with a nephrologist or urologist • Patient has a documented diagnosis of severe homozygous cystinuria • Patient has elevated urinary cystine concentration (> 250 mg/L) as demonstrated by a 24-hour urine test • Patient has tried and failed treatment with all of the following conservative treatment measures: o High fluid intake ≥ 3 L/day o Urinary alkalization with potassium citrate or potassium bicarbonate o Diet modification with restricted protein and sodium consumption Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• upadacitinib (Rinvoq) **TIBs: Non-Tumor Necrosis Factor Inhibitors**	Note that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis. Manual PA criteria apply to all new users of Rinvoq. Manual PA Criteria: Rinvoq is approved if all criteria are met: • Patient is ≥ 18 • Patient has diagnosis of active rheumatoid arthritis • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz or Olumiant OR • Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with the requested agent OR • Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq AND • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Patient has no evidence of neutropenia (ANC <1000) • Patient has no evidence of lymphocytopenia (ALC <500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine). Non-FDA-approved uses are not approved. PA does not expire.
New PAs	
• chlorzoxazone 375 mg and 750 mg (Lorzone, generics) **Skeletal Muscle Relaxants and Combinations**	Manual PA criteria applies to new and current users of chlorzoxazone 375 mg and 750 mg. Note: Chlorzoxazone 500 mg tablets are scored and available without a PA; providers are encouraged to consider changing the prescription to the 500 mg tablets and instructing the patient to cut the tablets appropriately. Manual PA Criteria: Coverage for chlorzoxazone 375 mg and 750 mg will be approved if all criteria are met: • The provider explains why the patient requires chlorzoxazone 375 mg or 750 mg and why the patient cannot take chlorzoxazone 500 mg tablet (blank write-in) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rotigotine (Neupro) patch **Parkinson's Agents**	Manual PA criteria applies to new users of Neupro patch. Manual PA Criteria: Coverage for Neupro patch is approved if all criteria are met: • Age ≥ 18 years • Patient has a diagnosis of: o Parkinson's disease OR o Moderate to severe primary restless legs syndrome • Patient cannot swallow tablets due to a documented medical condition (i.e. dysphagia, oral candidiasis, systemic sclerosis, etc.) and not due to convenience OR • Patient has tried and failed or has a contraindication to other dopamine agonist oral therapy: o pramipexole (Mirapex) OR ropinorole (Requip) Non-FDA-approved uses are NOT approved. Prior authorization does not expire.
• lidocaine-tetracaine 7%-7% topical cream **Anesthetic Agents: Local**	Manual PA criteria applies to new and current users of lidocaine-tetracaine 7%-7% topical cream. **PA does not apply to patients 12 years of age and younger (age edit)** Manual PA Criteria: Coverage for lidocaine-tetracaine 7%-7% topical cream is approved if all criteria are met: • Note: Multiple formulary topical local anesthetics are available for DoD beneficiaries without a PA including lidocaine 4% cream, lidocaine 5% cream or ointment, and lidocaine-prilocaine 2.5%-2.5% cream • Drug is prescribed by or in consultation with a dermatologist or surgeon • Not approved for use in back or joint pain • Not approved for use in compounding • Not approved for use as local anesthetic associated with cosmetic procedures including but not limited to dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal • The provider must document the clinical rationale of why patient cannot take any of the formulary topical local anesthetics. (blank write-in) Non-FDA-approved uses are NOT approved. New PA required per prescription fill

• venetoclax (Venclexta) **Oncological Agents**	Manual PA criteria applies to new users of Venclexta. <u>Manual PA Criteria:</u> Coverage for Venclexta is approved if <u>all</u> criteria are met: • Age ≥ 18 years • Drug is prescribed by or in consultation with a hematologist or oncologist • Venclexta will be used in one of the following contexts: o Frontline therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation ▪ Patient fits one of the following categories: • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patient < 65 years old ▪ Will be combined with obinutuzumab (Gazyva) infusion o Relapsed/refractory therapy for CLL/SLL without del(17p)/TP53 mutation ▪ Patient fits one of the following categories: • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patient < 65 years old o Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation o Patient has newly diagnosed acute myeloid leukemia (AML) and is a candidate for intensive remission induction therapy and meets the following criteria: ▪ Age ≥ 60 years old ▪ Unfavorable-risk cytogenetics (exclusive of AML with myelodysplasia-related changes) o Patient is ≥ 60 years old and has newly diagnosed AML and is not a candidate for intensive remission induction therapy o Patient is ≥ 60 years old and completed lower-intensity induction therapy for AML with a response o Patient has relapsed refractory AML • Will titrate to therapeutic dose in consideration of tumor lysis syndrome (TLS) • Will not be concomitantly used at initiation or during ramp-up with a strong CYP3A inhibitor • Will prophylax and monitor for tumor lysis syndrome (TLS) (based on tumor burden-defined risk) • Will monitor for neutropenia • Will monitor for signs and symptoms of infection • Will not administer live attenuated vaccines prior to, during, or after treatment with Venclexta until B-cell recovery occurs. • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed • Male patients have been informed of risk of infertility • Female patients of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation

Drug / Drug Class	Prior Authorization Criteria
	• The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Non-FDA approved uses are NOT approved. Prior Authorization does not expire.
• idelalisib (Zydelig) **Oncological Agents**	Manual PA criteria applies to new users of Zydelig. <u>Manual PA Criteria:</u> Coverage for Zydelig is approved if <u>all</u> criteria are met: • Age ≥ 18 years • Drug is prescribed by or in consultation with a hematologist or oncologist • Zydelig will be used in one of the following indications: o Relapsed/refractory therapy for CLL/SLL without del(17p)/TP53 mutation ▪ Patient fits one of the following categories: • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patient < 65 years old o Relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation o Relapsed/refractory follicular lymphoma AND: ▪ Patient has completed ≥ 2 prior therapies **OR** ▪ Patient has completed 1 prior therapy and relapsed ≤ 2 years o Relapsed/refractory marginal zone lymphoma after 2 prior therapies • Provider has reviewed the REMS program including the letter to healthcare providers and the fact sheet and has shared the medication guide and patient safety information card with the patient • Will monitor for hepatotoxicity, colitis, intestinal perforation, pneumonitis, infection, neutropenia, and Steven Johnson Syndrome/toxic epidermal necrolysis • Will monitor for cytomegalovirus reactivation • Will prophylax for *pneumocystis jiroveci* pneumonia • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed • Female patients of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation • Male patients of reproductive potential will use effective contraception during treatment and for at least 3 months after discontinuation • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Non-FDA approved uses are NOT approved. Prior Authorization does not expire.
Updated PAs (on next page)	

Drug / Drug Class	Prior Authorization Criteria
• abiraterone acetate 250 mg (Zytiga, generics) **Oncological Agents: CYP-17 Inhibitors**	Manual PA criteria applies to new users of abiraterone acetate (Zytiga and generics) 250 mg. **<u>Changes from the November 2019 meeting are strikethrough.</u>** ~~*DoD will allow clinical PA to provide information for the 250mg and 500mg tablets. Currently, the 250mg tablets are the preferred agent, so if the provider is willing to write for the 250mg tablets, then a new prescription will need to be written – but the PA will not need to be filled out more than once~~ <u>Manual PA Criteria</u>: Abiraterone acetate 250 mg is approved if <u>all</u> criteria are met: ~~• Yonsa is the Department of Defense's preferred CYP-17 Inhibitor Agent.~~ ~~o Has the patient tried Yonsa?~~ ~~OR~~ ~~o Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Yonsa that is not expected to occur with requested agent?~~ • Age ≥ 18 years • Drug is prescribed by or in consultation with an oncologist or urologist • Patient has documented diagnosis of non-localized disease including: o Metastatic castration-resistant prostate cancer (nmCRPC) o Metastatic castration-sensitive prostate cancer (mCSPC) o Regional disease (T_xN1M0) OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ • Patient must receive concomitant therapy with prednisone • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy ~~• Zytiga 250 mg is the DoD's preferred strength. Is the prescription for Zytiga 250 mg OR will the prescription be changed to the 250 mg~~ ~~o Note: If the prescription is being changed to the 250 mg strength, please submit a new prescription with this PA form~~ ~~OR~~ ~~o Please state why the patient cannot take multiple 250 mg tablets to achieve the patient's daily dose (fill-in blank)~~ Other non FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• apalutamide (Erleada) **Oncological Agents: 2nd-Gen Antiandrogens**	Manual PA criteria apply to new users of Erleada. **<u>Changes from the November 2019 meeting are in BOLD and strikethrough.</u>** <u>Manual PA Criteria</u>: Erleada is approved if <u>all</u> criteria are met: • Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. The patient must have tried Xtandi AND: • The patient has had an inadequate response to Xtandi OR • The patient has experienced an adverse reaction to Xtandi that is not expected to occur with Erleada OR • The patient has a contraindication to Xtandi AND • Age ≥ 18 years • Drug is prescribed by or in consultation with an oncologist or urologist • Patient has documented diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) AND o Negative CT scan of abdomen/pelvis and/or negative bone scan, AND o PSADT ≤ 10 months **OR** • **Patient has a documented diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)** OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non FDA-approved uses are NOT approved. **Prior authorization does not expire.** ~~PA expires in 365 days~~ ~~Renewal PA Criteria: Coverage will be approved for 1 year for continuation of therapy if:~~ ~~• Patient continues to be metastases free~~ ~~• No toxicities have developed~~ ~~Patient has not progressed onto subsequent therapy (such as abiraterone [Zytiga])~~

Drug / Drug Class	Prior Authorization Criteria
• enzalutamide (Xtandi) **Oncological Agents: 2nd-Gen Antiandrogens**	Manual PA criteria apply to new users of Xtandi. **<u>Changes from the November 2019 meeting are in BOLD.</u>** <u>Manual PA Criteria</u>: Xtandi is approved if <u>all</u> criteria are met: • Age ≥ 18 years • Drug is prescribed by or in consultation with an oncologist or urologist • Patient has documented diagnosis of metastatic OR non-metastatic castration-resistant prostate cancer (CRPC) o If used in non-metastatic castration-resistant prostate cancer (nmCRPC) patient must have: PSADT ≤ 10 months **OR** • **Patient has a documented diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)** OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non FDA-approved uses are NOT approved. Prior authorization does not expire.
• avatrombopag (Doptelet) **Hematologic Agents: Platelets**	**Updates from the November 2019 meeting are in ~~strikethrough~~** Manual PA is required for new users of Doptelet. Manual PA Criteria: Doptelet is approved if <u>all</u> criteria are met: • Age ≥ 18 years AND • Diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 10^9/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • Drug is prescribed by or in consultation with a gastroenterologist • ~~The patient tried, failed, has a contraindication to, or is expected to have an intolerance to lusutrombopag (Mulpleta)?~~ Or • Diagnosis of chronic immune thrombocytopenia (ITP) and has failed to adequately respond to previous therapy • Has tried and failed Nplate or Promacta OR • Has a contraindication to both Nplate and Promacta OR • Is expected to have an adverse effect to both Nplate and Promacta that would not be anticipated by Avatrombopag • Drug is prescribed by or in consultation with a hematologist/oncologist • Doptelet is not being used concomitantly with other chronic ITP therapy QL: 30-day supply at all POS for ITP Non-FDA-approved uses are not approved. For thrombocytopenia associated with liver disease: PA expires in 60 days. New PA required per prescription fill For ITP: PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• budesonide/formoterol (Symbicort) • mometasone/formoterol (Dulera) **Pulmonary-1 Agents: Combinations**	**Changes from the November 2019 meeting are in BOLD.** PA criteria apply to new users of Dulera and Symbicort who are older than 12 years of age. Automated PA criteria: The patient has filled a prescription for Advair Diskus or Advair HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Dulera or Symbicort is approved if all criteria are met: • Patient has experienced any of the following issues with Advair Diskus or Advair HFA, which is not expected to occur with the non-preferred ICS/LABA combination drug: • Inadequate response to the step-preferred drugs • Intolerable adverse effects • Contraindication • Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk OR • **Patient has asthma and requires rescue therapy with an ICS-formoterol combination in accordance with GINA Strategy** Other non-FDA-approved uses are not approved. PA does not expire.
• ivabradine (Corlanor) **Cardiovascular Agents Miscellaneous: Miscellaneous**	Manual PA is required for new users of Corlanor. **Changes from the November 2019 meeting are BOLD.** Manual PA criteria: Corlanor is approved if all criteria are met: • Drug is prescribed by a cardiologist or heart failure (HF) specialist AND • Age ≥ 18 years o Diagnosis of HF ▪ Diagnosis of stable, symptomatic HF with LVEF ≤ 35%, in sinus rhythm, and has a resting heart rate ≥ 70 beats per minute ▪ Patient has symptoms despite maximal therapy of a beta blocker therapy that has been shown to have survival benefit in HF (e.g., metoprolol succinate, carvedilol, bisoprolol; and NOT atenolol) • Metoprolol succinate: 200 mg once a day; carvedilol 25 mg BID, if > 85 kg 50 mg BID; carvedilol XR: 80 mg once a day; bisoprolol 10 mg BID (not FDA-approved for HF) OR ▪ Patient has a contraindication to beta blocker use • List the contraindication – (e.g., COPD) OR ▪ Patient has tried and experienced intolerance to a HF beta blocker (metoprolol succinate, carvedilol, bisoprolol) o Diagnosis of postural orthostatic tachycardia syndrome (POTS) and/or inappropriate sinus tachycardia (IST) OR • **Age ≥ 6 months to 17 years** o **Patient has stable symptomatic heart failure due to dilated cardiomyopathy and is are in sinus rhythm with and elevated heart rate** Non-FDA-approved uses other than POTS/IST are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ledipasvir/sofosbuvir (Harvoni) and authorized generic Harvoni • sofosbuvir (Sovaldi) **Hepatitis C Agents: Direct Acting Agents**	Manual PA is required for new users of Harvoni and Sovaldi. **Changes from the November 2019 meeting are BOLD.** Manual PA criteria: Harvoni or Sovaldi is approved if all criteria are met: • Note: Brand Hepatitis C products are the preferred agents in the DoD. If the authorized generics of either Epclusa or Harvoni are required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. • Age ≥ 18 years o Patient has genotype 1 infection with decompensated cirrhosis, in combination with ribavirin; and genotype 1 or 4 infection in liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin. OR • Age **≥ 3 years to 17 years Harvoni (genotype 1, 4, 5 or 6 HCV) and Sovaldi (genotype 2 or 3 HCV)** • Drug is prescribed in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of hepatitis C virus (HCV) infection • What is the HCV Genotype? (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) Non-FDA-approved uses are not approved. Prior authorization expires in 1 year.
• nintedanib (Ofev) **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)**	Manual PA is required for new users of Ofev. **Changes from the November 2019 meeting are BOLD.** Manual PA criteria: Ofev is approved if all criteria are met: • Esbriet is the Department of Defense's preferred Idiopathic Pulmonary Fibrosis Agent. The patient must have tried Esbriet • Patient is non-smoking • The patient is being actively managed by a pulmonologist • The patient is not currently receiving pirfenidone (Esbriet) and nintedanib (Ofev) concomitantly (no dual therapy) • Patient has a documented diagnosis of: o Idiopathic pulmonary fibrosis (IPF) AND o Patient has had a trial of Esbriet and either: ▪ Failed therapy with Esbriet due to progression of IPF rate of decline of forced vital capacity (FVC) of > minus 10% OR ▪ Experienced intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) OR o The provider will note the Patient clinical factors where Esbriet is not appropriate **OR** • **Patient has a documented diagnosis of: Systemic sclerosis-associated interstitial lung disease (SSc-ILD),** Non-FDA-approved uses are not approved. Prior authorization expires in one year. Renewal criteria: **(initial TRICARE PA approval is required for renewal)** • **Patient continues to refrain from smoking** • **Request submitted by a pulmonologist** • **Patient experienced significant reduction in the annual rate of decline of forced vital capacity (FVC)** Subsequent prior authorization will expire in one year.

Drug / Drug Class	Prior Authorization Criteria
• pirfenidone (Esbriet) **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis (IPF)**	Manual PA is required for new users of Esbriet. **<u>Changes from the November 2019 meeting are BOLD.</u>** <u>Manual PA criteria</u>: Esbriet is approved if <u>all</u> criteria are met: • Patient is non-smoking and has a documented diagnosis of idiopathic pulmonary fibrosis (IPF) • The patient is being actively managed by a pulmonologist • The patient is not currently receiving pirfenidone (Esbriet) and nintedanib (Ofev) concomitantly (no dual therapy) Non-FDA approved uses are not approved Prior authorization expires in one year. <u>Renewal criteria</u>: **(initial TRICARE PA approval is required for renewal)** • **Patient continues to refrain from smoking** • **Request submitted by a pulmonologist** • **Patient is not currently receiving Esbriet and Ofev concomitantly (no dual therapy)** • **Patient experienced significant reduction in the annual rate of decline of forced vital capacity (FVC)** Subsequent prior authorization will expire in one year.

Drug / Drug Class	Prior Authorization Criteria
• baricitinib (Olumiant) **Targeted Immunomodulatory Biologics (TIBs): Miscellaneous**	Prior authorization criteria originally approved August 2018 and updated November 2018 to standardize with other TIBs PAs. **Changes from the November 2019 meeting are in BOLD and strikethrough.** Step therapy and manual PA criteria apply to new users of Olumiant. Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, coverage for Olumiant is approved if all criteria are met: • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira • ~~Provider acknowledges that if a JAK inhibitor is desired, Xeljanz/Xeljanz XR is an alternative to baricitinib (Olumiant) without the black box warning risk of thrombosis~~ • Age ≥ 18 years • Patient has a diagnosis of: o Moderate to severe active rheumatoid arthritis (RA) • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.) • The patient will not be receiving other biologic DMARDs or potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly • Patient has no history of thromboembolic disease • Patient hemoglobin (Hgb) must be > 9 g/dL • **Patient absolute neutrophil count (ANC) < 1,000/mm^3** • **Patient absolute lymphocyte count (ALC) < 500/ mm^3** • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents **except for Otezla** Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ixekizumab (Taltz) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	Prior authorization criteria originally approved May 2016 and updated February 2018 to reflect indication change, and November 2018 to standardize with other TIBs PAs. **<u>Changes from the November 2019 meeting are in BOLD.</u>** **Step therapy and manual PA criteria apply to new users of Taltz.** <u>Automated PA Criteria</u>: The patient has filled a prescription for adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria</u>: If automated criteria are not met, Taltz is approved if <u>all</u> criteria are met: • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira, Cosentyx, and Stelara AND: • The patient had an inadequate response to Humira, Cosentyx, and Stelara OR • The patient experienced an adverse reaction to Humira, Cosentyx, and Stelara that is not expected to occur with the requested agent o **Exception to trial of Stelara is if Taltz is used for ankylosing spondylitis (AS) indication (Humira and Cosentyx are still required)** OR • The patient has a contraindication to Humira, Cosentyx, and Stelara • Age ≥ 18 years • Patient has a diagnosis of: o Active psoriatic arthritis (PsA) o Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy o **Active ankylosing spondylitis (AS): only Humira and Cosentyx step required** • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• tofacitinib (Xeljanz, Xeljanz XR) **Targeted Immunomodulatory Biologics (TIBs): Miscellaneous**	**Changes from the November 2019 meeting are in BOLD and strikethrough.** **Step therapy and manual PA criteria apply to new users of Xeljanz, Xeljanz XR.** Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, coverage for Xeljanz, Xeljanz XR is approved if all criteria are met: • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira • Age ≥ 18 years • Patient has a diagnosis of: o Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate ▪ The prescription is for 5 mg BID or 11 mg once a day o Active psoriatic arthritis (PsA) ▪ The prescription is for 5 mg BID or 11 mg once a day o Moderately to severely active ulcerative colitis (UC) ▪ Will allow doses up to 10 mg BID • **Patient has no history of thromboembolic disease** • Patient hemoglobin (Hgb) must be > 9 g/dL • **Patient absolute neutrophil count (ANC) < 1,000/mm^3** • **Patient absolute lymphocyte count (ALC) < 500/ mm^3** • The patient is not receiving potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)? • May not be used concomitantly with other TIBs agents **except for Otezla** Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ustekinumab (Stelara) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**Changes from the November 2019 meeting are in BOLD.** Manual PA criteria apply to new users of Stelara. Manual PA Criteria: Stelara is approved if all criteria are met: • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira • Age ≥ 18 years AND • Patient has a diagnosis of: o Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy o Active psoriatic arthritis (PsA) alone or in combination with methotrexate o Moderately to severely active Crohn's disease (CD) o **Moderately to severely active ulcerative colitis (UC)** • Age ≥ 12 years AND • Patient has a diagnosis of moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy • The patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• sildenafil generic • tadalafil generic **Phosphodiesterase-5 Inhibitors**	▪ Retail: 10 tablets per 30 days (collective of all PDE-5 inhibitors) ▪ MTF/Mail: 30 tablets per 90 days (collective of all PDE-5 inhibitors) Note that a collective QL a maximum of 10 tablets in Retail and 30 tablets in MTF/Mail of generic sildenafil or generic tadalafil is allowed Implementation will occur along with the Tier 4 recommendation of 120-days after signing of the minutes.
• bremelanotide injection (Vyleesi) **Gynecological Agents Miscellaneous**	▪ Retail/MTF/Mail: 8 syringes/30 days and 30-day supply at all POS
• budesonide/formoterol (Symbicort) • mometasone/formoterol (Dulera) **Pulmonary-1 Agents: Combinations**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• darolutamide (Nubeqa) **Oncological Agents: Second-Generation Antiandrogens**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• entrectinib (Rozlytrek) • fedratinib (Inrebic) • idelalisib (Zydelig) • larotrectinib (Vitrakvi) tabs and oral solution • pexidartinib (Turalio) • venetoclax (Venclexta) **Oncological Agents:**	▪ Retail/MTF/Mail: 30-day supply at all POS
• glucagon injection (Gvoke Hypopen and Pre-Filled Syringe) **Binders-Chelators-Antidotes-Overdose Agents**	▪ Retail/MTF/Mail: 2 syringes/pens per fill (one two-pack or two individual)
• glucagon kit (Glucagon Emergency) • glucagon powder for injection (GlucaGen Hypokit and GlucGen Diagnostic) **Binders-Chelators-Antidotes-Overdose Agents**	▪ Retail/MTF/Mail: 2 kits per fill

Drug / Drug Class	Quantity Limits
• glucagon nasal spray (Baqsimi) **Binders-Chelators-Antidotes-Overdose Agents**	▪ Retail/MTF/Mail: 2 nasal spray units per fill (one two-pack or two individual)
• lidocaine-tetracaine 7%-7% cream (Pliaglis) **Anesthetic Agents: Local**	▪ Retail/MTF/Mail: 2 tubes per fill at all POS
• lidocaine-tetracaine 7%-7% patch (Synera) **Anesthetic Agents: Local**	▪ Retail/MTF/Mail: 1 box per fill at all POS
• midazolam nasal spray (Nayzilam) **Anticonvulsants-Antimania Agents**	▪ Retail: 5 boxes/30 days ▪ MTF/Mail: 15 boxes/90 days
• pitolisant (Wakix) **Sleep Disorders: Wakefulness Promoting Agents**	▪ Retail/MTF/Mail: 30-day supply at all POS
• selinexor (Xpovio) **Oncological Agents: Multiple Myeloma**	▪ Retail/MTF/Mail: 28-day supply at all POS, due to packaging
• upadacitinib (Rinvoq) **TIBs**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply

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
amlodipine oral suspension (Katerzia)	Calcium Channel Blockers (CCBs)	• amlodipine • felodipine • isradipine • nifedipine ER tabs • lisinopril susp (Qbrelis) – same mfg • enalapril susp (Epaned) – same mfg	Hypertension in adults and children > 6 yrs. Coronary Artery Disease (CAD) – adults with chronic stable angina, vasospastic angina, angiographically documented CAD in patients without heart failure or an ejection fraction < 40%	• First calcium channel blocker available in an oral suspension • Manufactured by the same company that has several other oral suspensions (lisinopril [Qbrelis], enalapril [Epaned]) • No clinical trials; approved using the same clinical data as amlodipine tablets (Norvasc) • Compounded formulations of amlodipine suspension are easy to prepare and stability data is available. • Katerzia suspension has no compelling clinical advantages compared to other UF dihydropyridine CCBs other than offering a convenience for patients with swallowing difficulties.	• NF • Add to EMMPI list
bremelanotide injection (Vyleesi)	Gynecological agents miscellaneous	• flibanserin (Addyi)	Treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulties and is NOT due to: 1. A co-existing medical or psychiatric condition 2. Problems with the relationship 3. The effects of a medication or drug substance	• Only melanocortin receptor agonist FDA-approved for treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder. • Increased sexual desire and decreased distress associated with low sexual desire was modestly more than placebo in two clinical trials. This change was found to be clinically meaningful in 25% of patients for the desire measure and 35% of patients for the distress measure. • No head-to-head studies with the other agent approved for HSDD (Addyi) • Administered subcutaneously at least 45 minutes before anticipated sexual activity; maximum of 1 dose per 24 hours and 8 doses per month • Most common ADRs included nausea (40%), flushing, injection site reactions, headache, vomiting, cough, fatigue, hot flush, paresthesia, dizziness, nasal congestion • Contraindicated in patients with cardiovascular disease or uncontrolled hypertension and may cause focal hyperpigmentation • Vyleesi, as the second medication and the only as needed option, adds to the HSDD treatment armamentarium.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
darolutamide (Nubeqa)	Oncological Agents: 2nd-Gen Antiandrogens	▪ apalutamide (Erleada) ▪ enzalutamide (Xtandi)	Non-metastatic castration-resistant prostate cancer (nmCRPC); patients should also be receiving a gonadotropin-releasing hormone analog concurrently or have had a bilateral orchiectomy	• Nubeqa is the third 2nd-Generation androgen receptor inhibitor approved for treatment of nmCRPC. • Highly effective when compared with placebo (more than double time to metastases and prolonged time to pain progression) • Similar efficacy when indirectly compared (no head-to-head trials) to the other two 2nd-Generation antiandrogen (2nd-Gen AA) agents for treatment of nmCRPC • Has unique side effect/safety profile due to limited structural permeability through the blood-brain barrier, which appears to have lower incidences of central nervous system adverse events such as seizures, dizziness, and falls when indirectly compared to the other two 2nd-Gen AA agents • Provides a therapeutic alternative to the other two 2nd-Gen AA agents for treatment of nmCRPC	• UF and non-step-preferred • Do not add to EMMPI list
duloxetine extended-release (Drizalma Sprinkle)	Antidepressants & Non-Opioid Pain Syndrome Agents: Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)	• duloxetine capsules (Cymbalta) • venlafaxine (Effexor XR) • desvenlafaxine (Pristiq) • levomilnacipran (Fetzima)	Major depressive disorder (MDD), generalized anxiety disorder (children 7-17 years old), diabetic peripheral neuropathy, chronic musculoskeletal pain	• New sprinkle formulation of duloxetine approved via 505(b)(2) pathway • No new clinical data • Drizalma Sprinkle provides a formulation for patients with swallowing difficulties; however, it provides no compelling advantage compared to existing formulary agents.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
entrectinib (Rozlytrek)	Oncological Agents: Lung Cancer	▪ larotrectinib (Vitrakvi)	1.) Adult patients with ROS1 (+) metastatic non-small cell lung cancer (NSCLC) 2.) Patients ≥ 12 years with solid tumors that meet all of the following criteria: a.) Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation; b.) Are metastatic or where surgical resection is likely to result in severe morbidity; c.) Have either progressed following treatment or have no satisfactory alternative therapy	• Multikinase inhibitor with two indications: ▪ *ROS1* (+) NSCLC ▪ *NTRK* gene fusion (+) solid tumors • Second FDA approval based on molecular target absent cancer subtype • Low-quality evidence supporting efficacy (single-arm, open-label, limited to phase 1 and 2 trials) • However, robust overall response and duration of response and outcomes similar to those of comparators (similarly limited by low-quality evidence) • Despite high rate of serious adverse events, dose interruptions and reductions, low overall discontinuation rate; safety profile similar to comparators • Entrectinib offers another treatment option for patients with cancer with rare molecular alterations	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
fedratinib (Inrebic)	Oncological Agents	▪ ruxolitinib (Jakafi)	Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis	• Indicated for patients with intermediate-2 or high-risk myelofibrosis supported by National Comprehensive Cancer Network (NCCN) 2B recommendation • Robust statistically and clinically significant reduction in splenomegaly • Substantial background data supporting surrogate endpoint as valid measure of reduction of disease burden and suggests correlation with survival • High rate of GI toxicity that can cause severe malnutrition resulting in fatal Wernicke's encephalopathy (WE) ▪ Black Box Warning (BBW) for encephalopathy; WE requires emergent IV thiamine ▪ Risk mitigation requires aggressive management of GI AEs to prevent malnutrition • Effective even in patients with ruxolitinib (Jakafi)-refractory disease	• UF • Do not add to EMMPI list
formoterol/ aclidinium (Duaklir Pressair)	Pulmonary-2 Agents: COPD	▪ umeclidinium/ vilanterol (Anoro Ellipta) ▪ tiotropium/ olodaterol (Stiolto Respimat) ▪ glycopyrrolate/ indacaterol (Utibron Neohaler) ▪ glycopyrrolate/ formoterol (Bevespi Aerosphere)	For the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	• Duaklir is the fifth long-acting muscarinic antagonist (LAMA)/long-acting beta agonist (LABA) combination product. • No evidence to suggest Duaklir is superior in efficacy or safety to LABA/LAMA combinations currently available. • Similar to Stiolto, Duaklir improves spirometric endpoints and reduces hospitalization due to COPD exacerbations; however, it requires BID dosing. • Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend LAMA/LABA therapy for COPD severity classification stage D or as a second-line option for dyspnea and exacerbations. • There was a statistically difference favoring aclidinium/formoterol over single-ingredient LABA or LAMA. There are no head-to-head trials with other LAMA/LABA combinations. • A clinically relevant difference was seen with aclidinium/formoterol over placebo with the trough FEV_1 endpoint. • Provides little/no clinically compelling advantages over existing UF agents used in the long-term maintenance treatment of COPD.	• Tier 4 (Not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
glucagon injection (Gvoke Hypopen and Prefilled syringe [PFS])	Binders-Chelators-Antidotes-Overdose Agents	▪ glucagon nasal powder (Baqsimi) ▪ glucagon 1 mg vial injection (Glucagon Emergency Kit) ▪ Glucagen 1 mg HypoKit	Severe hypoglycemia in patients with diabetes ages 2 and above	• Gvoke is a new formulation of glucagon available as a prefilled syringe and auto-injector for rescue of hypoglycemia. • Evaluated in two clinical trials compared to glucagon IM injection and established non-inferiority in terms of efficacy • In one drug administration study evaluating the ability of caretakers, first responders, and adults not familiar with diabetes to administer glucagon correctly, 88% administered Gvoke Auto Injector correctly, while only 31% administered the Glucagon Emergency Kit correctly. • Common adverse effects are limited to nausea and vomiting, as well as injection site edema and headache. • Ready-to-use formulation offers a significant advantage over existing agents, which may be preferable in emergencies.	• UF • Do not add to EMMPI list
glucagon nasal spray (Baqsimi)	Binders-Chelators-Antidotes-Overdose Agents	▪ glucagon nasal powder (Baqsimi) ▪ glucagon 1 mg vial injection (Glucagon Emergency Kit) • Glucagen 1 mg HypoKit	Severe hypoglycemia in patients with diabetes ages 4 years and above	• Baqsimi is a new formulation of glucagon available as an intranasal powder for rescue of hypoglycemia. • Evaluated in 3 clinical trials compared to glucagon IM injection and established non-inferiority in terms of efficacy • In one drug administration study evaluating the ability of acquaintances and caregivers to administer Baqsimi vs injection glucagon, 93/94% administered Baqsimi correctly in 0.27/0.44 min compared to 0/13% administered injection glucagon correctly in 1.89 min. • Common adverse effects are limited to nausea and vomiting, as well as localized upper respiratory tract irritation. • Route of administration offers a significant advantage over existing agents, which may be preferable in emergencies.	• UF • Do not add to EMMPI list
istradefylline (Nourianz)	Parkinson's Agents	• pramipexole IR/ER tab (Mirapex IR, ER) • ropinirole IR/ER tab (Requip, XL) • rotigotine patch (Neupro) • selegiline (Zelapar) • rasagiline (Azilect) • entacapone tab (Comtan) • tolcapone tab (Tasmar)	For adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes	• Nourianz is a new medication with a novel mechanism of action for adult patients with Parkinson's disease (PD) experiencing "off" episodes while taking levodopa/carbidopa. • Fourth class of drugs to be used for this indication. • Nourianz was denied approval in 2008 for lack of efficacy and needed further studies to show efficacy. • In the approval studies, statistical benefit over placebo was seen in all but one study. Decrease in "off" time was around 1 hour, which was similar to other agents using an indirect comparison. • Nourianz provides an additional option from a new class of drugs that may be used in PD patients with advanced disease who experience "off" episodes.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lamivudine/ tenofovir disoproxil fumarate (TDF) (Temixys)	Antiretrovirals: Combinations	• lamivudine (3TC)/tenofovir disoproxil fumarate (TDF) (Cimduo) • emtricitabine (FTC)/ tenofovir disoproxil fumarate (TDF) (Truvada)	For use in combination with another antiretroviral for the treatment of HIV-1 infection in adults & pediatric patients weighing ≥ 35 kg	• Temixys is only FDA approved for use in combination with another antiretroviral (ARV) for treatment of HIV-1 infection in adults & pediatric patients weighing ≥ 35 kg. • Two-drug combination of lamivudine & TDF (both nucleotide reverse transcriptase inhibitor [NRTIs]) • Could provide a 1st-line NRTI backbone in HIV treatment if coupled with one more ARV according to both Centers for Disease Control and Prevention (CDC) & World Health Organization (WHO) guidelines • Per CDC HIV guidelines, lamivudine may substitute for emtricitabine or vice versa. • However, per CDC pre-exposure prophylaxis (PrEP) guidelines do not substitute 3TC/TDF for FTC/TDF (Truvada). • Temixys has a boxed warning for post-treatment acute exacerbations of hepatitis B. • Most common adverse reactions with Temixys include headache, pain, depression, diarrhea, & rash. • Provides no clinical advantage over previously reviewed Cimduo, which has same medications & doses	• UF • Do not add to EMMPI list
lefamulin (Xenleta)	Antibiotics	• moxifloxacin (Avelox)	Adults with community-acquired bacterial pneumonia (CABP) caused by susceptible bacteria	• Xenleta is the 1st available pleuromutilin antibiotic for systemic treatment of bacterial infections in humans. • Non-inferior to guideline-recommended moxifloxacin in the treatment of CABP • Treatment guidelines do not yet assess Xenleta's place in therapy for CABP. • Common side effects include diarrhea, nausea, & vomiting. • Special populations limitations: pregnancy (embryo-fetal toxicity), breastfeeding (pump & dump milk), pediatrics (not studied), and moderate to severe hepatic impairment (not studied for oral version) • Offers another treatment option for CABP with low likelihood of bacterial resistance in light of high rates of resistance to macrolides and other CABP antibiotics • More cost-effective options than Xenleta are available to treat CABP.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
midazolam nasal spray (Nayzilam)	Anticonvulsants-Antimania Agents	• diazepam rectal (Diastat) • clonazepam ODT(Klonopin)	The acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older	• Nayzilam is a new formulation of midazolam. • First approved intranasal benzodiazepine for acute intermittent seizures or seizure clusters • Third benzodiazepine with alternate dosage form used for acute intermittent seizures. Clonazepam ODT and Diazepam Rectal are the other options. • Nayzilam showed a statistically significant difference from placebo in the percentage of patients successful in eliminating seizures for at least 6 hours post administration. • Provides a clinically meaningful addition for the treatment of acute intermittent seizures or seizure clusters	• UF • Do not add to EMMPI list
pexidartinib (Turalio)	Oncological Agents	• nilotinib (Tasigna) • imatinib (Gleevec)	Turalio is a kinase inhibitor indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery	• Turalio is medically appropriate for patients with symptomatic unresectable TGCT associated with severe morbidity or functional limitations. • It is the first-line agent for such cases due to substantial benefit with the highest level of evidence among its comparators. • Turalio has a BBW and associated Risk Evaluation and Mitigation Strategies (REMS) for severe hepatotoxicity. • In select patients, Turalio offers an effective treatment option.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
pitolisant (Wakix)	Sleep Disorders: Wakefulness Promoting Agents	• modafinil (Provigil, generics) • armodafinil (Nuvigil, generics) • sodium oxybate (Xyrem) • solriamfetol (Sunosi)	Excessive daytime sleepiness (EDS) in adults with narcolepsy	• Pitolisant is a new agent with a novel mechanism of action for excessive daytime sleepiness in those with narcolepsy • Pitolisant is the only non-scheduled drug for this indication • Histamine-3 (H3) receptor antagonist/inverse agonist • Common ADRs include nausea, anxiety, and insomnia • Contraindicated in those with severe hepatic impairment • FDA warning for QT prolongation and drug interactions with CYP2D6 inhibitors and CYP3A4 inducers • Efficacy of pitolisant was found to be superior when compared to placebo; not non-inferior when compared to modafinil • Advantages of Wakix include a novel mechanism of action for narcolepsy and a non-scheduled option; however, efficacy is no better than existing therapies, and there are limitations regarding safety (i.e., renal and hepatic impairment, drug interactions, and QT prolongation)	• NF • Add to EMMPI list
segesterone acetate/ ethinyl estradiol vaginal ring (Annovera)	Contraceptive Agents: Miscellaneous	• etonogestrel/ ethinyl estradiol (NuvaRing)	For use by females of reproductive potential to prevent pregnancy	• Annovera is the second available contraceptive vaginal ring in the US. • Patient-controlled, procedure-free, long-acting (1 year), reversible birth control • Similar efficacy compared to other combined hormonal contraceptives (CHCs) • 12% of women discontinued due to adverse reactions. • Not adequately evaluated in women with a body mass index (BMI) > 29 • FDA will require post-marketing studies to evaluate risk for venous thromboembolism (VTE) & effects of CYP3A modulating drugs & tampon use on pharmacokinetics. • Loss of contraceptive protection if removed for > 2 hours per 21-day cycle • Annovera does not require refrigeration, unlike NuvaRing • Ring must be cleaned regularly & kept in case when not in use. • Annovera provides no compelling clinical advantage other than convenience.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
selinexor (Xpovio)	Oncological Agents: Multiple Myeloma	▪ none	Xpovio is a nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody	• Xpovio is a newly approved agent for RRMM indicated as a fifth line agent (i.e., triple-class refractory disease). • Xpovio was granted accelerated approval based on one phase 2 single-arm study supported by an ongoing phase 3 randomized controlled trial. • Demonstrable benefit for discrete group of patients • Responders gain *significant* survival advantage (especially given refractoriness of their disease). • Xpovio showed high toxicity with a high dose interruption/reduction rate. • Multiple ongoing trials assessing various combination (triple) regimens in RRMM • Xpovio provides an option for patients with refractory RRMM when no other non-chemotherapy options are available.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
semaglutide oral tablet (Rybelsus)	Diabetes Non-Insulin: Oral Glucagon-Like Peptide-1 Receptor Agonists	• exenatide extended-release (Bydureon/ BCise) • dulaglutide (Trulicity) • liraglutide (Victoza) • exenatide immediate-release (Byetta) • lixisenatide (Adlyxin) ▪ semaglutide (Ozempic)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	• Rybelsus is the first oral GLP1RA and the seventh agent in the class. • Oral semaglutide requires dose titration and must be taken QAM 30 minutes before food, drink, and medications with ≤ 4 ounces of water. • Rybelsus has been studied in treatment-naïve patients and as add-on therapy to all oral antidiabetic agents and to insulin. • Oral semaglutide was statistically and clinically superior to sitagliptin in glycemic control (1.4% vs 0.8%) and effect on weight. • Oral semaglutide was statistically and clinically superior to empagliflozin in change in A1c from baseline (1.4% vs 0.9%) with similar effect on weight loss. • When used at appropriate doses, there is no clinically significant difference in change in A1c from baseline in the GLP1RA active comparator trials. • Weight loss was observed in all studies with better results at higher doses. • Limitations of studies include use of lower than optimal doses of liraglutide (0.9 mg) and dulaglutide (0.75 mg). • ICER completed a systematic review of oral semaglutide, which showed a decrease in A1c that was greatest for oral semaglutide > placebo, empagliflozin, and sitagliptin, and more than liraglutide at 52 weeks but not at 26 weeks. Reduced body weight was greatest for oral semaglutide > placebo, liraglutide, and sitagliptin • Rybelsus provides the convenience of an oral formulation with no requirement for refrigeration; however, there is insufficient evidence to suggest superiority to the other GLP1RAs.	• UF • Add to EMMPI list
sumatriptan nasal spray (Tosymra)	Migraine Agents: Triptans	• sumatriptan nasal spray (Imitrex, generics) • zolmitriptan nasal spray (Zomig) ▪ sumatriptan nasal powder (Onzetra Xsail)	For the acute treatment of migraine with or without aura in adults	• 4th approved intranasal triptan • Approved based on 87% bioequivalence to sumatriptan 4 mg injectable • Did not receive an indication for cluster headache like the injectable • Provides no compelling clinical advantage over existing agents	• Tier 4 (Not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tegaserod (Zelnorm)	Gastrointestinal-2 (GI-2) Agents: CIC and IBS-C	• linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Amitiza)	Adult women < 65 years of age with constipation-predominant irritable bowel syndrome (IBS-C)	• Zelnorm is a serotonin-4 (5-HT_4) receptor agonist newly indicated only for adult women < 65 years of ago with IBS-C; previously indicated for all adult women with IBS-C and chronic idiopathic constipation (CIC). • Removed from the market in 2007 due to CV concerns; reintroduced in 2019 with new CV contraindication and suicidality warnings • New warning concerning suicide, suicidal attempt and ideation, and self-injurious behaviors • No head-to-head studies with other agents • Statistically significant results compared to placebo; clinical significance unclear and a significant placebo effect • Most common ADRs included abdominal pain, diarrhea, nausea, flatulence, headache, dizziness. • Provides no clinical benefit relative to similar agents for IBS-C (Linzess, Trulance, Amitiza) and has significant safety concerns	• Tier 4 (Not covered)
tiopronin (Thiola EC)	Urinary Agents Miscellaneous	• tiopronin IR (Thiola) • d-penicillamine	Prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria	• New delayed-release, enteric-coated, formulation of tiopronin indicated for pediatric and adult patients with cystinuria • New dosage form available (300 mg), compared to 100 mg of Thiola • Advantages of the delayed-release tablet compared to the immediate-release include a decreased pill burden and administration without regard to meals. • No new studies performed with the EC formulation • Most common ADRs included nausea, diarrhea, soft stools, oral ulcers, rash, fatigue, fever, arthralgia, proteinuria, and emesis. • Although Thiola EC provides ease of administration, there are no additional clinical advantages compared to existing formulary agents	• UF • Do not add to EMMPI list
upadacitinib (Rinvoq)	Targeted Immuno-modulatory Biologics (TIBs): Miscellaneous	• tofacitinib (Xeljanz) • baricitinib (Olumiant)	Moderate to severe active rheumatoid arthritis (RA) that has had an inadequate response to methotrexate	• Rinvoq is the third Janus kinase (JAK) inhibitor for disease-modifying antirheumatic drug (DMARD)-refractory rheumatoid arthritis (RA) • Similar to other JAK inhibitors in that it is effective across an array of patient characteristics and previous treatment histories • American College of Rheumatology (ACR) Criteria responses comparable among JAK agents by indirect comparison; some ACR responses are incrementally higher with Rinvoq but no head-to-head studies for quantitative analysis • Comparable safety among JAK inhibitors for RA • Black Box Warnings for serious infection, malignancy, and thrombosis	• NF and non-step-preferred • Add to EMMPI list

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

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
November 2019	**Rapid Acting Insulins** • maintain Humalog, Novolog **Designated NF:** *No reason to exempt from EMMPI requirement* • add Inhaled insulin (Afrezza) • maintain Apidra **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Similar agents are already on list* ▪ oral semaglutide (Rybelsus) **Designated NF:** *No reason to exempt from EMMPI requirement:* ▪ amlodipine oral suspension (Katerzia) ▪ duloxetine extended-release (Drizalma Sprinkle) ▪ pitolisant (Wakix) *Similar agents are already on list:* ▪ upadacitinib (Rinvoq)	**Rapid Acting Insulins** • remove insulin lispro (Admelog) [no cost advantage] **PDE-5 Inhibitors** • remove sildenafil • remove tadalafil • remove Stendra, Staxyn, Levitra, Viagra, Cialis (due to Tier 4 status) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Drugs for acute or limited duration use*: ▪ glucagon nasal (Baqsimi) ▪ glucagon injection (Gvoke Hypopen and Pre-filled Syringe) ▪ lefamulin (Xenleta) *C-II exception applies:* ▪ midazolam nasal spray (Nayzilam) *Drugs in classes not currently represented on the EMMPI list*: ▪ bremelanotide injection (Vyleesi) ▪ darolutamide (Nubeqa) ▪ entrectinib (Rozlytrek) ▪ fedratinib (Inrebic) ▪ lamivudine/tenofovir disoproxil fumarate (Temixys) ▪ pexidartinib (Turalio) ▪ segesterone acetate/ethinyl estradiol (Annovera) ▪ selinexor (Xpovio) ▪ tiopronin (Thiola EC) **Designated NF:** *Drugs in classes not currently represented on the EMMPI list*: ▪ istradefylline (Nourianz)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2019	**Phosphodiesterase-5 Inhibitors**	UF Class Review Class most recently reviewed in Nov 2011	**Tier 4/Not Covered Medications** **MTFs <u>must not</u> have on formulary** **Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies** ▪ avanafil (Stendra) ▪ vardenafil ODT (Staxyn, generics) ▪ vardenafil tablet (Levitra, generics) ▪ branded sildenafil (Viagra) ▪ branded tadalafil (Cialis)			Pending signing of the minutes / 120 days The effective date is June 3, 2020	Quantity Limits increased to: ▪ Retail: 10 tablets per 30 days ▪ MTF/Mail 30 tablets per 90 days	▪ Generic tadalafil moves from NF to UF, but non-step-preferred – requires a trial of sildenafil first in new users ▪ No PA required for male patients 40 years and older for ED (no change from previous) ▪ See Appendix C for full PA criteria. ▪ New Tier 4/Not Covered recommendation for Levitra, Stendra, Staxyn, brand Cialis, and brand Viagra
			Step-preferred ▪ sildenafil tablets (generic Viagra) only	*Non-step-preferred* ▪ tadalafil (generic Cialis only)	▪ None			

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

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<tr><th>Date</th><th>DoD PEC Drug Class</th><th>Type of Action</th><th>BCF/ECF Medications

MTFs must have BCF meds on formulary</th><th>UF Medications

MTFs may have on formulary</th><th>Nonformulary Medications

MTFs may not have on formulary</th><th>Decision Date / Implement Date</th><th>PA and QL Issues</th><th>Comments</th></tr>
<tr><td rowspan="2">Nov 2019</td><td rowspan="2">Insulins: Rapid-Acting Agents</td><td rowspan="2">UF Class Review

Class not previously reviewed</td><td colspan="3">Tier 4/Not Covered Medications

MTFs <u>must not</u> have on formulary

Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies

▪ insulin aspart/ niacinamide (Fiasp)</td><td rowspan="2">Pending signing of the minutes / 150 days

The effective date is July 1, 2020</td><td rowspan="2">New and current users of Apidra, Admelog, and Afrezza must first try both step-preferred agents Novolog and Humalog or authorized generic lispro)
▪ Updated manual PA criteria for all users of Apidra, Admelog, and Afrezza.</td><td rowspan="2">▪ Fiasp moved from NF to Tier 4 (not covered).
▪ Admelog moved to NF and non-step preferred.
▪ Afrezza remains NF.

▪ See Appendices B and C for MN and PA criteria.</td></tr>
<tr><td><u>Step-preferred</u>

▪ insulin aspart (Novolog Flexpen, Novolog FlexTouch, Novolog vial)</td><td><u>Step-preferred</u>

▪ insulin lispro (Humalog and authorized generic lispro)</td><td><u>Non-step-preferred</u>

▪ insulin glulisine (Apidra)
▪ insulin lispro (Admelog)
▪ inhaled insulin (Afrezza)</td></tr>
</table>

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2019	PDE-5 inhibitor	• avanafil tablet (Stendra) • brand Viagra tablet • brand Cialis tablet • vardenafil tablet (Levitra and generics) • vardenafil oral disintegrating tablet (ODT) (Staxyn and generics)	• sildenafil tablet (generic Viagra only) • tadalafil tablet (generic Cialis only)	• June 3, 2020
Nov 2019	Rapid Acting Insulins	• Insulin plus niacinamide (Fiasp)	• insulin aspart (Novolog) • insulin lispro (Humalog or authorized generic lispro) • insulin lispro (Admelog) [nonformulary] • insulin glulisine (Apidra) [nonformulary]	• July 1, 2020
Nov 2019	Pulmonary-2 Agents: COPD	• formoterol/aclidinium (Duaklir Pressair)	• umeclidinium/vilanterol (Anoro Ellipta) • tiotropium/olodaterol (Stiolto Respimat) • glycopyrrolate/indacaterol (Utibron Neohaler) [nonformulary] • glycopyrrolate/formoterol (Bevespi Aerosphere) [nonformulary]	• 120-days after signing
Nov 2019	Migraine Agents: Triptans	• sumatriptan nasal spray (Tosymra)	• sumatriptan nasal spray (Imitrex, generics) • sumatriptan nasal powder (Onzetra Xsail) • zolmitriptan nasal spray (Zomig)	• 120-days after signing
Nov 2019	GI2 Agents: CIC and IBS-C	• tegaserod (Zelnorm)	• linaclotide (Linzess) • plecanatide (Trulance) • lubiprostone (Amitiza) • pruclaopride (Motegrity) [nonformulary]	• 120-days after signing

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	ADHD	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.025% cream (Impoyz) • diflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog)	• betamethasone/propylene glycol 0.05% cream • clobetasol propionate 0.05% cream • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream • fluocinonide 0.05% cream • fluocinonide/emollient base 0.05% cream	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• halcinonide 0.1% ointment (Halog)	• betamethasone dipropionate 0.05% ointment • betamethasone/propylene glycol 0.05% ointment • clobetasol propionate 0.05% ointment • desoximetasone 0.25% ointment • fluocinonide 0.05% ointment • halobetasol propionate 0.05% ointment	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.05% shampoo/ cleanser (kit) (Clodan kit) • halobetasol propionate 0.05% lotion (Ultravate) • halobetasol propionate 0.05% foam (authorized generic for Lexette) *(see Feb 2019 for brand Lexette recommendation)* • halobetasol propionate 0.01% lotion (Bryhali)	• betamethasone propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % emulsion foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2019	PPIs	• dexlansoprazole (Dexilant) • esomeprazole strontium	• esomeprazole • omeprazole • pantoprazole • rabeprazole	• Nov 28, 2019
Feb 2019	High-Potency Topical Corticosteroids	• halobetasol propionate 0.05% foam (Lexette brand)	• betamethasone/propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % emulsion foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• Aug 28, 2019
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	• metformin ER gastric retention 24 hours (Glumetza)	• metformin IR (Glucophage generic) • metformin ER (Glucophage XR generic)	• Aug 28, 2019
Feb 2019	Pain Agents – Combinations	• naproxen / esomeprazole (Vimovo)	• PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs)	• Aug 28, 2019

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents, based on an interim final rule published on December 11, 2018. https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms .

Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service.

Appendix I—Table of Abbreviations

Term	Definition	Term	Definition
ADR	Adverse reaction	GINA	Global Initiative for Asthma
AR	Adverse event	HCV	Hepatitis C Virus
ALC	Absolute Lymphocyte Count	HIV	Human Immunodeficiency Virus
ANC	Absolute Neutrophil Count	HSDD	Hypoactive Sexual Desire Disorder
ANDA	Abbreviated New Drug Application	IBS-C	Constipation-predominant Irritable Bowel Syndrome
AS	Ankylosing Spondylitis	ICS	Inhaled corticosteroids
ASAS	Spondylo Arthritis International Society	IPF	Idiopathic Pulmonary Fibrosis
AUA	American Urology Association	JAK	Janus Associated Kinase
BCF	Basic Core Formulary	LABA	Long-acting beta agonist
BIA	Budget impact analysis	LAMA	Long-acting muscarinic antagonist
BPH	Benign Prostatic Hyperplasia	mCSPC	Metastatic castration-Sensitive prostate Cancer
CBC	Complete blood count	MGD	Meibomian glad Disorder
CFR	Code of Federal Regulations	MHS	Military Health System
CHCS	Composite Health Care System	MN	Medical Necessity
CLL	Chronic Lymphocytic Leukemia	MOA	Mechanism of action
CMA	Cost minimization analysis	MTF	Military Treatment Facility
COPD	Chronic Obstructive Pulmonary Disease	NCCN	National Comprehensive Cancer Network
CSII	Continuous subcutaneous insulin infusion	NDAA	National Defense Authorization Act
DHA	Defense Health Agency	NDC	National Drug Codes
DHA	docosahexaenoic acid	NF	Non-Formulary
DKA	Diabetic ketoacidosis	nmCRPC	Non-Metastatic Castration-Resistant Prostate Canter
DoD	Department of Defense	nr-axSpA	non-radiographic axial spondyloarthritis
DR	Delayed release	NSCLC	Non-Small Cell Lung Cancer
ECF	Extended Core Formulary	NTRK	Orally dissolving tablet
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	OTC	Over the counter
ER	Extended release	P&T	Pharmacy and Therapeutics
EULAR	European League against Rheumatism	PA	Prior authorization
FDA	U.S. Food and Drug Administration	POD	Pharmacy Operations Division
FY	Fiscal year	POS	Point of service
GCN	Generic code number	QL	Quantity limits

Term	Definition	Term	Definition
RCT	Randomized controlled trial		
Rx	Medical Prescription		
SABA	Short-acting beta agonist		
SQ	Subcutaneous		
TAA	Trade Agreement Act		
TIB	Targeted immunomodulatory biologic		
TNF	Tumor Necrosis Factor		
UC	Ulcerative colitis		
UF	Uniform Formulary		
XR	Extended release		

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

August 2019

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on August 7 and 8, 2019, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of May 2019 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the May 2019 DoD P&T Committee meeting on July 26, 2019.

2. **Clarification of Previous Minutes**

   a) **May 2019 Meeting—Brand over Generic Requirement for ambrisentan (Letairis):** The brand over generic authorization and Tier 1 copay for Letairis was not implemented, as cost-effective generic ambrisentan formulations were widely available after the meeting.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. All Uniform Formulary (UF), Basic Core Formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year 2018. Medical necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a nonformulary (NF) medication.

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

IV. UF DRUG CLASS REVIEWS

A. High-Potency Topical Corticosteroids

Background—The full Topical Corticosteroid class was previously reviewed in August 2013. The current review was limited to only the high-potency corticosteroids. The subclass is comprised of 9 parent drugs, amcinonide, fluocinonide, halcinonide, flurandrenolide,

desoximetasone, betamethasone dipropionate, clobetasol propionate, halobetasol propionate, and diflorasone diacetate. These nine drugs are distributed across three Coopman structural classes (B, C, and D_1), and two Stoughton-Cornell potency groups (super high-potent and high-potent). Nine different potential vehicles are available: ointments, creams, lotions, solutions, foams, gels, sprays, shampoos, and tape. No one drug is available in all nine vehicles. Based on parent compound and vehicle, there are 39 total products in the subclass. Generic formulations are available for several of the products.

The clinical effectiveness review considered Coopman structural class, Stoughton-Cornell potency group, and vehicle, among other factors, when comparing the individual products, along with clinical effectiveness and safety.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- There were no major changes to the previous conclusions from the 2013 review for the following:
  - Issues of efficacy and safety within the Topical Corticosteroid class are considered class effects.
  - No particular agent within the same Stoughton-Cornell potency group and vehicle demonstrates a compelling advantage or disadvantage in either efficacy or safety compared to other agents in that same potency and vehicle group.
  - Topical corticosteroids within a potency group and vehicle are clinically interchangeable.
  - At least one product from each Coopman structural class is required on the formulary.
- Coopman Class C agents have the lowest cross-reactivity compared to products in the Coopman Class B and D_1 structural classes. Desoximetasone is the only Coopman C agent in the high-potency topical corticosteroid subclass.
- Both super high-potent and high-potent agents are necessary on the formulary, as patients refractory to less potent (Stoughton-Cornell Group 2) agents may still respond to super-high potent (Stoughton-Cornell Group 1) agents. There are currently 21 super high-potent and 18 high-potent products marketed, and there is no inherent additional clinical value to retaining all 39 products on the formulary.
- In addition to the parent structure and drug concentration, the type of vehicle also contributes to the potency classification of an individual topical corticosteroid. With regard to specific vehicle, the P&T Committee concluded the following:
  - Ointments and creams are individually unique vehicles and remain necessary options to include on the formulary. There are 9 ointments and 12 creams commercially available, and not all these products are required for Military Health System (MHS) beneficiaries.
  - Lotions, solutions, foams, and gels have overlapping utility and are advantageous for treating the scalp and large body surface areas. Foams and solutions are the preferred

vehicles for scalp use. Although hair-friendly products are necessary on the formulary, not all of the commercially available lotion, foams, and solutions are necessary for MHS beneficiaries.

  - Sprays and tape have unique features, in that sprays offer patients the convenience of treating hard-to-reach body locations (e.g., the back) while the tape offers a physical barrier.
  - The primary advantage offered by gels, sprays, shampoos, and tape is patient convenience, and none are absolutely clinically necessary components of the benefit.

- With regard to efficacy, clinical trials conducted with the high-potency topical steroids are all of low quality. There is no robust phase III clinical trial evidence available. Clobetasol continues to be the high-potency topical corticosteroid with the largest amount of literature available.
- A comprehensive updated review of safety found no major differences from the conclusions reached in 2013, except for potential issues with inactive ingredients. Inactive ingredients, including propylene glycol, can cause allergic contact dermatitis. However, there are representative members within each Coopman class (B, C, and D_1) that do not contain propylene glycol.
- Professional treatment guidelines continue to support the use of high-potency topical corticosteroids across a wide array of dermatoses, with varying levels of evidence and recommendation strengths.
- Overall, the P&T Committee agreed that there were several candidates for Tier 4/not covered status due to the clinical conclusions discussed above and the numerous representatives from each Coopman structural class, Stoughton-Cornell potency classification, and vehicle.

Relative Cost-Effectiveness Analysis and Conclusion—Cost-minimization analysis (CMA) and budget impact analysis (BIA) were performed to evaluate the High-Potency Topical Corticosteroids. For the cost analysis, branded high-potency topical steroids without generic equivalents were evaluated in detail. The P&T Committee concluded (16 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results for the subclass showed the following branded products were substantially less cost-effective than the remainder of the class: halobetasol propionate 0.01% lotion (Bryhali), flurandrenolide 4 mcg/sq. cm tape (Cordran), clobetasol propionate 0.025% cream (Impoyz), halobetasol propionate 0.05% lotion (Ultravate), and halobetasol propionate 0.05% foam (Lexette) respectively.
- BIA was performed for the subclass to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that the following designations demonstrated cost avoidance for the Military Health System (MHS):
  - Designating halobetasol propionate 0.05% cream (Ultravate & generic), clobetasol propionate/emollient 0.05% foam (Olux-E & generic),

flurandrenolide 4 mcg/sq. cm tape (Cordran), and desoximetasone 0.05% gel (Topicort & generic) as NF

- Designating clobetasol propionate 0.025% cream (Impoyz), diflorasone diacetate/emollient 0.05% cream (Apexicon-E & generic), halcinonide 0.1% cream (Halog), halobetasol propionate 0.05% foam (Lexette and authorized generic), clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan Kit), halobetasol propionate 0.01% lotion (Bryhali), halobetasol propionate 0.05% lotion (Ultravate), and halcinonide 0.1% ointment (Halog) as Tier 4

1. ***COMMITTEE ACTION: HIGH-POTENCY TOPICAL CORTICOSTEROIDS UF/TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent for all the members of the class, except for Cordran Tape: 14 for, 2 opposed, 0 abstained, 1 absent) the following formulary recommendations for the High-Potency Topical Corticosteroids as outlined below, based on clinical and cost-effectiveness.

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

   - UF
     - betamethasone dipropionate 0.05% ointment
     - betamethasone/propylene glycol 0.05% ointment, cream, lotion, gel
     - clobetasol propionate 0.05% ointment, cream, solution, lotion, shampoo, spray, gel, foam
     - clobetasol propionate/emollient 0.05% cream
     - clobetasol propionate/emollient 0.05% emulsion foam
     - desoximetasone 0.25% ointment, cream
     - fluocinonide 0.05% ointment, cream, solution, gel
     - fluocinonide/emollient base 0.05% cream
     - halobetasol propionate 0.05% ointment
     - *Note that all the agents recommended for UF status are currently on the formulary.*
   - NF
     - amcinonide 0.1% ointment (Cyclocort, generics)

- clobetasol propionate/emollient 0.05% foam (Olux-E, generics) *(moves from UF to NF status)*
- desoximetasone 0.05% gel (Topicort, generic) *(moves from UF to NF status)*
- diflorasone diacetate 0.05% ointment (Psorcon, Apexicon, generics)
- diflorasone diacetate 0.05% cream (Psorcon, Apexicon, generics)
- fluocinonide 0.1% cream (Vanos, generics)
- flurandrenolide 4 mcg/sq. cm tape (Cordran) *(moves from UF to NF status)*
- halobetasol propionate 0.05% cream (Ultravate, generics) *(moves from UF to NF status)*

- Tier 4/Not Covered
  - clobetasol propionate 0.025% cream (Impoyz)
  - clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit)
  - diflorasone diacetate/emollient 0.05% cream (Apexicon-E)
  - halcinonide 0.1% ointment (Halog)
  - halcinonide 0.1% cream (Halog)
  - halobetasol propionate 0.05% lotion (Ultravate)
  - halobetasol propionate 0.05% foam (Lexette and authorized generic) *(note that Lexette foam was previously recommended for Tier 4 status in February 2019, with implemented scheduled for August 28, 2019)*
  - halobetasol propionate 0.01% lotion (Bryhali)

  For all eight products recommended for Tier 4/Not Covered status, the P&T Committee concluded that Impoyz, Clodan kit, Apexicon-E, Halog ointment and cream, Ultravate, Lexette and authorized generic, and Bryali provide very little to no additional clinical effectiveness relative to the other high-potency topical corticosteroids. Overall, the P&T Committee felt that that the needs of TRICARE beneficiaries can be met by the other high-potency topical steroids. See Appendix H for the formulary alternatives for the Tier 4 drugs.

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) maintaining clobetasol 0.05% ointment, clobetasol 0.05% cream, fluocinonide 0.05% ointment, and fluocinonide 0.05% cream on the BCF and adding fluocinonide 0.05% solution to the BCF.

3. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for amcinonide 0.1% and diflorasone diacetate 0.05% ointments, diflorasone diacetate 0.05% cream, clobetasol propionate/emollient 0.05% foam, desoximetasone 0.05% gel, and flurandrenolide 4 mcg/sq. cm (Cordran) tape in all new and current users, due to the large number of clinically and cost-effective formulary alternatives available. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) RECOMMENDATION—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) MN criteria for amcinonide 0.1% ointment, diflorasone diacetate 0.05% ointment, diflorasone diacetate 0.05% cream, fluocinonide 0.1% cream, halobetasol propionate 0.05% cream, clobetasol propionate/emollient 0.05% foam, desoximetasone 0.05% gel, and flurandrenolide 4 mcg/sq. cm (Cordran) tape. See Appendix B for full requirements.

5. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS—*** The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing halobetasol (Ultravate) from the EMMPI list and excluding the NF topical corticosteroids from the NF to mail requirement due to acute use. See Appendix F for details.

6. ***COMMITTEE ACTION: UF/TIER 4, PA, MN, AND EMMPI IMPLEMENTATION PERIOD—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of 120 days from signing of the minutes in all points of service (POS), and 2) DHA send letters to beneficiaries who are affected by the Tier 4 decision and those affected by a change from UF to NF status. Based on the P&T Committee's recommendation, the effective date is March 4, 2020.

B. Multiple Sclerosis: Interferons and Methyl Fumarate

Background—The full Multiple Sclerosis (MS) drug class was previously evaluated for formulary status at the November 2014 P&T Committee meeting. However, this review focused on two subclasses, the Interferons and Methyl Fumarate. The other MS subclasses, including glatiramer, symptomatic agents, and oral miscellaneous drugs, were not reviewed and will maintain their current formulary status.

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

Background

- The interferons and dimethyl fumarate, along with glatiramer and the oral miscellaneous drugs, are all considered disease-modifying therapies (DMTs). DMTs are not prescribed for symptom improvement but for reducing relapses and new lesions on MRI.
- Professional treatment guidelines and MS organizations recommend availability of all DMTs without limitations and recommend choosing the appropriate MS therapy based on efficacy, safety, and individualized patient factors.

Interferons

- The five products in the subclass include the interferon beta-1b subcutaneous (SC) products (Betaseron and Extavia) and the interferon beta-1a products, Avonex intramuscular (IM), Rebif/Rebif Rebidose SC, and Plegridy IM.
- There were no significant changes from the November 2014 previous clinical conclusions which stated no one individual interferon is preferred over another in terms of efficacy or safety.
- Professional treatment guidelines from the American Academy of Neurology also do not give preference to one product over another.
- A 2017 network meta-analysis from the Institute for Clinical and Economic Review (ICER) stated the interferons are relatively similar in terms of efficacy for the relative risk of relapse rate and disability progression. Compared to placebo, the interferons have a 17%-36% reduction in the relative risk of relapse rate and a 19%-34% reduction in the relative risk of disability progression.
- The interferons have similar rates of serious adverse events and discontinuation due to adverse events. For the class, flulike symptoms are most common.
- The peginterferon beta-1a product Plegridy is similar to Avonex and Rebif, with the exception that it is a pegylated formulation. Plegridy may be associated with more serious adverse events than other interferons but shows a similar discontinuation rate with the other products.
- Interferons generally have fewer adverse events compared to other DMTs.
- Although Betaseron and Extavia utilized the same registration studies to gain FDA approval and contain the same active ingredient, the two products are not interchangeable at the pharmacy.
- There is a high degree of therapeutic interchangeability between the interferons.

Methyl Fumarate

- Dimethyl fumarate (Tecfidera) is an oral tablet and is currently the only product in the methyl fumarate subclass.
- There are no head-to-head trials comparing dimethyl fumarate and other DMTs.

- The 2017 ICER network meta-analysis showed that compared to placebo, treatment with dimethyl fumarate resulted in a 47% reduction in the relative risk of relapse rate and a 38% reduction in the relative risk of disability progression.
- Dimethyl fumarate (Tecfidera) has more serious adverse events and a greater discontinuation rate compared to the interferons.
- Dimethyl fumarate requires monitoring of the complete blood count and lymphocytes, due to the potential risk of developing progressive multifocal leukoencephalopathy (PML)
- At least two methyl fumarate products are pending FDA approval for late 2019 and mid-2020.

Overall Conclusion

- Patients with MS who are stable on an individual DMT should continue their current therapy unless the patient and provider decide a trial off therapy is warranted.
- In order to meet the needs of MHS beneficiaries, at least one interferon and one methyl fumarate product are required on the UF.
- The other DMT MS classes will remain on the UF.

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

Interferon Subclass

- CMA results for the Interferon subclass showed that Extavia and Betaseron were the most cost effective products, followed by the interferon beta-1a products.
- BIA was performed for the Interferon subclass to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating interferon beta-1a SQ (Rebif and Rebif Rebidose), interferon beta-1a IM (Avonex IM), interferon beta-1b SC (Betaseron), and interferon beta-1b SC (Extavia) as UF and peginterferon beta-1a SC (Plegridy) as NF demonstrated cost avoidance for the Military Health System (MHS).

Methyl Fumarate Subclass

- BIA results for the Methyl Fumarate subclass showed that designating dimethyl fumarate (Tecfidera) as UF demonstrated cost avoidance for the MHS.

1. ***COMMITTEE ACTION: MULTIPLE SCLEROSIS INTERFERONS AND METHYL FUMARATE UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) the following:

Interferons

- UF
    - interferon beta-1a IM (Avonex)
    - interferon beta-1a SC (Rebif, Rebif Rebidose)
    - interferon beta-1b SC (Betaseron)
    - interferon beta-1b (Extavia)
- NF:
    - peginterferon beta-1a SC (Plegridy)

Methyl Fumarate

- UF
    - dimethyl fumarate (Tecfidera)
- NF
    - None

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) removing Betaseron from the BCF; as a result there will not be an MS drug on the BCF.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—For dimethyl fumarate (Tecfidera) PA criteria have been in place since November 2013 to ensure appropriate safety monitoring. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) updating the current manual PA criteria for dimethyl fumarate (Tecfidera) in new users to only allow use for the FDA-labeled indication of MS. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) maintaining the current MN criteria for peginterferon beta-1a (Plegridy), which have been in place since May 2015. See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: MAIL ORDER REQUIREMENTS FOR INTERFERON AGENTS—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) adding dimethyl fumarate (Tecfidera) to the EMMPI program.

6. ***COMMITTEE ACTION: SPECIALTY CARE DRUG LIST—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) adding Plegridy to the Specialty Care Drug List, since the other MS drugs are in the program.

7. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) implementation effective the first Wednesday one week after signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is November 6, 2019.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 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 August 2019 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. ***COMMITTEE ACTION: UF/TIER 4/NOT COVERED RECOMMENDATION—*** The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
  - alpelisib (Piqray) – Oncological Agent for breast cancer
  - amifampridine (Ruzurgi) – Miscellaneous Neurological Agent for Lambert-Eaton myasthenic syndrome (LEMS)
  - amphetamine sulfate orally disintegrating IR tablet (Evekeo ODT) – Attention Deficit Hyperactivity Disorder (ADHD)
  - dolutegravir/lamivudine (Dovato) – Single-tablet regimen (STR) antiretroviral for Human Immunodeficiency Virus (HIV)
  - erdafitinib (Balversa) – Oral Oncological Agent for urothelial cancer
  - halobetasol propionate 0.01%/tazarotene 0.045% lotion (Duobrii) – Combination product for Plaque Psoriasis
  - immunoglobulin subcutaneous injection (Cutaquig) – Immunoglobulin for Immune Deficiency Disorders
  - mepolizumab injection (Nucala) – Miscellaneous Pulmonary I Agent severe asthma and eosinophilic granulomatosis with polyangiitis (EGPA) *(note refers to self-administered syringe and auto-injector, not the vial)*
  - methylphenidate extended-release sprinkle capsules nighttime dosing (Jornay PM) – ADHD

        - tafamidis (Vyndaqel) – Miscellaneous Neurological Agents cardiomyopathy associated with hereditary transthyretin-mediated amyloidosis (ATTR-CM)
        - triclabendazole (Egaten) – Antiinfectives: Anthelmintics for fascioliasis
    - NF:
        - drospirenone (Slynd) – Progestogen-only contraceptive agent
        - galcanezumab-gnlm 100 mg injection (Emgality) – Migraine Agents: Calcitonin gene-related peptide (CGRP) inhibitors for cluster headache. *Note that the Emgality 120 mg injection formulation for prevention of migraine headache remains on the UF.*
        - risankizumab-rzaa injection (Skyrizi) – Targeted Immunomodulatory Biologic (TIB) for Plaque Psoriasis
        - rosuvastatin sprinkle capsules (Ezallor Sprinkle) – Antilipidemics-I
        - solriamfetol (Sunosi) –Wakefulness Promoting Agent
    - Tier 4 (Not Covered):
        - methylphenidate extended-release sprinkle capsules (Adhansia XR) – ADHD
            - Adhansia XR was recommended for Tier 4 status as it has very little to no additional clinical effectiveness relative to similar ADHD drugs; there is a significant safety risk due to its very long duration of action (particularly in children for insomnia and weight loss) relative to other ADHD drugs; and the needs of TRICARE beneficiaries are met by alternative agents.
                - Formulary methylphenidate ER alternatives to Adhansia XR include Aptensio XR sprinkle cap and Quillivant XR suspension for patients with swallowing difficulties; Concerta, generics; Ritalin LA, generics; Metadate CD, generics; dexmethylphenidate ER (Focalin XR, generics) and mixed amphetamine salts (Adderall XR, generics). (See Appendix H.)

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Sunosi, Ezallor Sprinkle, Slynd, Skyrizi, and Emgality 100 mg injection. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- ADHD: Applying manual PA criteria to new and current users of Jornay PM, requiring a trial of other clinically efficacious, safe, and cost-effective methylphenidate ER formulations with long durations of action first,

including branded products targeted for patients with swallowing difficulties (i.e., Quillivant XR suspension or Aptensio XR sprinkle capsule).

- TIBs: Applying the same manual PA criteria in new users of Skyrizi that is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira). Additionally for Skyrizi a trial of both secukinumab (Stelara) and ustekinumab (Cosentyx) is required if the patient cannot be treated with Humira.
- Migraine Agents: CGRP Inhibitors for Cluster Headache: Manual PA criteria apply to the CGRP Inhibitors that are approved for prevention of migraine headache, including Emgality 120 mg injection. PA criteria will apply to new users of Emgality 100 mg syringe for cluster headache, requiring a trial of traditional preventive therapies, including verapamil, topiramate or lithium. Use of Emgality 100 mg will not be allowed for prevention of migraine headache.
- Applying manual PA criteria to new and current users of Sunosi and Nucala.
- Applying manual PA criteria to new users of Ruzurgi, Ezallor Sprinkle, Piqray, Balversa, Vyndaqel, and Evekeo ODT.

D. ***COMMITTEE ACTION: UF/TIER 4/NOT COVERED, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 0 abstained, 0 absent) the following:

- **New Drugs Recommended for UF or NF Status:** an effective date upon two weeks after signing of the minutes in all points of service, on November 13, 2019.

- **New Drugs Recommended for Tier 4 Status methylphenidate extended-release capsules (Adhansia XR):** 1) an effective date of the first Wednesday after a 120-day implementation period at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is March 4, 2020.

VI. BCF CLARIFICATION: POTASSIUM CHLORIDE (KCl) PRODUCTS

The BCF currently includes several potassium chloride (KCl) formulations. The P&T Committee responded to an MTF request to delete KCl 20 mEq packets from the BCF, based on cost. A lower-cost alternative product, 20 mEq dispersible tablets (generic Klor-Con M20 tablets), which can be mixed with water to form a suspension, is currently on the BCF and commonly dispensed by the MTFs. A review of all the KCl BCF formulations found the

20 mEq packet and 20 mEq/15 mL (10%) liquid are significantly more costly than the other KCl formulations.

A. ***COMMITTEE ACTION: POTASSIUM CHLORIDE (KCl) PRODUCTS ON THE BCF—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) removing both the KCl 20 mEq packets (GCN 03404) and 20 mEq/15 mL (10%) liquid (GCN 03443) from the BCF. The KCl products remaining on the BCF are the 10 mEq ER tablets (generic K-Tab ER) (GCN 03510), 20 mEq dispersible tablets (generic Klor-Con M20) (GCN 03513), and 10 mEq ER caps (GCN 03321).

VII. UTILIZATION MANAGEMENT

A. PA Criteria and Step Therapy

1. New Manual PA Criteria—New manual PA criteria were recommended by the P&T Committee due to a variety of reasons. The new manual PAs outlined below will apply to new users for the oncology drugs Alecensa, Alunbrig, Zykadia, and Xalkori, the orthostatic hypotension product Northera and to new and current users for the prescription multivitamin Azesco and tetracycline product doxycycline hyclate ER 80 mg. See Appendix C for the full criteria of the drugs with new manual PA criteria.

a) Antibiotics: Tetracyclines – Doxycycline hyclate extended-release 80 mg – Oral tetracycline antibiotic for acne vulgaris or rosacea

PA criteria were recommended for this new 80 mg ER doxycycline hyclate available from a single manufacturer. The P&T Committee reviewed the oral tetracycline class in February 2017 and agreed there is little evidence to support advantages of the newer doxycycline products over the traditional generic formulations in terms of salt (monohydrate versus hyclate), dosage form (tablet versus capsule versus scored tablets), or release mechanisms (IR versus ER versus DR). Cost-effective generic formulations of doxycycline hyclate (i.e., 50 mg and 100 mg immediate release) are available on the UF without a PA required.

COMMITTEE ACTION: DOXYCYCLINE HYCLATE EXTENDED-RELEASE 80 MG MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of doxycycline hyclate ER 80 mg tablets. See Appendix C for the full criteria.

b) Oral Oncologic Agents: alectinib (Alecensa), brigatinib (Alunbrig), ceritinib (Zykadia), and crizotinib (Xalkori)

PA criteria have not previously been required for the non-small cell lung cancer (NSCLC) drugs; however, PA is in place for several oncological drug classes. The P&T Committee reviewed four oral oncologic agents, Alecensa, Alunbrig, Zykadia,

and Xalkori. PA criteria were recommended for these four products in new users in order to ensure prescribing in accordance with FDA-approved indications or National Comprehensive Cancer Network (NCCN) Guideline-endorsed off-label indications.

COMMITTEE ACTION: ALECTINIB (ALECENSA), BRIGATINIB (ALUNBRIG), CERITINIB (ZYKADIA), AND CRIZOTINIB (XALKORI) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new users. See Appendix C for the full criteria.

c) Vitamins: Prenatal – Prenatal multivitamin (Azesco)

Azesco is a prenatal multivitamin manufactured by a single manufacturer and requires a prescription prior to dispensing. The primary ingredients of Azesco are 13 mg of iron and 1 mg of folic acid. Prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than age 45. This agent was identified as having numerous cost-effective alternatives (including Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA) that are available on the UF, where a PA is not required.

COMMITTEE ACTION: PRENATAL MULTIVITAMIN (AZESCO) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for new and current users of Azesco, regardless of the woman's age. See Appendix C for the full criteria.

d) Cardiovascular Agents Miscellaneous: Droxidopa (Northera)

Droxidopa (Northera) is an alpha/beta agonist approved in February 2014 for neurogenic orthostatic hypotension (NOH). The product labeling for Northera contains a black box warning that it may cause or exacerbate supine hypertension. A consensus statement from the American Autonomic Society and the National Parkinson Foundation for NOH was published in 2017 and recommends treatments include midodrine, fludrocortisone, and pyridostigmine, in addition to droxidopa. No one pharmacologic treatment is preferred over another in the guidelines. PA criteria were recommended for Northera to ensure appropriate use of clinically and cost-effective alternative therapies for neurogenic orthostatic hypotension first.

COMMITTEE ACTION: DROXIDOPA (NORTHERA) MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for droxidopa in new users. See Appendix C for the full criteria.

2. **Updated Manual PA Criteria and Step Therapy**—Updates to the step therapy and manual PA criteria for several drugs were recommended by the P&T Committee due to a variety of reasons, including expanded FDA indications, pediatric uses, clinical trial data or to be consistent with existing PAs for the drug class. The updated manual PAs outlined below will apply to new users. See Appendix C for the full criteria of the drugs with updated manual PA criteria.

   a) Updated Criteria for reasons other than new FDA indications

   - Gastrointestinal-2 Agents: telotristat ethyl (Xermelo) – Manual PA criteria for Xermelo were first recommended in May 2017. Manual PA criteria for Xermelo were updated to reflect the TELECAST trial, which allowed for use in carcinoid syndrome diarrhea in persons having fewer than 4 bowel movements per day with or without concurrent somatostatin analog therapy.
   - Neurological Agents Miscellaneous: amifampridine (Firdapse) – Manual PA criteria for Firdapse for treating LEMS were first recommended in May 2019. Ruzurgi is another amifampridine formulation (see section V, A on page 10). Although the package labeling for Ruzurgi states it is approved for pediatric patients, the clinical trial used to gain FDA approval was conducted in adult patients with a mean age of 52 years, and the maximal dosing is higher with Ruzurgi than Firdapse (100 mg vs. 80 mg, respectively). Ruzurgi is cost-effective compared to Firdapse. Manual PA criteria for Firdapse were updated to require a trial of the cost-effective amifampridine agent Ruzurgi first in new patients.
   - Parkinson's Agents: levodopa inhalation powder (Inbrija) – Manual PA criteria for Inbrija were first recommended in May 2019. Manual PA criteria were updated to remove the 1-year expiration date and renewal criteria, as the other Parkinson's drugs have PAs that do not expire.

   b) New FDA-Approved Indications or Age Ranges

   - ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents: sodium oxybate (Xyrem) – Manual PA criteria were updated to reflect a new FDA-approved indication for use in children ≥ 7 years of age for the treatment of cataplexy in patients with narcolepsy.
   - Corticosteroids – Immune Modulators: Atopic Dermatitis: dupilumab (Dupixent) – Manual PA criteria were updated for the new indication for add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.
   - Cystic Fibrosis Agents: tezacaftor/ivacaftor (Symdeko) – Manual PA criteria were updated to reflect a new indication for treatment of patients ≥ 6 years of age in the treatment of cystic fibrosis.
   - Hematological agents: Platelets: avatrombopag (Doptelet) – Manual PA criteria were updated to reflect a new indication for thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

- Immunosuppressives: belimumab (Benlysta) – Manual PA criteria were updated to reflect a new indication for the treatment of patients as young as 5 years of age with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy.
- Oncological Agents: Acute Myelogenous Leukemia: ivosidenib (Tibsovo) – Manual PA criteria were updated to reflect a new indication for the treatment of adult patients with newly diagnosed acute myelogenous leukemia (AML) who are aged 75 years and older or who have comorbidities that preclude use of intensive induction chemotherapy.
- Targeted Immunomodulatory Biologics (TIBs) – Non-Tumor Necrosis Factor (TNF) Inhibitors: apremilast (Otezla) – Manual PA criteria were updated to reflect a new indication for treatment of adult patients with oral ulcers associated with Behçet's disease. Note that for Behçet's disease, a trial of adalimumab (Humira) is not required first.
- Targeted Immunomodulatory Biologics (TIBs) – Tumor Necrosis Factor (TNF) Inhibitors: adalimumab (Humira) – Manual PA criteria for Humira were updated to allow for off-label use in pediatric patients for plaque psoriasis. In the European Union, Humira is approved in the pediatric population for plaque psoriasis, and data exists to support its use in this age group. Note that pediatric patients are not required to use the DoD's step-preferred Humira first for plaque psoriasis given that it is currently off-label in the United States.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA— The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Xyrem, Dupixent, Symdeko, Doptelet, Benlysta, Tibsovo, Otezla, Humira, Xermelo, Firdapse, and Inbrija. See Appendix C for the full criteria.

c) Weight Loss Agents—The P&T Committee was briefed on trends in the current utilization and spend for the weight loss agents, which were reviewed in November 2017. Generic phentermine is the most utilized weight loss agent, while liraglutide 3 mg injection (Saxenda) is the second most utilized weight loss agent, but ranks first in total cost per patient. A review of Saxenda claims data found that the majority of patients did not meet the criteria for a trial of other branded weight loss drugs first. The P&T Committee recommended updating the manual PA criteria for liraglutide 3 mg (Saxenda) to streamline the PA form and more closely reflect the original intent of the November 2017 P&T Committee meeting

A. ***COMMITTEE ACTION: LIRAGLUTIDE 3 MG (SAXENDA) MANUAL PA CRITERIA—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) updating the manual PA criteria for new and current users of Saxenda who do not have a diagnosis of diabetes. Affected patients will receive letters notifying them of this

decision. Previous trials of other weight loss drugs must be documented prior to use of Saxenda. See Appendix C for the full criteria.

B. COMMITTEE ACTION: LIRAGLUTIDE 3 MG (SAXENDA) PA IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date 60 days after the signing of the minutes in all points of service, on January 8, 2020.

B. Quantity Limits (QLs)

1. General QLs: QLs were reviewed for 28 drugs from several classes, including 8 newly approved drugs, 3 drugs where existing QLs were either updated or new QLs placed, and 17 nasal steroid inhalers for allergic rhinitis.

COMMITTEE ACTION: QLs—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) QLs for Vyndaqel, Skyrizi, Balversa, Piqray, Emgality 100 mg syringe, Nucala, Ruzurgi, Sunosi, Northera, Lucemyra, Doptelet, and nasal steroids including Astepro, Atrovent 0.03%, Atrovent 0.03% 15 mL, Atrovent 0.06%, Beconase AQ, Qnasl 40 mcg and 80 mcg, Rhinocort Aqua, Dymista, flunisolide, Nasonex, Patanase, Omnaris, Zetonna, Nasacort AQ, Flonase, Veramyst, and Xhance. See Appendix D for the QLs.

C. PA and QLs Implementation Periods

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

- (16 for, 0 opposed, 0 abstained, 1 absent) New PAs for Alecensa, Alunbrig, Zykadia, Xalkori, Azesco, Northera, and doxycycline hyclate ER 80 mg become effective 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for Azesco and doxycycline hyclate extended-release 80 mg if applicable, as new and current users will be subject to the PA.
- (15 for, 0 opposed, 0 abstained, 2 absent) Updates to the current PA criteria for Firdapse, Xermelo, Inbrija, Xyrem, Symdeko, Benlysta, Otezla, Tibsovo, Dupixent, Doptelet, and Humira in new users become effective 30 days after the signing of the minutes.
- (16 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 28 drugs listed in section VI B above, and in Appendix D, become effective on the first Wednesday two weeks after the signing of the minutes in all POS.

VIII. LINE EXTENSIONS

The P&T Committee clarified the formulary status for 2 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 (16 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following 2 products to reflect the current formulary status and applicable step therapy, PA criteria, MN criteria, QLs, and EMMPI status for the parent compound. Implementation will occur on the first Wednesday two weeks after signing of the minutes.

- Neurological Agents Miscellaneous: Movement Disorders – Valbenazine (Ingrezza) initiation pack is now available. Previously, Ingrezza was only available in 40 mg and 80 mg capsules. The P&T Committee recommended designating the Ingrezza initiation pack as UF with the same manual PA requirements as the Ingrezza capsules.

- Oncological Agents: Lung Cancer – Ceritinib (Zykadia) tablets are now available whereas they were previously available only in capsules. The P&T Committee recommended designating Zykadia tablets as UF with the same PA and QL requirements as the Zykadia capsules.

IX. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE MAIL ORDER PROGRAM

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

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

1. ***COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—***The P&T Committee recommended (group 1: 16 for, 0 opposed, 0 abstained, 1 absent; group 2: 17 for, 0 opposed, 1 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI program for the reasons outlined in the table. See Appendix F.

B. Drugs Selected for Removal from the Program

The P&T Committee reviewed the status of three products currently included on the EMMPI List: conjugated estrogens vaginal cream (Premarin cream), estradiol vaginal cream (Estrace), and leuprolide depot injection for 4-month administration (Lupron Depot 4-month kit). Dosing for all three of these drugs exceeds (Lupron Depot 4-month kit) or potentially may exceed (Premarin and Estrace creams) a duration of use longer than 30 days. Express Scripts maintains these agents on specialized adjudication lists that allow pharmacies to enter the correct days' supply; however, this logic conflicts with the 30-day-per-fill rule for the EMMPI program (which allows two 30-day fills at retail before the branded maintenance medications included on the EMMPI list must be filled at MTFs or Mail).

2. ***COMMITTEE ACTION: CHANGES TO THE EXPANDED MTF/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM—***The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) removing conjugated estrogens (Premarin) cream, estradiol (Estrace) cream, and leuprolide depot injection for 4-month administration (Lupron Depot 4-month kit) from the EMMPI List.

X. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OVER-THE-COUNTER (OTC) FORMULARIES AT MTFS: TOPICAL CORTICOSTEROIDS AND TOPICAL ANTIFUNGALS

Background—The DoD P&T Committee continued reviewing the OTC drugs on the MHS GENESIS OTC list. For a full description of the background and process details, refer to the May 2019 DoD P&T Committee meeting minutes, found at http://health.mil/PandT. Factors influencing whether a particular OTC product was retained or removed from the MHS GENESIS OTC List included such things as volume and utilization across multiple MTFs; feedback from MTF providers to include the Primary Care Clinical Communities, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

1) *OTC Topical Corticosteroids: hydrocortisone*

- The OTC topical steroids category includes only topical products, and not those intended for rectal use, which will be reviewed at a future meeting.
- The most commonly dispensed OTC hydrocortisone products at the MTFs were for the 1% cream and 1% ointment. The hydrocortisone 1% cream with aloe vera and 1% lotion were infrequently dispensed. Hydrocortisone 1% lotion is about 8 times more costly than the cream or ointment.
- There is relatively low utilization of OTC hydrocortisone 0.5% products, and feedback revealed that the 0.5% strength is seen as generally less effective or unnecessary compared to the 1% strength.
- Hydrocortisone cream, ointment, and lotion are also available in a 2.5% concentration as legend products, with hydrocortisone 2.5% cream accounting for the bulk of legend use at the MTFs.

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

- removing the following products from the MHS GENESIS OTC List: hydrocortisone 0.5% cream, lotion, and ointment; hydrocortisone 1% lotion; and hydrocortisone 1% cream with aloe vera;
- retaining hydrocortisone 1% cream (GCN 30942) and 1% ointment (GCN 30951) on the MHS GENESIS OTC list.
- The P&T Committee did not recommend adding or retaining any other OTC hydrocortisone product on the list.

B. COMMITTEE ACTION: IMPLEMENTATION—Removal of the above items from the MHS GENESIS OTC List is expected to have relatively little impact at the current GENESIS sites or the next wave sites expected to implement MHS GENESIS in September 2019 (Mountain Home, Lemoore, Monterey, and Travis). The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 120 days following signing of the minutes. Letters were not recommended due to the limited duration of use for these products.

2) *OTC Topical Antifungals*

- *Azole antifungals*
  - This category includes only topical OTC clotrimazole, miconazole, and ketoconazole products, with vaginal products to be reviewed by the P&T Committee at a later date.
  - Products in this category are most commonly used for cutaneous candidiasis; the non-azole antifungals appear more effective for tinea infections.
  - The most commonly dispensed OTC antifungals at the MTFs include clotrimazole 1% cream, miconazole 2% cream, clotrimazole 1% solution, miconazole 2% powder, miconazole 2% tincture, and miconazole 2% aerosolized powder.
  - OTC ketoconazole 1% shampoo was not dispensed at the MTFs, in contrast to the prescription 2% concentration, which had a significant amount of use.
- *Non-azole antifungals*
  - The majority of MTF utilization of the OTC non-azole antifungals included terbinafine 1% cream and tolnaftate 1% powder. There was relatively little use of tolnaftate 1% cream, OTC butenafine 1% cream, and tolnaftate 1% solution.
  - MTF feedback indicated a preference for terbinafine (when a preference was expressed), with several respondents expressing support for a powder formulation (i.e., tolnaftate powder). Tolnaftate 1% powder is less costly on a per package basis, relative to terbinafine 1% cream.
- *Gentian violet*

- Gentian violet is an antiseptic dye with antifungal and weak antibacterial effects; it can be used on minor cuts and scrapes to prevent infection. It also may be used for *tinea corporis* and oral candidiasis, but it is not the preferred treatment for either condition.
- There may be a potential association of gentian violet with cancer development, but supporting data are sparse and primarily based on studies in rats and mice. There is also some evidence suggesting potential efficacy of gentian violet as an anti-cancer agent.
- MTF feedback indicated that it is used primarily as a back-up if nystatin suspension is unavailable and that overall Gentian violet is rarely used.

- *Need for provider group feedback*–Having feedback from a wider community of providers is desirable when changes are recommended to the OTC MHS GENESIS test list. The P&T Committee requested that input from the relevant clinical communities of MTF providers established under DHA be routinely sought.

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

- removing clotrimazole 1% solution; miconazole 2% cream, powder, aerosolized powder, and tincture;
- removing tolnaftate 1% cream;
- removing gentian violet 1% and 2% solution; and
- retaining clotrimazole 1% cream (GCN 30370), terbinafine 1% cream (GCN 62498), and tolnaftate 1% powder (GCN 30310) on the MHS GENESIS OTC List.
- The P&T Committee did not recommend adding or retaining any other OTC antifungal product on the list.

B. *COMMITTEE ACTION: IMPLEMENTATION*—Removal of the above OTC antifungals from the MHS GENESIS OTC List is expected to have relatively little impact at the current GENESIS sites or the next wave sites expected to implement MHS GENESIS in September 2019 (Mountain Home, Lemoore, Monterey, and Travis). The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 120 days following signing of the minutes. Letters were not recommended due to the limited duration of use for these products.

Note that the Primary Care Clinical Communities that serve to advise DHA on various matters that affect providers and the patients served by those providers provided feedback that concurred with the conclusions of the P&T Committee.

XI. SPECIALTY CARE LIST

Background—The Specialty Care Drug List (also known as the Clinical Services Drug List) identifies drugs for which Express Scripts provides additional clinical services at the Mail Order Pharmacy under the TRICARE pharmacy contract, which started in May 2015. Services provided at Mail Order include dedicated call lines for patient support, refill reminders, outgoing clinical calls to encourage adherence and provide patient education, and expedited/scheduled delivery. Medications on this list must be filled either through Mail Order, at an MTF, or at a retail network pharmacy in the Specialty Drug Network, which currently includes Kroger, Rite-Aid, Walgreens, and Walmart pharmacies. Adding new medications to the Specialty Care Drug List would require patients currently filling prescriptions for these medications at a retail pharmacy not in the Specialty Drug Network to move their prescriptions to one of these preferred points of service.

The Specialty Care program is distinct from the Enhanced MTF/Mail Pharmacy Initiative (EMMPI) program, which requires select branded maintenance medications to be filled at MTFs or Mail Order after two initial fills at retail. It is possible for medications to be added to both the Specialty Care Program and the EMMPI program: in this case, patients would be required to fill prescriptions for these medications at MTFs or Mail Order after two initial fills at retail and would receive additional clinical services and expedited/schedule delivery at Mail Order. There is less potential patient impact if medications are added to both programs simultaneously, since patients currently receiving their medications at a retail network pharmacy not in the Specialty Drug Network would only have to move their prescriptions once.

The cost of branded specialty medications is typically higher at retail pharmacies than at MTFs or Mail Order; however, availability of specialty medications at Mail Order depends on a number of factors, including manufacturer access programs (e.g., limited distribution agreements), drug safety program requirements, and prime vendor availability. In some cases, Express Scripts is able to work with manufacturers and the prime vendor to establish mail order availability for specialty products.

Drugs Added to the Specialty Care Program

Oral Oncologic Agents for Non-Small Cell Lung Cancer: alectinib (Alecensa) —The P&T Committee reviewed alectinib (Alecensa), an oral medication for advanced non-small cell lung cancer, for addition to the EMMPI and Specialty Care programs. Alectinib is both feasible to provide at Mail Order according to Express Scripts and more costly to provide at retail than at MTFs or Mail Order. Adding a drug to the Specialty Care Program provides additional clinical services and ensures an expedited and scheduled delivery. The P&T Committee requested that the impact of adding alectinib to the two programs should be monitored by Express Scripts for review by the P&T Committee, prior to considering further additions to the program.

A. ***COMMITTEE ACTION: SPECIALTY CARE DRUG LIST***—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 1 absent) adding alectinib (Alecensa) to the Specialty Care Drug List and the EMMPI program, with implementation as soon as feasible following signing of the minutes. No specific letters are necessary since, under the EMMPI program, beneficiaries filling prescriptions for alectinib at retail will receive letters following each of

their next two retail prescription fills. Beneficiaries will also receive an introductory mailing from the Specialty Care program.

Note that Plegridy was also added to the Specialty Care Drug List (see p. 9).

XII. ITEMS FOR INFORMATION

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

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

XIII. ADJOURNMENT

The meeting adjourned at 1600 hours on August 8, 2019. The next meeting will be in November 2019.

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

Mr. Guy Kiyokawa
Deputy Director, DHA
for Ronald J. Place
LTG, MC, USA
Director

30 OCT 19
Date

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

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Mr. David Bobb	Chief, DHA Pharmacy Operations Division (POD)
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder) POD
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Peter Cole, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
LCDR Christopher Janik, USCG for CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Kelly Echevarria, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Erik Troff	DHA, Deputy General Counsel
Lt Col Derek Underhill, BSC	DLA Troop Support
Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Ms. Kimberlymae Wood	DHA Contracting Office
Mr. James Berns	Chief, DHA Contracting Office
Ms. Viktoria Reed	DHA Contracting
CAPT Chris Lamer	Indian Health Service
Maj Rachel Copeland, BSC	Director of Pharmacy, Lackland AFB

Appendix A—Attendance (continued)

Guests Continued	
LCDR Garret Hand, MSC	NAS Corpus Christi
MAJ Allison Sternberg, MSC	Chief, Pharmacy Branch, Ft Sam Houston
CDR Marisol Martinez	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program
Others Present	
CDR Heather Hellwig, MSC	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
CDR Scott Raisor, BCACP	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
MAJ Matthew Krull	DHA Formulary Management Branch
Eugene Moore, PharmD, BCPS	DHA Purchased Care Branch
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Cortney Raymond	DHA Formulary Management Branch Contractor
LT Danielle Kerr	Naval Medical Center San Diego Pharmacy Resident
Alana Coleman	University of Texas at Austin Pharmacy Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• amcinonide 0.1% ointment • diflorasone diacetate 0.05% ointment **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** betamethasone dipropionate 0.05%, betamethasone/propylene glycol 0.05%, clobetasol propionate 0.05%, desoximetasone 0.25%, fluocinonide 0.05%, halobetasol propionate 0.05% ointments
• clobetasol propionate/emollient 0.05% foam • desoximetasone 0.05% gel **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** fluocinonide 0.05% solution and gel, clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo, betamethasone/propylene glycol 0.05% lotion, betamethasone dipropionate 0.05% gel, and clobetasol propionate/emollient 0.05% (emulsion) foam
• diflorasone diacetate 0.05% cream • fluocinonide 0.1% cream • halobetasol propionate 0.05% cream **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** betamethasone/propylene glycol 0.05%, clobetasol propionate 0.05%, clobetasol propionate/emollient 0.05%, desoximetasone 0.25%, fluocinonide 0.05%, and fluocinonide/emollient base 0.05% creams
• flurandrenolide 4 mcg/sq. cm (Cordran) tape **High-Potency Topical Corticosteroids**	• Patient has experienced or is likely to experience significant adverse effects from all formulary agents. **Formulary Alternatives:** fluocinonide 0.05% ointment, solution, and gel, clobetasol propionate 0.05% ointment, cream, solution, lotion, gel, foam, spray, and shampoo, betamethasone/propylene glycol 0.05% ointment, cream, and lotion, betamethasone dipropionate 0.05% ointment and gel, clobetasol propionate/emollient 0.05% (emulsion) foam, clobetasol propionate/emollient 0.05% cream, desoximetasone 0.25% ointment and cream, fluocinonide/emollient 0.05% cream, and halobetasol propionate 0.05% ointment
• Peginterferon beta-1a (Plegridy) **Multiple Sclerosis: Injectable – Interferons**	• No alternative formulary agent: patient requires Plegridy and cannot be treated with Avonex or Rebif. **Formulary Alternatives:** interferon beta-1a (Rebif), interferon beta-1a (Avonex), Copaxone, Betaseron, Extavia, and the oral agents
• drospirenone (Slynd) **Contraceptive Agents: Progestogen-Only**	• Patient has experienced significant adverse effects from formulary agent **Formulary Alternative:** norethindrone (Nor-QD, Jolivette, generics)
• galcanezumab-gnlm injection (Emgality 100 mg) **Migraine Agents: CGRP Cluster Headache**	• Other drugs for cluster headache have resulted in therapeutic failure **Formulary Alternatives:** verapamil, topiramate, lithium

Drug / Drug Class	Medical Necessity Criteria
• risankizumab-rzaa injection (Skyrizi) **TIBs**	• Use of adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) is contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) • Adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara) result or are likely to result in therapeutic failure. **Formulary Alternative:** Adalimumab (Humira), secukinumab (Cosentyx), and ustekinumab (Stelara)
• rosuvastatin sprinkle (Ezallor Sprinkle) **Antilipidemics-1**	• No alternative formulary agent: Patient requires simvastatin, atorvastatin, or rosuvastatin and cannot swallow tablets **Formulary alternatives:** rosuvastatin, simvastatin, atorvastatin
• solriamfetol (Sunosi) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	• Use of three formulary agents (armodafinil, modafinil, and methylphenidate or amphetamine) have resulted in therapeutic failure **Formulary Alternatives:** armodafinil, modafinil, methylphenidate, amphetamine

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
• amcinonide 0.1% ointment • diflorasone diacetate 0.05% ointment **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of amcinonide 0.1% ointment and diflorasone diacetate 0.05% ointment. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives, including clobetasol propionate 0.05% and fluocinonide 0.05% ointments. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to fluocinonide 0.05% AND desoximetasone 0.25% AND betamethasone dipropionate 0.05% ointments. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time
• clobetasol propionate/emollient 0.05% foam **High-Potency Topical Corticosteroids**	PA apply to all new and current users of clobetasol propionate/emollient 0.05% foam. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives, including fluocinonide 0.05% solution and clobetasol propionate 0.05% solution. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to clobetasol propionate 0.05% solution, lotion, gel, AND foam. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time
• desoximetasone 0.05% gel **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of desoximetasone 0.05% gel. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives including fluocinonide 0.05% solution and clobetasol propionate 0.05% solution. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to fluocinonide 0.05% solution AND gel. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days. No PA renewals allowed; patients must fill out a new PA each time
• diflorasone diacetate 0.05% cream **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of diflorasone diacetate 0.05% cream. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • This agent has been identified as having cost-effective alternatives, including fluocinonide 0.05% and betamethasone/propylene glycol 0.05% creams. These agents do not require a PA. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to fluocinonide 0.05% AND betamethasone/propylene glycol (augmented) 0.05% AND desoximetasone 0.25% creams. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time

Drug / Drug Class	Prior Authorization Criteria
• flurandrenolide 4 mcg/sq. cm (Cordran) tape **High-Potency Topical Corticosteroids**	PA criteria apply to all new and current users of Cordran tape. Manual PA Criteria: Coverage is approved if ALL of the following criteria are met: • Written by a dermatologist or plastic surgeon • The provider acknowledges that this agent has been identified as having cost-effective alternatives, including clobetasol propionate 0.05% ointment and fluocinonide 0.05% cream and solution. These agents do not require a PA. • The provider acknowledges that barrier function can be accomplished by using an alternative agent (e.g., fluocinonide 0.05% cream) with an occlusive dressing. Please note occlusion increases transmission (i.e., potency); a lower potency agent should be used as an alternative to flurandrenolide tape if used with a barrier. • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to clobetasol propionate 0.05% ointment OR halobetasol propionate 0.05% ointment OR betamethasone dipropionate 0.05% ointment. • Please describe why this agent is required as opposed to available alternatives. PA expiration: 30 days No PA renewals allowed; patients must fill out a new PA each time
• dimethyl fumarate (Tecfidera) **Multiple Sclerosis: Methyl Fumarate**	**Changes from August 2019 are in BOLD** Manual PA criteria apply to new users of Tecfidera. Manual PA Criteria: Coverage approved for patients with: • Documented diagnosis of relapsing forms of multiple sclerosis (MS). • Complete blood count drawn within six months prior to initiation of therapy, due to risk of lymphopenia. • Coverage NOT provided for concomitant use with other disease-modifying drugs of MS **Non-FDA-approved uses are not approved.** PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• alpelisib (Piqray) **Oncological Agents: Breast Cancer**	Manual PA is required for all new users of Piqray. Manual PA Criteria: Piqray is approved if all criteria are met: • Patient must be ≥18 years. • Patient is diagnosed with advanced or metastatic HR positive, HER2 negative breast cancer with PIK3CA mutation as confirmed by an FDA-approved test. • Drug is prescribed by, or in consultation with, an oncologist/hematologist. • Female patients are post-menopausal, or if pre-menopausal, they are receiving ovarian ablation/suppression. • Female patients of reproductive potential will use effective contraception during therapy and for one week after the last dose. • Patient has tried and failed, or is not a candidate for, adjuvant or neoadjuvant chemotherapy. • Patient has had disease progression while on or after endocrine-based therapy. • Patient will receive fulvestrant injection (Faslodex) therapy along with alpelisib (Piqray). • Patient has no history of Stevens Johnson Syndrome, Erythema Multiforme, or Toxic Epidermal Necrolysis. • Provider is aware and has informed patient of risk of serious, life-threatening skin reactions, including Stevens Johnson Syndrome; severe hyperglycemia; gastrointestinal toxicity, including severe diarrhea; kidney injury; lung injury including pneumonitis; pancreatitis; and severe hypersensitivity reactions. • Provider is aware and has informed patient that safety has not been established in type 1 or uncontrolled type 2 diabetic patients. • Male patients with female partners of reproductive potential should use condoms and effective contraception during therapy and for one week after last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis:_____ Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• amifampridine (Ruzurgi) **Neurological Agents Miscellaneous**	Manual PA is required for all new users of Ruzurgi. Manual PA Criteria: Ruzurgi is approved if all criteria are met: • Patient has Lambert-Eaton myasthenic syndrome (LEMS) Non-FDA-approved uses other than LEMS in adults are not approved. PA does not expire.
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	**Updates from the August 2019 meeting are in bold.** Manual PA applies to all new users of Firdapse. Manual PA Criteria: Firdapse is approved if: • **Provider acknowledges that amifampridine (Ruzurgi) is a cost-effective alternative to Firdapse and is the preferred amifampridine agent. The provider should consider writing a new prescription for Ruzurgi.** • Age ≥ 18 years old • Firdapse is prescribed by an oncologist or neurologist • The patient has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS) • **The patient must try amifampridine (Ruzurgi) first** Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT) **ADHD-Wakefulness Promoting Agents: Stimulants**	Manual PA is required for all new users of Evekeo ODT. Manual PA Criteria: Evekeo ODT is approved if ALL criteria are met: • Patient is 6-17 years of age with a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record • Patient has tried for at least two months and failed or has difficulty swallowing Adderall tabs (generic) • Patient has tried for at least two months and failed or the patient has a contraindication to IR methylphenidate tablets or solution Non-FDA-approved uses are not approved. PA does not expire.
• erdafitinib (Balversa) **Oncological Agents**	Manual PA criteria apply to all new uses of Balversa. Manual PA Criteria: Erdafitinib (Balversa) is approved if all criteria are met: • Age ≥ 18 • Patient has locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR3 or FGFR2 mutation confirmed with an FDA-approved test • The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy) • Prescribed by or in consultation with an oncologist • The patient will be evaluated by an ophthalmologist before starting treatment and every month for the first 4 months; every 3 months thereafter • The patient will be advised to seek emergent evaluation for new ocular symptoms • The patient will be monitored for hyperphosphatemia. (Note that 33% of patients required a phosphate binder in the trial supporting FDA approval for erdafitinib) • If the patient is female, she is not pregnant or planning to become pregnant. • Female patients will not breastfeed. • All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• galcanezumab-gnlm 100 mg injection (Emgality) **Migraine Agents: CGRP Cluster Headache**	Note that this PA applies to the Emgality 100 mg cluster headache formulation. The Emgality 120 mg migraine prophylaxis indication PA criteria is on a separate form. Manual PA criteria apply to all new users of Emgality for episodic cluster headaches. Manual PA Criteria: Emgality 100 mg at a dosage of 300 mg/month is approved if all criteria are met: • Patient ≥ 18 years old and not pregnant • The drug must be prescribed by or in consultation with a neurologist • Patient has a diagnosis of episodic cluster headaches • Patient has a contraindication to, intolerability to, or has failed an adequate trial of: – Verapamil, topiramate, or lithium • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Emgality 120 mg, Ajovy) is not allowed Non-FDA-approved uses, including for migraine prophylaxis, chronic cluster headache, medication overuse headache, etc., are not approved. PA expires after 6 months. Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if there is a clinically appropriate reduction in weekly attacks (≥ 50% reduction in weekly cluster headache attack frequency) during an episode as reported by the patient.
• mepolizumab injection (syringe and autoinjector) (Nucala) **Pulmonary-1 Agents: Pulmonary Miscellaneous**	Manual PA is required for all new and current users of Nucala. Manual PA Criteria: Nucala is approved if all criteria are met: For eosinophilic asthma: • The patient has a diagnosis of severe persistent eosinophilic asthma • Patient must be ≥ 12 years • The drug is prescribed by an allergist, immunologist, or pulmonologist • Patient has an eosinophilic phenotype asthma as defined as either • blood eosinophil count of > 150 cells/mcL within the past month while on oral corticosteroids OR • ≥ 300 cells/mcL within the past year • The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen, with uncontrolled asthma defined as • Hospitalization for asthma in the past year OR • Required course of oral corticosteroids twice in the past year OR • Daily high-dose inhaled corticosteroid (ICS) with inability to taper off the ICS • The patient has tried and failed an adequate course (3 months) of at least two of the following while using a high-dose inhaled corticosteroid: • Inhaled long-acting beta agonist (LABA) (e.g., Serevent, Striverdi), long-acting muscarinic antagonist (LAMA) (e.g., Spiriva, Incruse), leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) For eosinophilic granulomatosis with polyangiitis (EGPA): • Patient must have diagnosis of EGPA • The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist, or hematologist • Patient must be ≥ 18 years • The patient has had an adequate trial of at least 3 months of one of the following with either an inadequate response to therapy or significant side effects/toxicity or the patient has a contraindication to therapy with • Corticosteroids, cyclophosphamide, azathioprine, or methotrexate • An quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication only Non-FDA-approved uses are not approved. Prior authorization does not expire.

Drug / Drug Class	Prior Authorization Criteria
• methylphenidate extended-release capsules nighttime dosing (Jornay PM) **ADHD-Wakefulness Promoting Agents: Stimulants**	Manual PA is required for all new and current users of Jornay PM. Manual PA Criteria: Jornay PM is approved if all criteria are met: • Patient is 6 years and older with a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record • The patient must have tried for at least two months and failed Concerta (generic) or have difficulty swallowing pills • The patient must have tried for at least two months and failed another long-acting methylphenidate (Methylphenidate ER/CD/LA, Quillivant XR, Aptensio XR) • The patient must have tried for at least two months and failed or have a contraindication to Adderall XR (generic) • Must have tried for at least two months an immediate release formulation methylphenidate product in conjunction with Concerta or another long-acting methylphenidate • Please explain why the patient needs Jornay PM. Non-FDA-approved uses are not approved. PA does not expire.
• risankizumab-rzaa injection (Skyrizi) **TIBs: Non-Tumor Necrosis Factor Inhibitors**	PA criteria apply to all new users of Skyrizi. The patient must have tried Humira, Stelara, and Cosentyx. Manual PA Criteria: Skyrizi is approved if ALL criteria are met: • The patient has a contraindication or has had an inadequate response to Humira, Cosentyx, AND Stelara OR • The patient has had an adverse reaction to Humira, Cosentyx, AND Stelara that is not expected with the requested non-step-preferred TIB AND • Patient ≥ 18 years old • The patient is diagnosed with moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy • Patient has tried and had an inadequate response to non-biologic systemic therapy (e.g., methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) • Coverage NOT provided for concomitant use with other TIBs • The patient has had a negative TB test result in past 12 months (or TB is adequately managed) Non-FDA-approved uses are not approved. PA does not expire.
• rosuvastatin sprinkle capsules (Ezallor Sprinkle) **Antilipidemics-1**	**PA does not apply to patients 12 years of age and younger (age edit)** PA criteria apply to all new users of Ezallor Sprinkle older than 12 years of age. Manual PA Criteria: Ezallor Sprinkle is approved if all criteria are met: • Provider must explain why the patient requires rosuvastatin sprinkle capsules and cannot take simvastatin, atorvastatin, OR rosuvastatin tablets. Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• solriamfetol (Sunosi) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	Manual PA is required for all new and current users of Sunosi. Manual PA Criteria: Sunosi is approved if all criteria are met: • Patient must be ≥ 18 years • Sunosi is not approved for use in children, adolescents, or pregnant patients. • Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy or a documented diagnosis of obstructive sleep apnea (OSA) • For narcolepsy: narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing • For narcolepsy: Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea • For OSA: Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least 1 month prior to initiation, and the patient demonstrated adherence to therapy during this time • For OSA: Patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of treatment • Sunosi is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • The patient is not concurrently taking any of the following: – Central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic – Monoamine oxidase inhibitor (MAOI) within the past 14 days – Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • The patient must have tried and failed and had an inadequate response to modafinil • The patient must have tried and failed and had an inadequate response to armodafinil • The patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient and provider agree to monitor blood pressure and heart rate at baseline and periodically throughout treatment. If the patient has hypertension, the blood pressure is controlled. • Patient does not have unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, major depression, ADHD, or shift work disorder). Prior authorization expires in 1 year. No renewal allowed. A new prescription will require a new PA to be submitted.

Drug / Drug Class	Prior Authorization Criteria
• tafamidis meglumine (Vyndaqel) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Vyndaqel. Manual PA Criteria: Tafamidis (Vyndaqel) is approved if all criteria are met: • Age ≥ 18 • Patient has a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis • Prescribed by or in consultation with a specialist who manages hereditary transthyretin amyloidosis (e.g., cardiologist, geneticist, neurologist) • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed • Female patients of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose Non-FDA-approved uses (other than ATTR disease manifestations) are not approved. PA does not expire.
• alectinib (Alecensa) • brigatinib (Alunbrig) • ceritinib (Zykadia) **Oncological Agents: Lung Cancer**	Manual PA applies to new users of Alecensa, Alunbrig, and Zykadia. Manual PA Criteria: Alecensa, Alunbrig, or Zykadia is approved if all criteria are met: • The patient has *metastatic* anaplastic lymphoma kinase (*ALK*)-positive NSCLC as detected by an FDA-approved test AND ▪ The drug is prescribed by or in consultation with a hematologist/oncologist OR ▪ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• crizotinib (Xalkori) **Oncological Agents: Lung Cancer**	Manual PA applies to new users of Xalkori. Manual PA Criteria: Xalkori is approved if all criteria are met: • Patient has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an FDA-approved test OR • Patient has NSCLC with ROS1 rearrangement AND ▪ The drug is prescribed by or in consultation with a hematologist/oncologist OR ▪ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• doxycycline hyclate extended-release 80 mg **Antibiotics: Tetracyclines**	Manual PA applies to new and current users of doxycycline hyclate extended-release 80 mg. Note: Generic doxycycline hyclate immediate-release (IR) 50 mg and 100 mg tablets and capsules are available without a PA; providers are encouraged to consider changing the prescription to generic IR doxycycline hyclate 50 mg or 100 mg tablets or capsules. Manual PA Criteria: doxycycline hyclate extended-release 80 mg is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this drug is required as opposed to available alternatives._____ Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• droxidopa (Northera) **Cardiovascular Agents Miscellaneous**	Manual PA applies to new users of Northera. <u>Manual PA Criteria:</u> Northera is approved if all criteria are met: • Patient is ≥ 18 years of age • Patient has been diagnosed with symptomatic Neurogenic Orthostatic Hypotension (NOH) due to primary autonomic failure (Parkinson's disease [PD], multiple system atrophy [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy • The drug is prescribed by or in consultation with a cardiologist or a neurologist • The patient has tried two other medications (e.g., fludrocortisone, pyridostigmine, or midodrine) and failed to respond to therapy • Patient has initiated non-pharmacological measures including but not limited to elevation of the head of the bed, orthostatic compression garments, increased salt intake, and appropriate physical training Non-FDA-approved uses are not approved. PA does not expire.
• prenatal multivitamin (Azesco) **Vitamins: Prenatal**	Manual PA applies to new and current users of Azesco, regardless of the woman's age. Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin + Low Iron, and Prenatal Plus DHA are all available without a PA. Providers are encouraged to consider changing the prescription to Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi+ DHA, Prenatal Vitamin + Low Iron, or Prenatal Plus DHA. <u>Manual PA Criteria:</u> Azesco is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives. Please describe why this drug is required as opposed to available alternatives._____ Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors**	**<u>Updates from the August 2019 meeting are in bold.</u>** Manual PA criteria apply to all new users of Humira. <u>Manual PA Criteria</u>: Coverage is approved for Humira if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy. • Moderate to severely active Crohn's disease (CD). • Moderate to severely active ulcerative colitis (UC). • Moderate to severe hidradenitis suppurativa (HS). • Non-infectious intermediate, posterior, and panuveitis. • Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation. Coverage approved for pediatric patients ≥ 6 years with: • Moderate to severely active Crohn's disease. Coverage approved for pediatric patients ≥ 12 years with: • Moderate to severe hidradenitis suppurativa (HS) **Coverage approved for pediatric patients 4-17 years with:** • **Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate** Coverage approved for pediatric patients 2-17 years with: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA). • Non-infectious intermediate, posterior, and panuveitis. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? (applies to adults for all indications except for ophthalmic uses, and applies for pediatric patients with plaque psoriasis or Crohn's disease) • AS only: Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Coverage for non-FDA-approved uses not listed above. Please provide diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Drug / Drug Class	Prior Authorization Criteria
• apremilast (Otezla) **Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors**	**<u>Updates from the August 2019 meeting are in bold.</u>** Step therapy and manual PA criteria apply to all new users of Otezla. <u>Automated PA Criteria</u>: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria</u>: If automated criteria are not met, coverage is approved for Otezla if: • Contraindications exist to Humira. • Inadequate response to Humira. • Adverse reactions to Humira not expected with requested non-step-preferred TIB. AND Coverage approved for patients ≥ 18 years with: • **Oral ulcers associated with Behçet's disease (Please note: A trial of Humira first is not required for Behçet's disease.)** • Active psoriatic arthritis (PsA). • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR? • If yes: Fill in the blank write-in referencing literature to support combination, and patient will be monitored closely for adverse effects. Has the patient had an inadequate response to non-biologic systemic therapy? (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])? Patient has negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are not approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**<u>Updates from the August 2019 meeting are in bold.</u>** Manual PA criteria apply to all new users of Doptelet. <u>Manual PA Criteria</u>: Avatrombopag (Doptelet) is approved if all criteria are met: **Patients with chronic liver disease who are scheduled to undergo a procedure** • Age ≥ 18 • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 10^9/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • Prescribed by or in consultation with a gastroenterologist **Or** **<u>Chronic immune thrombocytopenia (ITP)</u>** • **Age <u>></u> 18** • **The patient has a diagnosis of chronic immune thrombocytopenia (ITP) and has had an insignificant response to previous therapy** • **The patient has tried and failed or has a contraindication to Nplate or Promacta OR** • **The patient is anticipated to have an adverse effect to both Nplate and Promacta that would not be anticipated with avatrombopag (Doptelet)** • **The drug is prescribed by or in consultation with a hematologist/oncologist** • **Doptelet is not being used concomitantly with other chronic ITP therapy** Non-FDA-approved uses are not approved. For thrombocytopenia associated with liver disease: PA expires in 60 days. **For ITP: PA does not expire.**

• dupilumab (Dupixent)
 	
Corticosteroids – Immune Modulators: Atopic Dermatitis
	<u>Updates from the August 2019 meeting are in bold.</u>
	
	Manual PA criteria apply to all new users of Dupixent.
	
	<u>Manual PA Criteria:</u> Coverage will be approved for initial therapy for 6 months if all criteria are met:
	Atopic Dermatitis
	• Patient has moderate to severe or uncontrolled atopic dermatitis
	• Patient must be 12 years of age or older
	• Prescribed by a dermatologist, allergist, or immunologist
	• Patient has a contraindication to, intolerability to, or failed treatment with at least ONE high potency/class 1 topical corticosteroid
	• Patient has a contraindication to, intolerability to, or failed treatment with at least ONE systemic immunosuppressant
	• Patient has a contraindication to, intolerability to, inability to access treatment, or failed treatment with Narrowband UVB phototherapy
	OR
	Asthma
	• Patient has moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma
	• Patient must be 12 years of age or older
	• Prescribed by a pulmonologist, asthma specialist, allergist, or immunologist
	• Patient has baseline eosinophils ≥ 150 cells/mcL
	• Patient's symptoms are not adequately controlled on stable high-dose inhaled corticosteroid AND either a Long-Acting Beta Agonist or a Leukotriene Receptor Antagonist for at least 3 months
	• Will not be used for relief of acute bronchospasm or status asthmaticus
	• Dupixent will be only used as add-on therapy to other asthma controller medications
	OR
	Chronic rhinosinusitis with nasal polyposis
	• **Patient has chronic rhinosinusitis with nasal polyposis and is refractory to treatment with other therapies**
	• **Patient must be 18 years of age or older**
	• **Written by or in consultation with an allergist, immunologist, pulmonologist, or otolaryngologist**
	• **Nasal polyposis is confirmed by imaging or direct visualization**
	• **Dupixent will only be used as <u>add-on</u> therapy**
	• **The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following maximized treatments**
	  • **Adequate duration of at least two different high-dose intranasal corticosteroids AND**
	  • **Nasal saline irrigation AND**
	  • **The patient has failed two courses of oral corticosteroids in the past year or has a contraindication to oral corticosteroids AND**
	  • **The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery**
	• **Patient is not currently taking any other type-2 allergic immunobiologics (mepolizumab, omalizumab, etc.)**
	• **Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength**
	
	Non-FDA-approved uses are not approved.
	PA expires after 6 months.
	
	<u>Renewal PA Criteria:</u> Coverage will be approved indefinitely for continuation of therapy if:
	1. Atopic Dermatitis: The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear (1)
	2. Asthma: The patient has had a positive response to therapy with a decrease in exacerbations, improvements in FEV_1, or decrease in oral corticosteroid use.

Drug / Drug Class	Prior Authorization Criteria
	3. Chronic rhinosinusitis with nasal polyposis : Evidence of effectiveness as documented by decrease in nasal polyps score (NPS) or nasal congestion score (NC)
• ivosidenib (Tibsovo) **Oncological Agents: Acute Myelogenous Leukemia**	**<u>Updates from the August 2019 meeting are in bold.</u>** Manual PA criteria apply to all new users of Tibsovo. <u>Manual PA Criteria</u>: Tibsovo is approved if all criteria are met: • Patient ≥ 18 years old • ~~Has laboratory evidence of relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test~~ • **Patient has a diagnosis of acute myeloid leukemia with a susceptible IDH1 mutation as detected by an FDA-approved test** ▪ **Patient has relapsed or refractory acute myeloid leukemia OR** ▪ **Patient has newly diagnosed AML and is aged 75 years and older or who has comorbidities that preclude use of intensive induction chemotherapy OR** ▪ **The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____.** • The patient will be monitored for differentiation syndrome • The patient will be monitored for Guillain-Barre syndrome • Prescribed by or in consultation with a hematologist/oncologist **Other** non-FDA-approved uses, please cite supporting literature. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• liraglutide 3 mg injection (Saxenda) **Weight Loss Agents**	**<u>Updates from the August 2019 meeting are in bold</u>** Manual PA criteria apply to all new and current users of Saxenda. <u>Manual PA Criteria</u>—Saxenda is approved if ALL of the following criteria are met: • Patient is ≥ 18 years old • **Patient has tried and failed all 5 weight loss medications (generic phentermine, Qsymia, Xenical, Contrave, and Belviq or Belviq XR) or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** • **Phentermine: Date_____ Duration of therapy _____** • **Qsymia: Date_____ Duration of therapy _____** • **Xenical: Date _____ Duration of therapy _____** • **Contrave: Date _____ Duration of therapy _____** • **Belviq/Belviq XR: Date _____ Duration of therapy _____** • If the patient is diabetic, they must have tried and failed metformin and the preferred GLP1-RAs (Bydureon **and Trulicity**) • Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, **Trulicity**, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy AND will remain engaged throughout course of therapy. • Patient is not pregnant. Non-FDA-approved uses are not approved, including Diabetes Mellitus. Prior authorization expires after 4 months and then annually. <u>Renewal PA Criteria:</u> Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.

Drug / Drug Class	Prior Authorization Criteria
• sodium oxybate (Xyrem) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	**Updates from the August 2019 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Xyrem. Manual PA Criteria: Coverage of Xyrem is approved if the following criteria are met: • **Patient is 18 years of age** AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND • The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) **OR** • **Patient is child ≥ 7 years AND** • **The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND** • **Xyrem is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND** • **Xyrem is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.** ▪ **Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR** • **Xyrem is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND** ▪ **The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND** • **Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders)** Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy. PA expires after 1 year**. Renewal not allowed; patient must fill out a new PA.** ~~PA Renewal criteria: Xyrem will be renewed on a yearly basis if:~~ • ~~There is documentation demonstrating the patient has had a reduction in frequency of cataplexy attacks associated with Xyrem therapy OR~~ • ~~There is documentation demonstrating the patient has had a reduction in the symptoms of excessive daytime sleepiness associated with Xyrem therapy AND~~ • ~~Patient is not receiving a concomitant CNS depressant~~

Drug / Drug Class	Prior Authorization Criteria
• telotristat ethyl (Xermelo) **Gastrointestinal-2 Agents**	**Updates from the August 2019 meeting are in bold.** Manual PA criteria apply to all new users of Xermelo. Manual PA Criteria: Coverage approved for one year if all criteria are met: • Patient has diagnosis of carcinoid syndrome diarrhea. • Patient has had an inadequate treatment response to at least a 3-month trial of somatostatin analog (SSA) therapy. • Telotristat must be used in combination with an SSA (i.e., octreotide or lanreotide). • Patient has > 4 bowel movements daily **or** • **Patient has < 4 bowel movements/day while receiving somatostatin analogs (SSAs) or patient has ≥ 1 symptom or ≥ 4 bowel movements/day if not receiving concurrent SSAs** **Non-FDA-approved** uses are not approved. PA expires in one year. • PA criteria for renewal: After one year, PA must be resubmitted. Continued use of Xermelo will be approved when a) used in combination with a somatostatin analog, b) decrease from baseline in amount of average daily bowel movements, c) prescriber agrees to continue to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops, d) no severe constipation or abdominal pain develops. • Renewal PA criteria is limited to one year.
• tezacaftor/ivacaftor (Symdeko) **Cystic Fibrosis Agents**	**Updates from the August 2019 meeting are in bold and strikethrough.** 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's age is appropriate according to the FDA-approved indication for Symdeko. AND** • 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.

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• alpelisib (Piqray) **Oncological Agents: Breast Cancer**	▪ Retail/MTF/Mail: 28-day supply at all POS, due to packaging
• amifampridine (Ruzurgi) **Neurological Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply at all POS
• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**August 2019 updates are in BOLD.** **For Idiopathic Thrombocytopenia (ITP):** ▪ **30-day supply** at Mail/MTF/Retail
• droxidopa (Northera) **Cardiovascular Agents Miscellaneous**	▪ Retail/MTF/Mail: 180 capsules per fill at all POS
• erdafitinib (Balversa) **Oncological Agents**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• galcanezumab-gnlm (Emgality) 100 mg injection **Migraine Agents: CGRP Cluster**	▪ Retail: 1 package (3 syringes) per fill ▪ MTF/Mail: 3 packages (9 syringes) per fill
• lofexidine (Lucemyra) **Narcotic Analgesics and Combinations**	**August 2019 updates are in BOLD.** ▪ Retail/MTF/Mail: **108 tablets per fill at all POS**
• mepolizumab injection (Nucala) **Pulmonary-1 Agents: Pulmonary Miscellaneous**	For asthma ▪ Retail: 1 syringe per fill ▪ MTF/Mail: 3 syringes per fill For EGPA ▪ Quantity limit overrides for the 300 mg EGPA dose are provided for in the Prior Authorization
• risankizumab-rzaa (Skyrizi) **TIBs**	▪ Retail: 30-day supply ▪ MTF/Mail: 90-day supply to allow for loading doses at initiation, 4 weeks, and 12 weeks
• solriamfetol (Sunosi) **ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents**	▪ Retail/MTF/Mail: 30 tablets per fill at all POS
• Tafamidis (Vyndaqel) **Neurological Agents Miscellaneous**	▪ Retail/MTF/Mail: 30-day supply all POS

Drug / Drug Class	Quantity Limits
• azelastine and fluticasone nasal (Dymista) **Nasal Allergy Agents: Antihistamines**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• azelastine nasal (Astepro 0.15%, generics) **Nasal Allergy Agents: Antihistamines**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• beclomethasone nasal (Beconase AQ) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 4 inhalers per fill
• beclomethasone nasal (Qnasl 40 mcg and 80 mcg) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• budesonide nasal (Rhinocort Aqua, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• ciclesonide 50 mcg nasal (Omnaris) • ciclesonide37 mcg nasal (Zetonna) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• fluticasone furoate nasal (Veramyst) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• fluticasone propionate nasal (Flonase, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 6 inhalers per fill
• fluticasone propionate 93 mcg nasal (Xhance) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• flunisolide nasal inhaler **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 3 inhalers per fill ▪ MTF/Mail: 7 inhalers per fill

Drug / Drug Class	Quantity Limits
• ipratropium 0.03% nasal (Atrovent 0.03%, generics) • ipratropium 0.03% Nasal Spray (Atrovent 0.03%, generics), pack size 15 mL • ipratropium 0.06% Nasal Spray (Atrovent 0.06%) **Nasal Allergy Agents: Anticholinergics**	▪ Retail: 2 inhalers per fill ▪ MTF/Mail: 4 inhalers per fill
• mometasone nasal (Nasonex, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• olopatadine 0.06% (Patanase 0.06%, generics) **Nasal Allergy Agents: Antihistamines**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill
• triamcinolone Acetonide (Nasacort AQ, generics) **Nasal Allergy Agents: Corticosteroids**	▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill

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
alpelisib (Piqray)	Oncological agents: breast cancer	• abemaciclib (Verzenio) • palbociclib (Ibrance) • ribociclib (Kisqali)	Hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, PIK3CA-mutated advanced or metastatic breast cancer in combination with fulvestrant	• 1st PI3K Inhibitor and is the only drug indicated for breast cancer with the specific PIK3CA mutation • Must be used in combination with fulvestrant (medical benefit) • The CDK 4/6 inhibitors (Verzenio, Ibrance, and Kisqali) are also approved for advanced metastatic breast cancer. • No head-to-head trials are available. • The primary endpoint of progression-free survival was statistically significant compared to placebo, with a difference of about 5 months. • Is also associated with severe hypersensitivity reactions including anaphylaxis and pulmonary toxicity. • Safety has not been evaluated in Type 1 or uncontrolled Type 2 diabetic patients. • Severe AEs include Stevens Johnson Syndrome, severe hyperglycemia, severe diarrhea and kidney injury, lung injury including pneumonitis, pancreatitis, and severe hypersensitivity reactions. • Almost 70% of patients required dose interruption with 62% needing dose reduction due to adverse events. • The most recent NCCN guidelines rate Piqray as a category 1 drug, which is the lowest level of recommendation. • Compared to placebo, alpelisib provided benefit in the treatment of advanced breast cancer in patients with the specific PIK3CA mutation who have failed previous therapy, based on the limited data available.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
amifampridine (Ruzurgi)	Neurological agents miscellaneous	• Firdapse	Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to 17 years of age	• Ruzurgi is the first FDA-approved drug for LEMS in pediatric patients in the U.S.; however, in the clinical trial used to gain FDA approval, the average patient age was 52 years, with only adults enrolled. • Ruzurgi is available in the exact same formulation as Firdapse, the adult version which was approved earlier in 2019. • Amifampridine was approved by the European Commission as an orphan drug in December of 2002. • Amifampridine was previously available in a compounded formulation through compassionate use; however, this will no longer be an option. The company marketing Ruzurgi was previously compounding the original formulation. • Apart from the AEs listed, amifampridine may cause seizures, including seizures in patients with no prior history. • Dosing for adults can be obtained by using the Ruzurgi formulation, since both Firdapse and Ruzurgi are 10 mg scored tablets. Ruzurgi's package insert states the maximal dose is 100 mg daily, compared to Firdapse's max dose of 80 mg daily. • Ruzurgi provides the first available FDA-approved pediatric therapy to treat this very rare disorder in a more cost-effective manner than Firdapse, with dosing and clinical trial data based on adults.	• UF • Do not add to EMMPI list
amphetamine sulfate orally disintegrating IR tablets (Evekeo ODT)	ADHD – Wakefulness Promoting Agents: Stimulants	• Adzenys XR ODT, Adderall XR, Vyvanse, Dyanavel XR, Mydayis	ADHD in pediatric patients 6-17 years old	• 2nd Evekeo formulation on the market with an ADHD indication • Evekeo ODT was approved through a 505(b)(2) pathway, with no new clinical studies. • Immediate release dosage formulation • There are many alternatives available in this crowded therapeutic space – including multiple amphetamine ODTs, multiple agents with the same duration of action for those with difficulties swallowing, and multiple stimulants that are also approved for this age group. • Effects 4-6 hours, similar to other short-acting stimulants in the class. • Evekeo carries the same black box warning as all other stimulant agents for potential abuse, dependency, and sudden cardiac death. • Clinically, children who experience adverse events to Adderall are more commonly switched to dexedrine, rather than an amphetamine product. • There are no compelling clinical advantages over other formulary products at this time.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
dolutegravir/ lamivudine (Dovato)	Antiretrovirals: Combinations	• Tivicay + Truvada • Biktarvy • Triumeq	Human immuno-deficiency virus (HIV) treatment	• Dovato is a 2-drug antiretroviral combination of dolutegravir and lamivudine FDA approved for initial therapy of HIV in adults. • Based on HIV guidelines, Dovato provides another second-line single-tablet regimen (STR) treatment option for HIV. • Dovato was non-inferior to the combination of Tivicay + Truvada in two phase III, non-inferiority trials (GEMINI 1 & 2). • Side effects are generally mild and include nausea, headache, diarrhea, fatigue, and insomnia. • Additional data on long-term efficacy, studies in pediatric and geriatric populations, safety, and viral suppression sustainability are needed to better characterize strengths and weaknesses. • Dovato provides an additional single-tablet regimen option for patients who cannot take abacavir or tenofovir disoproxil fumarate (TDF)/tenofovir alafenamide (TAF).	• UF • Do not add to EMMPI list
drospirenone (Slynd)	Contraceptive agents: progestogen-only	• norethindrone 0.35 mg	Progestogen-only contraceptive tablet	• 2nd Progestin-only pill (POP) for contraception • Compared to norethindrone, Slynd has an extended window for allowable late dose without need for back-up protection. • POPs are commonly used when contraindications or adverse reactions (severe nausea, headache, etc.) exist to combined oral contraceptives (COCs). • Progestin-only pills are often used in breastfeeding patients. • Many contraindications to COCs are related to thromboembolic potential of estrogen. • Drospirenone unlike other progestins has some likely thromboembolic risk. • Additional lab monitoring may be needed with drospirenone. • Slynd has no compelling clinical advantages over existing progestogen-only formulary agents.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
erdafitinib (Balversa)	Oncological agents	• None	Locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR mutation and has progressed during or following at least one line of prior platinum-containing chemotherapy	• 1st drug with FDA approval for FGFR gene-altered metastatic urothelial carcinoma • Superior overall response rate (ORR) but unknown survival advantage • Better tolerated than National Comprehensive Cancer Network (NCCN)-directed comparator chemotherapy regimens • Very limited data, but progression-free survival of about 5 months, which can be significant for this particular cancer which has a high mortality rate. • Risk of severe ophthalmic AEs, including central serous retinopathy/retinal pigment epithelial detachment. • AE profile is less severe than pembrolizumab (Keytruda) chemotherapy. NCCN guidelines recommend Balversa as an alternative preferred regimen behind pembrolizumab (Keytruda – medical benefit "checkpoint inhibitor") for recurrent invasive or metastatic disease.	• UF • Do not add to EMMPI list
galcanezumab injection 100 mg (Emgality)	Migraine Agents: CGRP Cluster	• topiramate • lithium • verapamil • galcanezumab (Emgality 120 mg)	Treatment of episodic cluster headache	• New formulation of galcanezumab approved for episodic cluster headache. • 1st calcitonin gene-related peptide (CGRP) approved for cluster headache; others are in the pipeline. • Galcanezumab 120 mg is approved for migraine headache prophylaxis. • One clinical trial showed a reduction in the frequency of weekly cluster headaches compared to placebo. • Unpublished data provides conflicting results. • Verapamil is the agent of choice for preventive therapy of cluster headache, with glucocorticoids, lithium, and topiramate also showing efficacy. • Limited data (1 small trial in 100 patients with an 8-week duration vs. placebo) showed efficacy of this formulation for prevention of cluster headache. How it compares to other treatments, including verapamil, is unknown.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
halobetasol propionate 0.01%/ tazarotene 0.045% lotion (Duobrii)	Psoriasis Agents	• Enstilar • Taclonex • Tazarotene	Plaque psoriasis	• Duobrii is the 3rd topical combination agent for the treatment of plaque psoriasis, but it is the first to combine a high-potency topical corticosteroid with a retinoid (tazarotene). • Guidelines recommend the combination of a topical corticosteroid with a retinoid only after a full treatment course of an individual high-potency topical corticosteroid treatment has failed. • The combination of a high-potency topical corticosteroid and a topical non-corticosteroid (either a vitamin D analogue or a retinoid) offers improved clinical efficacy over either agent alone and is supported by Level 1 evidence with a strength A recommendation from the American Academy of Dermatology (AAD). • However, Duobrii offers no compelling clinical advantage over concomitant use of individual topical components (halobetasol and tazarotene).	• UF • Do not add to EMMPI list
immunoglobulin SC injection (Cutaquig)	Immunological agents miscellaneous	• Gammagard • Gamunex-C • Cuvitru • Hizentra • Hyqvia	Treatment of primary humoral immuno-deficiency (PI) in adults	• 6th subcutaneous (SC) human immune globulin indicated for the treatment of primary humoral immunodeficiency (PI) in adults. • Cutaquig was evaluated in one open-label, non-controlled study that demonstrated efficacy in preventing serious bacterial infections. • No head-to-head studies with other human immune globulin products were conducted. • Most common ADRs included local reaction (46%), headache (11.5%), fever (8.2%), diarrhea (8.2%), dermatitis (8.2%), asthma (6.6%), and skin abrasion (6.6%). • The large injection volume required will likely result in patients needing a pump for administration. • Cutaquig provides little to no clinical benefit relative to existing formulary agents.	• UF • Do not add to EMMPI list
mepolizumab injection (Nucala)	Pulmonary 1-Agents: Pulmonary Miscellaneous	• dupilumab (Dupixent) • benralizumab (Fasenra) • reslizumab (Cinqair) • omalizumab (Xolair)	Add-on maintenance treatment of severe asthma in patients ≥ 12 yo with an eosinophilic phenotype or for adults with eosinophilic granulomatosis with polyangiitis (EGPA)	• Nucala is the 2nd biologic for asthma that is part of the TRICARE pharmacy benefit (after Dupixent). • With the introduction of Nucala, there are now 5 approved biologics for type 2 inflammatory asthma. • In a network meta-analysis (NMA) and randomized controlled trial (RCT), there was statistically significant and clinically relevant benefits of Nucala over placebo in treating eosinophilic asthma and EGPA. • Indirect comparison of Nucala with the other biologics for asthma (Dupixent, Fasenra, Cinqair, and Xolair) did not show statistically significant differences in efficacy. • Nucala provides a clinically meaningful addition to pharmacy benefit in the treatment of type 2 inflammatory asthma over placebo via a mechanism of acting through the IL-5 pathway.	• UF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
methylphenidate ER sprinkle capsule (Adhansia XR)	ADHD – Wakefulness Promoting Agents: Stimulants	• methylphenidate ER tab (Concerta) • methylphenidate ER sprinkle (Aptensio XR) • methylphenidate ER suspension (Quilivant XR • methylphenidate ER (Metadate CD, Ritalin LA, • dexmethylphenidate XR (Focalin XR) • Mixed amphetamine salts XR (Adderall XR)	ADHD in patients 6 years and older	• Adhansia XR was approved under a 505(b)(2) application and is indicated for treating ADHD in patients 6 years and older. • Multiple current formulary agents cover the same age range. • Adhansia XR is the 11th long-acting methylphenidate available on the market. • Several long-acting methylphenidate products are on the UF, including two products that are formulary alternatives for those who have difficulty swallowing (Quillivant XR, Aptensio XR). • Effects can last 16 hours, which is the "marketing claim" for this agent – this may be more useful for adults, as children rarely need to concentrate for 16 hours. • Other methylphenidate ER formulations have 10-14 hour durations of action (e.g., Concerta, Aptensio XR sprinkle, Jornay PM). • Adhansia XR carries the same Black Box Warning as other methylphenidates for abuse potential, dependency, and sudden cardiac death. • The long duration of action is concerning for adverse effects of insomnia and weight loss in children • Adhansia XR has little to no additional clinical effectiveness relative to similar drugs in the class.	• Tier 4/Not Covered • Do not add to EMMPI list
methylphenidate ER capsule nighttime dosing (Jornay PM)	ADHD – Wakefulness Promoting Agents: Stimulants	• methylphenidate ER tab (Concerta) • methylphenidate ER sprinkle (Aptensio XR)	ADHD in patients 6 years and older	• Jornay PM is the 12th long-acting methylphenidate approved via 505(b)(2) pathway for ADHD in patients ≥ 6 years. • Jornay is administered at night before bedtime; it has a delayed onset of action so that therapeutic effects occur 8 hours after administration; stimulating effects may last 14 hours. • Rates of insomnia (up to 41%) were twice that of placebo. • Jornay PM has the same Black Box Warning as other methylphenidates for abuse potential, dependency, and sudden cardiac death. • Jornay PM shows no clinical advantage when compared to current formulary alternatives and showed a higher rate of insomnia versus other agents in this class.	• UF • Do not add to EMMPI list
risankizumab-rzaa injection (Skyrizi)	Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor Inhibitors	• adalimumab (Humira) • ustekinumab (Stelara) • guselkumab (Tremfya) • tildrakizumab (Ilumya)	Patients with moderate to severe plaque psoriasis who are candidates for systemic or phototherapy	• Skyrizi is the 3rd IL-23 antagonist and the 7th agent in the IL-17/23 subclass. • Same manufacturer as Humira • Solely indicated for plaque psoriasis • Head-to-head trials with appropriate comparators (e.g., Stelara) show superiority for psoriasis; however, higher neutralizing antibody rate with corollary efficacy impact, due to reduced drug concentration • No unique safety concerns • Skyrizi provides an additional robust option in the management of plaque psoriasis but has fewer indications than Humira or Stelara and a higher neutralizing antibody rate.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
rosuvastatin sprinkle capsules (Ezallor Sprinkle)	Antilipidemics-1	• rosuvastatin • atorvastatin • simvastatin oral suspension (FloLipid)	• Increased triglycerides • Type III hyper-lipoproteinemia • Homozygous Familial Hypercholesterolemia (HoFH) • To reduce total cholesterol, LDL-C, and ApoB	• Approved via 505(b)(2) application using clinical safety and efficacy data from rosuvastatin calcium (Crestor). • No clinical efficacy studies were conducted. • No cardiovascular (CV) outcome data • Can swallow capsules whole, open the contents of the granules/sprinkles and mix with applesauce, or administer in an NG tube. • Targeted for patients with swallowing difficulties or those who require NG tube feedings (nursing home patients) • Rosuvastatin tablets are not on the Institute for Safe Medication Practices (ISMP) Do Not Crush list, but all manufacturers recommend swallowing tablets whole due to bitter taste when crushed/chewed. • Moderate to high intensity (LDL lowering ≥ 50%) statin with same active ingredient as Crestor just in a sprinkle capsule formulation instead of tablets (convenience formulation) • No compelling advantages over formulary statins other than a convenience to patients with swallowing difficulties.	• NF • Add to EMMPI list
solriamfetol (Sunosi)	ADHD-Wakefulness Promoting Agents: Wakefulness Promoting Agents	• modafinil • armodafinil • sodium oxybate (Xyrem)	Improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)	• Sunosi is a new dopamine and norepinephrine reuptake inhibitor (DNRI) indicated for wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). • Sunosi was evaluated in 4 pivotal trials and demonstrated modest efficacy on a patient's ability to remain awake and their perceived likelihood of falling asleep during usual daily activities when compared to placebo. • No head-to-head studies with similar agents are available; indirect comparisons are confounded by differences in test methodology and baseline patient populations. • ADRs for Sunosi are similar to modafinil and armodafinil; however, drug interactions, warnings, and precautions differ since Sunosi may cause increases in blood pressure and heart rate. The 300 mg formulation was not approved due to AEs. • Sunosi may cause psychiatric symptoms including anxiety, insomnia, and irritability. Caution is advised in patients with a history of psychosis or bipolar disorders. • Sunosi is a CIV scheduled drug. • Sunosi provides no compelling clinical advantages over existing formulary agents.	• NF • Add to EMMPI list

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

Tafamidis (Vyndaqel)	Neurological agents miscellaneous	• inotersen (Tegsedi)
		• patisiran (Onpattro)
			Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce CV mortality and CV-related hospitalization	• 1st agent FDA-approved for transthyretin amyloid cardiomyopathy (ATTR-CM)
				• Statistically and clinically meaningful clinical efficacy in New York Heart Association (NYHA) Class 1 and 2 patients was seen for the following:
				  • All-Cause Mortality
				  • CV-related Hospitalizations
				  • Function (6-minute walk test [6MWT])
				  • Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS)
				• Non-statistically significant mortality benefit in NYHA Class 3, but statistically significant higher CV-related hospitalization rate in this sub-group
				• Favorable safety profile (especially in indirect comparison to Tegsedi)
				• Use in polyneuropathy is supported by weaker evidence.
				• Tafamidis is approved for transthyretin amyloid polyneuropathy (ATTR-PN) in 41 other countries, but the FDA denied approval.
				• Guidelines recommend tafamidis in ATTR and ATTR-PN.
					• UF
					• Do not add to EMMPI list

triclabendazole (Egaten)	Antiinfectives: Anthelmintics	• praziquantel • mebendazole • albendazole • ivermectin	Fascioliasis (liver flukes)	• Egaten is an anthelmintic and the first drug approved for the treatment of fascioliasis (liver flukes). • A dosage of 20 mg/kg was studied in seven relatively small open-label trials and found higher efficacy compared with artesunate and lower doses of Egaten. • The Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) recommend Egaten as the drug of choice for fascioliasis and as an option for paragonimus (lung flukes). • Most common ADRs included abdominal pain, hyperhidrosis, nausea, decreased appetite, headache, urticaria, diarrhea, vomiting, musculoskeletal chest pain, and pruritus. • Egaten demonstrated efficacy against fascioliasis and has a unique place in therapy for a neglected and rare tropical disease.	• UF • Do not add to EMMPI list

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

<table>
<tr><th>DoD P&T Meeting</th><th>ADD to the Select Maintenance List
(if Formulary, Add to EMMPI Program;
if NF, NOT Excepted from Mail Order Requirement)</th><th>Do NOT Add to the Select Maintenance List
(if Formulary, Do Not Add to EMMPI Program;
if NF, Excepted from Mail Order Requirement)</th></tr>
<tr><td rowspan="2">August 2019</td><td>Multiple Sclerosis drugs:
Note that the interferon products for MS, as well as glatiramer (Copaxone), will remain on the list.
▪ dimethyl fumarate (Tecfidera)

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

Designated UF:
▪ Other Pulmonary-1 agents are on the program: mepolizumab (Nucala)

Designated NF:
No reason to exempt from EMMPI requirement:
▪ risankizumab-rzaa (Skyrizi)
▪ rosuvastatin sprinkle caps (Ezallor)
▪ solriamfetol (Sunosi)</td><td>High-Potency Topical Steroids Designated NF:
Drugs for acute or limited duration use
▪ None of the high-potency topical steroids should be added to the EMMPI program.

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

Designated UF:
Not yet clear if feasible to provide through mail order:
▪ amifampridine (Ruzurgi)
▪ triclabendazole (Egaten)
▪ tafamidis meglumine (Vyndaqel)

Drugs in classes not currently represented on the EMMPI list:
▪ alpelisib (Piqray)
▪ dolutegravir/lamivudine (Dovato)
▪ erdafitinib (Balversa)
▪ halobetasol/tazarotene (Duobrii)
▪ immunoglobulin SQ (Cutaquig)

C-II drugs:
▪ methylphenidate ER caps (Jornay PM)
▪ amphetamine sulfate IR ODT (Evekeo ODT)

Designated NF:
Acute use exception applies:
▪ galcanezumab-gnlm 100 mg (Emgality)

Existing exclusion for contraceptives applies:
▪ drospirenone (Slynd)</td></tr>
<tr><td colspan="2">Remove from Select Maintenance List due to dosing exceeding or potentially exceeding 30 days duration of use
▪ conjugated estrogens vaginal cream (Premarin cream)
▪ estradiol vaginal cream (Estrace)
▪ leuprolide depot injection for 4-month administration (Lupron Depot 4-month kit)
Remove from Select Maintenance List due to limited duration of use
▪ halobetasol (Ultravate) Note that none of the other high-potency topical steroids are on the EMMPI program</td></tr>
</table>

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

<table>
<tr><th>Date</th><th>DoD PEC Drug Class</th><th>Type of Action</th><th>BCF/ECF Medications

MTFs must have BCF meds on formulary</th><th>UF Medications

MTFs may have on formulary</th><th>Nonformulary Medications

MTFs may not have on formulary</th><th>Decision Date / Implement Date</th><th>PA and QL Issues</th><th>Comments</th></tr>
<tr><td rowspan="2">Aug 2019</td><td rowspan="2">High-Potency Topical Corticosteroids</td><td rowspan="2">UF Sub-Class Review; full class previously reviewed in August 2013</td><td colspan="3">Tier 4/Not Covered Medications

MTFs <u>must not</u> have on formulary
Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies

▪ clobetasol propionate 0.025% cream (Impoyz)
▪ clobetasol propionate 0.05% shampoo/cleanser (kit) (Clodan kit)
▪ diflorasone diacetate/emollient 0.05% cream (Apexicon-E)
▪ halcinonide 0.1% ointment (Halog)
▪ halcinonide 0.1% cream (Halog)
▪ halobetasol propionate 0.05% lotion (Ultravate)
▪ halobetasol propionate 0.05% foam (Lexette & authorized generic)
▪ halobetasol propionate 0.01% lotion (Bryhali)</td><td rowspan="2">Pending signing of the minutes / 120 days

The effective date is March 4, 2020</td><td rowspan="2">▪ Manual PA criteria applies to all new and current users for the following products:
▪ amcinonide 0.1% ointment
▪ diflorasone diacetate 0.05% ointments
▪ diflorasone diacetate 0.05% cream
▪ clobetasol propionate/ emollient 0.05% foam
▪ desoximetasone 0.05% gel
▪ flurandrenolide 4 mcg/sq. cm (Cordran) tape</td><td rowspan="2">▪ See Appendix C for PA criteria
▪ Note the Lexette foam was previously rec for Tier 4 status at the February 2019 meeting, which will implement on August 28, 2019.</td></tr>
<tr><td>▪ clobetasol 0.05% ointment & cream
▪ fluocinonide 0.05% ointment, cream & solution</td><td>Note that all are currently UF
▪ betamethasone dipropionate 0.05% ointment
▪ betamethasone/propylene glycol 0.05%, ointment, cream, lotion, gel
▪ clobetasol propionate 0.05% ointment, cream, solution, lotion, shampoo, spray, gel, foam
▪ clobetasol propionate/emollient 0.05% cream
▪ clobetasol propionate/emollient 0.05% emulsion foam
▪ desoximetasone 0.25% ointment, cream
▪ fluocinonide 0.05% ointment, cream, solution, gel
▪ fluocinonide/emollient base 0.05% cream
▪ halobetasol propionate 0.05% ointment</td><td>▪ amcinonide 0.1% ointment (Cyclocort, generics)
▪ clobetasol propionate/emollient 0.05% foam (Olux-E, generics) moves from UF to NF
▪ desoximetasone 0.05% gel (Topicort, generic) moves from UF to NF
▪ diflorasone diacetate 0.05% ointment, cream (Psorcon, Apexicon, generics)
▪ fluocinonide 0.1% cream (Vanos, generics)
▪ flurandrenolide 4 mcg/sq. cm (Cordran) tape moves from UF to NF
▪ halobetasol propionate 0.05% cream (Ultravate, generics) moves from UF to NF</td></tr>
</table>

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2019	**Multiple Sclerosis: Interferons and Methyl Fumarate**	UF Class Review Class previously reviewed in November 2014.	Note that no BCF selection was made for the Interferons and Methyl Fumarate subclasses.	**Interferons** ▪ Interferon beta-1a (Avonex) ▪ Interferon beta-1a (Rebif, RebifRebidose) ▪ Interferon beta-1b (Betaseron) ▪ Interferon beta-1b (Extavia) **Methyl Fumarate** ▪ dimethyl fumarate (Tecfidera)	**Interferons** ▪ peginterferon beta-1a (Plegridy)	Upon signing of the minutes The effective date is November 6, 2019	▪ Updated manual PA criteria for all users of dimethyl fumarate (Tecfidera); off-label uses are not allowed	▪ The MS subclasses of Glatiramer, symptomatic agents, and Oral Miscellaneous were not reviewed ▪ Betaseron removed from BCF ▪ See Appendices B and C for MN and PA criteria.

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

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	ADHD	• methylphenidate ER sprinkle capsules (Adhansia XR)	• methylphenidate ER (Aptensio XR sprinkle capsule) for patients with swallowing difficulties • methylphenidate ER oral suspension (Quillivant XR suspension) for patients with swallowing difficulties • methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) • methylphenidate long-acting (Ritalin LA, generics) • methylphenidate controlled delivery (CD) (Metadate CD, generics) • dexmethylphenidate ER (Focalin XR, generics) • mixed amphetamine salts ER (Adderall XR, generics)	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.025% cream (Impoyz) • diflorasone diacetate/emollient 0.05% cream (Apexicon-E) • halcinonide 0.1% cream (Halog)	• betamethasone/propylene glycol 0.05% cream • clobetasol propionate 0.05% cream • clobetasol propionate/emollient 0.05% cream • desoximetasone 0.25% cream • fluocinonide 0.05% cream • fluocinonide/emollient base 0.05% cream	• March 4, 2020
Aug 2019	High-Potency Topical Corticosteroids	• halcinonide 0.1% ointment (Halog)	• betamethasone dipropionate 0.05% ointment • betamethasone/propylene glycol 0.05% ointment • clobetasol propionate 0.05% ointment • desoximetasone 0.25% ointment • fluocinonide 0.05% ointment • halobetasol propionate 0.05% ointment	• March 4, 2020

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2019	High-Potency Topical Corticosteroids	• clobetasol propionate 0.05% shampoo/ cleanser (kit) (Clodan kit) • halobetasol propionate 0.05% lotion (Ultravate) • halobetasol propionate 0.05% foam (authorized generic for Lexette) *(see Feb 2019 for brand Lexette recommendation)* • halobetasol propionate 0.01% lotion (Bryhali)	• betamethasone propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % emulsion foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• March 4, 2020
May 2019	PPIs	• dexlansoprazole (Dexilant) • esomeprazole strontium	• esomeprazole • omeprazole • pantoprazole • rabeprazole	• Nov 28, 2019
Feb 2019	High-Potency Topical Corticosteroids	• halobetasol propionate 0.05% foam (Lexette brand)	• betamethasone/propylene glycol 0.05% lotion • betamethasone dipropionate 0.05% gel • clobetasol propionate/emollient 0.05 % emulsion foam • clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo • fluocinonide 0.05% solution and gel	• Aug 28, 2019
Feb 2019	Diabetes Non-Insulin Drugs – Biguanides Subclass	• metformin ER gastric retention 24 hours (Glumetza)	• metformin IR (Glucophage generic) • metformin ER (Glucophage XR generic)	• Aug 28, 2019
Feb 2019	Pain Agents – Combinations	• naproxen / esomeprazole (Vimovo)	• PPIs: omeprazole, pantoprazole, esomeprazole, rabeprazole PLUS • NSAIDs: celecoxib, diclofenac, indomethacin, meloxicam, naproxen, (also includes other NSAIDs)	• Aug 28, 2019

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents, based on an interim final rule published on December 11, 2018. https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms .

Drugs recommended for Tier 4/Not Covered status will not be available at the MTFs or Mail Order points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the Tier 4/Not Covered drug at the Retail points of service.

Appendix I—Table of Abbreviations

Term	Definition	Term	Definition
6MWT	6-minute walk test	COPD	Chronic obstructive pulmonary disease
AAD	American Academy of Dermatology	CPAP	continuous positive airway pressure
AAN	American Academy of Neurology	CV	Cardiovascular
ADHD	Attention Deficit Hyperactivity Disorder	DHA	Defense Health Agency; docosahexaenoic acid
ADR	adverse reaction	DMT	Disease-modifying therapy
AE	adverse event	DNRI	dopamine and norepinephrine reuptake inhibitor
ALK	anaplastic lymphoma kinase	DoD	Department of Defense
AML	Acute Myelogenous Leukemia	DR	Delayed release
ANA	antinuclear antibodies	ECF	Extended Core Formulary
Anti-dsDNA	anti-double-stranded DNA	EGPA	eosinophilic granulomatosis with polyangiitis
AS	ankylosing spondylitis	EMMPI	The Expanded MTF/Mail Pharmacy Initiative
ATTR-CM	transthyretin-mediated amyloidosis	ER	extended release
ATTR-PN	transthyretin amyloid polyneuropathy	FDA	U.S. Food and Drug Administration
BCF	Basic Core Formulary	FEV_1	forced expiratory volume in one second
BIA	budget impact analysis	FY	fiscal year
BMI	Body mass index	GCN	Generic code number
CBC	Complete blood count	GLP1RA	Glucagon-Like Peptide-1 Receptor Agonists
CD	Crohn's Disease; continuous delivery	HER2	human epidermal growth factor receptor 2
CDC	Centers for Disease Control and Prevention	HIV	human immunodeficiency virus
CDK	Cyclin-dependent kinase	HoFH	Homozygous Familial Hypercholesterolemia
CF	Cystic Fibrosis	HR	Hormone receptor
CFR	Code of Federal Regulations	HS	hidradenitis suppurativa
CFTR	cystic fibrosis transmembrane conductance regulator	ICER	Institute for Clinical and Economic Review
CGRP	calcitonin gene-related peptide	ICS	Inhaled corticosteroids
CHCS	Composite Health Care System	IDH1	isocitrate dehydrogenase-1
CHF	chronic/congestive heart failure	IR	Immediate release
CMA	cost minimization analysis	ISGA	Investigator's Static Global Assessment
CMP	Complete metabolic panel	ISMP	Institute for Safe Medication Practices
COC	Combined oral contraceptive	ITP	immune thrombocytopenia

Term	Definition	Term	Definition
JC	John Cunningham	OSA	obstructive sleep apnea
KCCQ-OS	Kansas City Cardiomyopathy Questionnaire - Overall Summary	OTC	Over the counter
KCl	Potassium chloride	P&T	Pharmacy and Therapeutics
LA	long acting	PA	Prior authorization
LABA	Long-acting beta agonist	PAF	pure autonomic failure
LAMA	Long-acting muscarinic antagonist	PD	Parkinson's Disease
LEMS	Lambert-Eaton myasthenic syndrome	PI	primary humoral immunodeficiency
LFT	Liver function tests	pJIA	Polyarticular juvenile idiopathic arthritis
MAOI	Monoamine oxidase inhibitor	PML	progressive multifocal leukoencephalopathy
MHS	Military Health System	POD	Pharmacy Operations Division
MN	Medical Necessity	POP	Progestin-only pill
MOA	Mechanism of action	POS	Point of service
MRI	Magnetic resonance imaging	Ps	Plaque psoriasis
MS	Multiple Sclerosis	PsA	Psoriatic arthritis
MSA	multiple system atrophy	QL	Quantity limits
MSLT	mean sleep latency time	RA	Rheumatoid arthritis
MTF	Military Treatment Facility	RCT	Randomized controlled trial
NC	nasal congestion score	SC	subcutaneous
NCCN	National Comprehensive Cancer Network	SLE	systemic lupus erythematosus
NDAA	National Defense Authorization Act	SQ	subcutaneous
NF	Nonformulary	SSA	somatostatin analog
NG	nasogastric	STR	Single-tablet regimen
NMA	Network meta-analysis	TAF	tenofovir alafenamide
NOH	Neurogenic Orthostatic Hypotension	TB	tuberculosis
NPS	nasal polyps score	TDF	tenofovir disoproxil fumarate
nr-axSpA	non-radiographic axial spondyloarthritis	TIB	Targeted immunomodulatory biologic
NSAID	Nonsteroidal anti-inflammatory drug	TNF	Tumor Necrosis Factor
NSCLC	Non-Small Cell Lung Cancer	UC	Ulcerative colitis
NYHA	New York Heart Association	UF	Uniform Formulary
ODT	Orally dissolving tablet	WHO	World Health Organization
ORR	overall response rate	XR	Extended release

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2019

I. CONVENING

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

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

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

2. **Clarification of Previous Minutes**

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

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

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

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

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All TRICARE Tier 4/not covered drugs were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. All Uniform Formulary (UF), Basic Core Formulary (BCF), and TRICARE Tier 4/not covered recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year 2018. Medical necessity (MN) criteria were based on the clinical and cost evaluations, and the conditions for establishing MN for a nonformulary (NF) medication.

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

IV. UF DRUG CLASS REVIEWS

A. Proton Pump Inhibitors – Capsules and Tablets and Alternative Dosage Form Subclasses

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

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

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

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

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

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

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

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

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

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

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

Tablets and Capsules Subclass

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

Alternative Dosage Form Subclass

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

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

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

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

Capsules and Tablets Subclass

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

Alternative Dosage Form Subclass

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Guidelines

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

Endothelin Receptor Antagonists (ERAs)

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

Prostacyclins

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

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

Nitric Oxide Drugs

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

Overall Conclusion

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

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

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

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

   Prostacyclins

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

   Endothelin Receptor Antagonists (ERAs)

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

   Nitric Oxide Drugs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VI. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. QLs

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

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

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

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

C. PAs with Renewal Criteria and Definition

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

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

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

D. PA and QLs Implementation Periods

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

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

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

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

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

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

VIII. LINE EXTENSIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1) *Analgesics and NSAIDs:*

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

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

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

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

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

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

2) *Topical Irritants/Counter-irritants:*

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

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

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

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

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

3) *Irritants/Counter-irritants:*

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

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

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

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

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

XI. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS

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

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

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

XII. ITEMS FOR INFORMATION

A. Veteran's Administration Continuity of Care List

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

B. MHS and Commercial Pharmacy Trends

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

XIII. ADJOURNMENT

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

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

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

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

26 JULY 2019
Date

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

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

Appendix A—Attendance (continued)

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

Appendix B—Table of Medical Necessity (MN) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

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

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

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

Drug / Drug Class	Prior Authorization Criteria

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

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

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

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

Drug / Drug Class	Prior Authorization Criteria

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

Drug / Drug Class	Prior Authorization Criteria

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

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

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

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

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

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

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

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

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

Drug / Drug Class	Prior Authorization Criteria

• tofacitinib (Xeljanz/Xeljanz XR)
 	
Targeted Immunomodulatory Biologics (TIBs) – Miscellaneous
	Prior authorization criteria originally approved August 2014 and updated May 2016 to reflect XR formulation, February 2018, August 2018, and November 2018 to reflect indication changes.
	
	<u>Changes from the May 2019 meeting are in BOLD.</u>
	
	Step therapy and manual PA criteria apply to all new users of Xeljanz/Xeljanz XR.
	
	<u>Automated PA Criteria</u>: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.
	
	AND
	
	<u>Manual PA Criteria</u>:
	If automated criteria are not met, coverage is approved for Xeljanz/Xeljanz XR if:
	Coverage approved for patients ≥ 18 years with:
	• Moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate.
	  ◦ **This prescription for 5 mg BID or 11 mg daily.**
	• Active psoriatic arthritis (PsA).
	  ◦ **This prescription for 5 mg BID or 11 mg daily.**
	• Moderately to severely active ulcerative colitis (UC). **(Will allow doses up to 10 mg BID).**
	
	• Humira is the Department of Defense's preferred targeted biologic agent. The patient has tried Humira.
	• The patient has a contraindication to Humira (adalimumab) OR
	• The patient had an inadequate response to Humira. OR
	• The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent.
	
	• The patient is not receiving potent immunosuppressants (for example, azathioprine and cyclosporine) concomitantly
	• Patient hemoglobin (Hgb) must be > 9 g/dL.
	• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed).
	• The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])?
	
	Non-FDA-approved uses are not approved.
	Prior authorization does not expire.
	
	Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), rituximab (Rituxan), **secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya)**.

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

Appendix D—Table of Quantity Limits (QLs)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix I—Table of Abbreviations

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

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

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2019

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0800 hours on February 6 and 7, 2019, at the Defense Health Agency (DHA) Formulary Management Branch, San Antonio, Texas.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

1. **Approval of November 2018 Minutes—**Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2018 DoD P&T Committee meeting on February 1, 2019.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All 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. Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the CGRP antagonists, which provide a new mechanism for migraine headache prevention. The drugs in the subclass include erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm (Emgality). The CGRP antagonists are available as once monthly injections and were individually reviewed as new drugs at the August and November 2018 DoD P&T Committee meetings. All three products are FDA-approved for the preventive treatment of migraines in adults.

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

CGRP antagonists vs. oral preventive therapies

- Oral drugs, including the antiepileptics, beta-blockers and antidepressants, remain the first-line treatment for migraine headache prevention, based on the 2012/2015 American Academy of Neurology/American Headache Society (AHS) migraine prevention guidelines and the 2018 AHS consensus statement for instituting the new migraine treatments into clinical practice. CGRP antagonists are recommended following 2 or 3 trials of oral medications.
- A 2018 network meta-analysis from the Institute for Clinical and Economic Review (ICER) found that oral preventive treatment and CGRP antagonists decrease monthly migraine days (MMD) by approximately 2 days from baseline, compared to placebo. ICER also concluded that the evidence is inadequate to distinguish the net health benefit between treatment with the CGRP inhibitors versus oral preventive therapies (e.g., amitriptyline, topiramate, or propranolol).

CGRP antagonist vs. CGRP antagonist

- Although there are no head-to-head trials comparing erenumab, fremanezumab, or galcanezumab, there do not appear to be clinically relevant differences in efficacy, based on indirect comparisons. For episodic migraine, a meta-analysis showed similar improvements between the three CGRP antagonists in terms of change from baseline in MMD and the patients who had a ≥ 50% reduction in migraine days (50% responders) *(Zhu, et al., Neurological Sciences 2018*).
- The 2018 ICER network meta-analysis reported reductions in MMDs ranging from 1.2 to 1.9 days with the CGRP inhibitors for episodic migraine, with the odds of achieving a 50% response rate ranging from 1.7 to 2.7. For chronic migraine, the decrease in MMDs ranged from 1.3 to 2.4 days. ICER concluded the evidence was inadequate to distinguish the net health benefits among the three CGRP inhibitors.
- The FDA review noted that some patients treated with a CGRP antagonist experienced relatively large reductions in migraine headache days. However, there are no clinical characteristics to prospectively identify those patients most likely to respond to therapy. Additionally, there was a high placebo response rate noted in the individual trials used to gain FDA approval.
- Some distinguishing characteristics among the CGRP inhibitors are as follows:
  - Erenumab (Aimovig) is available in two dosages, 70 mg and 140 mg. There are no clear data to suggest that the two doses differ in their efficacy or safety.
  - Fremanezumab (Ajovy) is the only CGRP inhibitor approved for quarterly dosing in addition to monthly dosing. However, administration of three pens at the same time is required.
  - Galcanezumab (Emgality) requires a loading dose, administered as two pens at the same time.
  - All three products require refrigeration; however, advantages of Aimovig and Emgality include the ability to be stored up to 7 days at room temperature vs. only 24 hours with Ajovy.

Safety

- The CGRP antagonists have a relatively mild side effect profile, with injection site reactions the most commonly reported adverse event. Injection site reactions occurred at an incidence of 5.6% with Aimovig, 18%-23% with Emgality, and 45% with Ajovy.
- The ICER report concluded that there were no differences in the discontinuation rates due to adverse events among the CGRP inhibitors.
- There is concern for theoretical cardiovascular adverse events with long-term use of the CGRP antagonists. The FDA has required postmarketing surveillance for myocardial infarction and stroke for the class.

Other Factors

- Botulinum toxin (Botox) injection is approved for prevention of chronic migraine, but is not part of the TRICARE pharmacy benefit. Botulinum toxin has similar efficacy to the oral preventive medications and CGRP antagonists in chronic migraine patients, based on the 2018 ICER review.
- There is a high degree of interchangeability between the CGRP antagonists. However, there remains uncertainty regarding the long-term efficacy and safety of this new class of therapy. At least one CGRP inhibitor should be on the UF to meet the needs of the majority of patients in the MHS.

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

- CMA results showed that galcanezumab (Emgality) was the most cost-effective CGRP antagonist, followed by erenumab (Aimovig), and fremanezumab (Ajovy).
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results found that designating galcanezumab (Emgality), erenumab (Aimovig), and fremanezumab (Ajovy) as uniform formulary demonstrated significant cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following for the CGRP Antagonist Prophylaxis agents, as outlined below, based on clinical and cost-effectiveness:
    - UF
        - erenumab injection (Aimovig)
        - fremanezumab injection (Ajovy)
        - galcanezumab injection (Emgality)

- NF
    - None

- Note: A CGRP product was not added to the BCF, due to the unknown long-term efficacy and safety data. The BCF selections in the migraine class include sumatriptan and rizatriptan.

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—PA criteria currently apply to the CGRP products, requiring a trial of at least one drug from two oral classes used for migraine prophylaxis, including antiepileptic medications, beta-blockers or antidepressants. PA criteria were originally recommended when the individual CGRP products were first evaluated as new drugs.

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the current manual PA criteria for all three CGRP antagonists in new users. The PA criteria and updates reflect the recommendations from the 2018 AHS Consensus Statement regarding candidates for a CGRP and assessment of response. (See Appendix C for the full criteria.)

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the existing quantity limits for the three CGRP antagonists. See Appendix D.

4. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS FOR CGRP PROPHYLAXIS AGENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) excluding Aimovig, Ajovy, and Emgality from the Auto-Refill program administered by Express Scripts, Inc., at the TRICARE Mail Order Pharmacy, based on uncertainty regarding long-term safety and patient adherence.

5. ***COMMITTEE ACTION: UF, QL, PA AND AUTO-REFILL IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is May 29, 2019. Note that the recommendations for removal of the auto-refill requirements for the CGRP antagonists will occur 90 days after signing.

B. Oncological Agents – CYP-17 Inhibitors (CYP17) and 2nd-Generation Antiandrogens (2nd-Gen AA) Subclasses

Background—The P&T Committee evaluated the relative clinical effectiveness of two subclasses of drugs used for Prostate Cancer. The agents in the CYP17 inhibitor subclass include abiraterone acetate (Zytiga, generics) and abiraterone acetate micronized (Yonsa), while the 2nd-generation antiandrogen (AA) subclass is comprised of enzalutamide (Xtandi) and apalutamide (Erleada). The Committee reviewed new data available since the previous formulary decision in February 2015.

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

CYP17 Inhibitors Subclass

- The 2018 guidelines from the National Comprehensive Cancer Network (NCCN) included updated recommendations for metastatic castration-resistant prostate cancer (mCRPC). Abiraterone acetate micronized (Yonsa) used with methylprednisolone was added to the mCRPC algorithm. The guidelines continue to recommend abiraterone acetate (Zytiga, generics) with prednisone for this indication.
- The American Urological Association (AUA) guidelines for mCRPC were updated in 2018 and continue to include abiraterone with prednisone.
- Abiraterone acetate (Zytiga) and abiraterone acetate micronized (Yonsa) contain the same active ingredient. Both products must be co-administered with a corticosteroid to reduce the incidence and severity of mineralocorticoid excess (hypertension, hypokalemia, and fluid retention). Differences include that Zytiga is given with prednisone while Yonsa is administered with methylprednisolone.
- There is no clinical trial data available with Yonsa; FDA approval was based upon the clinical trial data with Zytiga and bioequivalence studies.
- There are no head-to-head comparative trials for the two abiraterone products. However, the NCCN guidelines recommend that either formulation can be used in place of the other.
- The micronized formulation of Yonsa results in a smaller tablet particle size; therefore, the dosages differ between the two preparations. Under fasting conditions, single doses of Yonsa 500 mg were equivalent to single doses of Zytiga 1,000 mg.
- Zytiga has an advantage of a lower tablet burden. Yonsa has an advantage in that it can be dosed without regard to meals, while Zytiga must be taken on an empty stomach.
- Generic formulations of Zytiga recently entered the market in December 2018, but the generics only include one tablet strength (250 mg).
- Based on available safety data, the FDA review of Yonsa concluded that there is no evidence that there are differences in safety between Zytiga and Yonsa. Both products have similar warnings and precautions for mineralocorticoid excess, adrenocortical insufficiency, and hepatotoxicity. The FDA review noted that adverse events occurred at similar rates between the two formulations.

- Overall, there is a high degree of therapeutic interchangeability between Zytiga and Yonsa. At least one CYP17 inhibitor is required on the formulary in order to meet the needs of MHS patients.

2nd-Generation AA Subclass

- Enzalutamide (Xtandi) and apalutamide (Erleada) are both FDA-approved for use in non-metastatic castration-resistant prostate cancer (nmCRPC). The 2018 NCCN and 2018 AUA guidelines also recommend both Xtandi and Erleada for nmCRPC. However, of the two 2nd-generation antiandrogens, only Xtandi has FDA approval for use in metastatic CRPC and is included in both the NCCN and AUA guidelines for mCRPC.
- FDA approval for the 2nd-generation AAs for non-metastatic CRPC was based on two randomized, placebo-controlled trials, PROSPER with Xtandi and SPARTAN with Erleada. Men with prostate-specific antigen (PSA) doubling times of ≤ 10 months were included in the trials.
    - Metastasis-free survival (MFS), defined as the delay in development of metastatic disease until metastasis is detected, was the primary endpoint used in both the PROSPER and SPARTAN trials. The study results showed that both 2nd-generation AAs provided a benefit in terms of MFS compared to placebo.
    - An indirect comparison of the two trials showed a similar effect on MFS. For Xtandi the median MFS was 36.6 months vs. 14.7 months with placebo, resulting in a 71% risk reduction for the endpoint. In comparison, with Erleada the median MFS was 40.5 months vs. 16.2 months with placebo, corresponding with a 72% risk reduction in the primary endpoint.
    - Although overall survival data are not yet mature, interim analyses indicate a trend toward improved survival with both drugs when compared to placebo.
- A 2018 ICER report concluded that, when compared to placebo, Erleada and Xtandi showed delays in disease progression and a trend toward improved survival in patients with non-metastatic CRPC, and were given an "A" rating.
- Xtandi and Erleada have relatively similar adverse effect profiles. Both drugs are associated with hypertension, fatigue, falls, fractures, and seizures.
- Although the PROSPER trial using Xtandi in patients with non-metastatic CRPC showed a disproportionate rate of adverse cardiac effects and death compared to placebo, this finding was not reproduced in other studies with Xtandi conducted in varying populations, including patients with non-metastatic hormone-sensitive prostate cancer (HSPC), metastatic HSPC, non-metastatic CRPC, and metastatic CRPC.
- Comparative effectiveness of Xtandi and Erleada, when used in non-metastatic CRPC, cannot be determined at this time, due to the lack of head-to-head trials.
- At least one 2nd-generation antiandrogen must be included on the formulary for MHS patients.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed to evaluate the prostate cancer agents. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

CYP17 Inhibitors

- CMA results for the CYP17 inhibitor subclass showed that abiraterone acetate micronized (Yonsa) was more cost-effective than abiraterone (Zytiga, and generics).
- BIA was performed for the CYP17 inhibitor subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating abiraterone acetate micronized (Yonsa) as formulary and step-preferred and abiraterone acetate (Zytiga, generics) as UF and non-step-preferred demonstrated the greatest cost avoidance for the MHS.

2nd-Generation AA Subclass

- CMA results for the 2nd-generation antiandrogen subclass showed that enzalutamide (Xtandi) was the most cost-effective 2nd-generation AA.
- BIA was performed for the 2nd-generation antiandrogen subclass to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating enzalutamide (Xtandi) as formulary and step-preferred and apalutamide (Erleada) as UF and non-step-preferred demonstrated significant cost avoidance for the MHS.

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

   CYP 17 Inhibitor Subclass

   - UF and step-preferred
     - abiraterone acetate micronized (Yonsa)
   - UF and non-step-preferred
     - abiraterone acetate (Zytiga, generics)
   - NF
     - None

   2nd-Generation Antiandrogen Subclass

   - UF and step-preferred
     - enzalutamide (Xtandi)
   - UF and non-step-preferred
     - apalutamide (Erleada)
   - NF
     - None

- Note that a CYP17 or 2nd-generation AA agent was not added to the BCF. Bicalutamide (Casodex) will remain on the BCF for the Prostate 1 subclass.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Updated manual PA criteria for abiraterone acetate micronized (Yonsa) and abiraterone acetate (Zytiga, generics) were recommended by the P&T Committee (18 for, 0 opposed, 0 abstained, 0 absent). For both Yonsa and Zytiga/generics, the prescription must be written by an oncologist or urologist, and off-label use for non-localized disease was added. The Zytiga PA criteria were also updated to include step therapy, requiring a trial of Yonsa first, unless there is a contraindication, inadequate response, or adverse reaction to Yonsa, for all new and current users of Zytiga/generics (i.e., "no grandfathering" scenario). Additionally, for Zytiga, the 250 mg tablets are the preferred formulation, based on cost-effectiveness. All new and current users of Zytiga/generic 500 mg tablets will need to try the 250 mg tablets first. See Appendix C for full criteria.

   The Committee also recommended updating the current PAs for enzalutamide (Xtandi) and apalutamide (Erleada) to include the Xtandi step-therapy requirements. All new users (i.e., "grandfathering" scenario) of Erleada will require a trial of Xtandi first, unless contraindicated or if the patient has had an inadequate response or adverse reaction to previous use of Xtandi. Additionally, for nmCRPC, both Xtandi and Erleada will require patients to have documented prostate-specific antigen doubling time (PSADT) of ≤ 10 months, consistent with the trial design of PROSPER and SPARTAN. See Appendix C for full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updating the current quantity limits for Yonsa, Zytiga, Xtandi, and Erleada. See Appendix D.

4. ***COMMITTEE ACTION: TIER 1 COST-SHARE—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) lowering the current tier 2 cost-share for the CYP17 inhibitor abiraterone acetate micronized (Yonsa) and the 2nd-generation AA enzalutamide (Xtandi) 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." Lowering the cost-share for both Yonsa and Xtandi will provide a greater incentive for beneficiaries to use the most cost-effective CYP 17 or 2nd-generation antiandrogen product, respectively, in the purchased care points of service.

5. ***COMMITTEE ACTION: UF, QL AND PA IMPLEMENTATION PERIOD—*** The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the P&T minutes at all points of service, and 2) DHA send letters to beneficiaries who are affected by the step decision in the CYP17 subclass (those patients currently on Zytiga, generics). Based on the P&T Committee's recommendation, the effective date is July 31, 2019.

V. SECTION 702, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2018: TRICARE TIER 4/NOT COVERED DRUGS PER 32 CFR 199.21(E)(3)

Background—An interim final rule implementing Section 702(b)(10) of the NDAA 2018 was published on December 11, 2018, and is found at: https://www.federalregister.gov/documents/2018/12/11/2018-26562/tricare-pharmacy-benefits-program-reforms. The interim rule allows for complete exclusion of drugs from TRICARE pharmacy benefit coverage when certain criteria are met.

The interim rule amends 32 CFR 199.21(e)(3). The P&T Committee may recommend, and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending. Specifically, the P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents.

The P&T Committee was briefed on the above provisions at the February 2019 meeting. The Committee considered several factors when identifying candidates for complete exclusion from the TRICARE pharmacy benefit. These factors include, but are not limited to, the availability and quality of clinical efficacy evidence compared to alternative similar agents, determination of significant safety issues in which risks may outweigh potential benefit, identification of drugs that contain ingredients not covered by the TRICARE pharmacy benefit, or other negative concerns identified by regulatory authorities or nationally recognized expert organizations. The Committee also reviewed the practices regarding exclusion of drugs from several commercial, state, and Federal Government health care plans. Complete exclusion of drugs from the TRICARE pharmacy benefit will apply to both new and current users.

Relative Clinical and Cost Effectiveness Summary/Rationale for Complete Exclusion—The Committee reviewed clinical efficacy, safety, and cost-effectiveness data for four candidates considered for Tier 4/Not Covered status under the TRICARE pharmacy benefit program.

- **Diabetes Non-Insulin Drugs – Biguanides Subclass: metformin ER gastric retention 24 hours (Glumetza brand and generics)** is an extended release formulation of metformin approved in 2005. It uses a polymer-based oral drug delivery system that makes the tablet swell, which causes retention in the stomach. Clinical trials show

Glumetza is at least as efficacious as metformin immediate-release (IR) (Glucophage) in all measures of glycemic control. There is no evidence to suggest that differences in the extended-release properties of Glumetza confer any benefits in efficacy or safety compared to the other metformin ER formulations (Glucophage XR).

Overall conclusion: A significant cost difference exists between Glumetza and other generic metformin ER formulations (Glucophage XR), with no additional clinical benefit. The P&T Committee concluded that the needs of TRICARE beneficiaries can be met by other metformin ER or metformin IR products available on the Uniform Formulary.

- **Pain Agents – Combinations Subclass: naproxen/esomeprazole** (**Vimovo**) is a fixed-dose combination of two over-the-counter (OTC) drugs, a nonsteroidal anti-inflammatory drug (NSAID) and a proton pump inhibitor (PPI). The Committee agreed that use of fixed dose combination therapies offers patients a convenient formulation for improving adherence. However, this particular combination of an NSAID, which is typically targeted for short-term use, and a PPI, which has limited data to support use beyond eight weeks, is potentially harmful. There is no data to suggest that using other prescription or OTC NSAIDs concurrently with PPIs would not provide the claimed benefit of the individual ingredients found in Vimovo.

  Overall conclusion: The Committee concluded that Vimovo is not cost-effective relative to other NSAIDs and PPIs used concurrently. The needs of TRICARE beneficiaries can be met by the concurrent use of similar single ingredient OTC or prescription NSAIDs and PPIs available on the Uniform Formulary.

- **Pancreatic Enzyme Replacement Therapy: pancrelipase (Zenpep)** and the other pancreatic enzyme replacement therapies (PERTs) were reviewed for formulary status in May 2018. The Committee concluded 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 Military Health System (MHS) patients. Creon was designated as the sole step-preferred PERT, and the cost-share was lowered to the generic Tier 1 cost-share to provide a greater incentive for beneficiaries to use the more cost effective PERT formulation. Zenpep was designated nonformulary and non-step-preferred, requiring a trial of Creon in all users. Zenpep provides very little to no clinical effectiveness relative to Creon or the other PERTs.

  Overall conclusion: The needs of TRICARE beneficiaries can be met by Creon and the other available PERTs.

- **Targeted Immunomodulatory Biologics (TIBs): brodalumab** (**Siliq**) is an injectable TIB approved for treating plaque psoriasis and is the only TIB that carries a black box warning for suicide. An FDA safety review of all clinical trials with Siliq reported 36 patients with attempted suicide, or suicidal ideation, and 6 patients with completed suicides. This safety risk is comparable to other biologic agents that the FDA denied marketing approval, and is significantly greater than any of Siliq's clinical comparators.

The drug also has Risk Evaluation and Mitigation Strategies (REMS) requirements that mandate certification of both prescribers and pharmacies.

Siliq was reviewed as a newly approved drug at the August 2017 DoD P&T Committee meeting and recommended for nonformulary status, with PA criteria requiring a trial of adalimumab (Humira) and secukinumab (Cosentyx) first.

Overall conclusion: The P&T Committee concluded that relative to the other nine TIBs that are FDA-approved to treat psoriasis, Siliq imposes a significant safety risk without offering any unique advantage in efficacy or in specific sub-populations. However, a subset of patients with plaque psoriasis will develop highly refractory disease, and Siliq may be of value as an alternate agent for patients who do not respond to other treatment options.

A. ***COMMITTEE ACTION: TRICARE TIER 4/NOT COVERED RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) designating the following products as Tier 4/Not Covered under the TRICARE pharmacy benefits program.

- metformin ER gastric retention 24 hours (Glumetza brand and generics)
- naproxen/esomeprazole (Vimovo)
- pancrelipase (Zenpep) **Please refer to the signature page (pages 25-26) for the revised decision and new prior authorization criteria.**

B. ***COMMITTEE ACTION***: ***RECOMMENDATION MAINTAINING CURRENT NF STATUS FOR SILIQ***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current formulary status for brodalumab (Siliq). The Committee acknowledged Siliq's place in therapy for highly selected patients who are refractory to other treatment options. Siliq will remain NF and non-step-preferred, requiring a trial of Humira, Cosentyx, Stelara, Tremfya, Ilumya and Taltz first. The current PA will remain in place to mitigate risk of suicidal ideation.

C. ***COMMITTEE ACTION: TIER 4/NOT COVERED IMPLEMENTATION PERIOD***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) for pancrelipase (Zenpep), metformin ER gastric retention 24 hours (Glumetza brand and generics), and naproxen/esomeprazole (Vimovo): 1) an effective date of the first Wednesday after a 120-day implementation period at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is August 28, 2019.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 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 February 2019 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations. See Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

A. *COMMITTEE ACTION: UF/TIER 4/NOT COVERED RECOMMENDATION—*

The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF:
  - amifampridine (Firdapse) – Miscellaneous Neurological Agent for Lambert-Eaton Myasthenic Syndrome (LEMS)
  - baloxavir (Xofluza) – Antiviral for Influenza
  - cenegermin-bkbj ophthalmic solution (Oxervate) – Anti-Inflammatory Immunomodulatory Ophthalmic Agent for Neurotrophic Keratitis
  - elapegademase-lvlr IM injection (Revcovi) – Miscellaneous Metabolic Agent for Adenosine Deaminase Severe Combined Immune Deficiency (ADA-SCID)
  - gilteritinib (Xospata) – Oncological Agent for Acute Myelogenous Leukemia (AML)
  - glasdegib (Daurismo) – Oncological Agent for AML
  - inotersen injection (Tegsedi) – Miscellaneous Neurological Agent for Hereditary Transthyretin Amyloidosis
  - larotrectinib (Vitrakvi) – Oncological Agent for Solid Tumors
  - lorlatinib (Lorbrena) – Oncological Agent for Non-Small Cell Lung Cancer (NSCLC)
  - loteprednol ophthalmic suspension (Inveltys) – Ophthalmic Corticosteroid for Postoperative Inflammation
  - pegfilgrastim-cbqv injection (Udenyca) – White Blood Cell Stimulant and Biosimilar to Neulasta
  - riluzole oral suspension (Tiglutik) – Miscellaneous Neurological Agent for Amyotrophic Lateral Sclerosis (ALS)
  - tafenoquine 100 mg tablet (Arakoda) – Antimalarial Agent for Prophylaxis of Malaria
  - tafenoquine 150 mg tablet (Krintafel) – Antimalarial Agent for Prevention of Relapse and Radical Cure of Malaria
  - talazoparib (Talzenna) – Oncological Agent for Breast Cancer

- testosterone enanthate, subcutaneous (SQ) injection (Xyosted) – Androgens-Anabolic Steroids: Testosterone Replacement Therapies

- NF:
  - aripiprazole tablet with ingestible event marker (Abilify MyCite) – Atypical Antipsychotic
  - clobazam oral film (Sympazan) – Anticonvulsant-Antimania Agent for Lennox-Gastaut Syndrome
  - cyclosporine 0.09% ophthalmic solution (Cequa) – Anti-Inflammatory Immunomodulatory Ophthalmic Agent for Dry Eye Disease
  - desmopressin acetate sublingual (SL) tablet (Nocdurna) – Miscellaneous Endocrine Agent for Nocturia due to Nocturnal Polyuria
  - filgrastim vials (Granix) – White Blood Cell Stimulant and Biosimilar to Neupogen
  - halobetasol propionate 0.01% lotion (Bryhali) – High Potency Corticosteroid-Immune Modulator for Plaque Psoriasis
  - itraconazole 65 mg capsules (Tolsura) – Antifungal Agent
  - latanoprost (Xelpros) – Ophthalmic Prostaglandin
  - omadacycline (Nuzyra) – Tetracycline Antibiotic for Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
  - revefenacin nebulized solution (Yupelri) – Pulmonary-2: Long Acting Anti-Muscarinic Agent (LAMA) for Chronic Obstructive Pulmonary Disease (COPD)
  - rifamycin (Aemcolo) – Miscellaneous Gastrointestinal Antibiotic for Traveler's Diarrhea
  - sarecycline (Seysara) – Tetracycline Antibiotic for Acne Vulgaris

- Tier 4/Not Covered
  - halobetasol propionate 0.05% foam (Lexette) – corticosteroids-Immune Modulators – High Potency for Plaque Psoriasis:

    The topical corticosteroids were reviewed for formulary placement in August 2013. There is a high degree of therapeutic interchangeability within a particular potency category and vehicle. There are currently 28 other high-potency topical corticosteroids on the formulary, including 12 products formulated in a hair-friendly vehicle, including foam, gel, lotion, shampoo, and solution. The new foam formulation of Lexette offers no clinically meaningful advantages over the high-potency topical steroids available on the UF.

Overall conclusion: The P&T Committee concluded that Lexette provides little to no clinical benefit and its cost is prohibitive relative to the numerous formulary alternatives. Currently, the needs of TRICARE beneficiaries can be met by the 28 other formulary high-potency topical steroids.

B. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Abilify MyCite, Aemcolo, Bryhali, Cequa, Granix, Nocdurna, Nuzyra, Seysara, Sympazan, Tolsura, Xelpros, and Yupelri. See Appendix B for the full criteria.

C. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) the following (see Appendix C for the full criteria):

- Oral Tetracycline Agents: Applying the same automated (step therapy) and manual PA criteria for sarecycline (Seysara) in new and current users that is currently in place for the other non-step-preferred oral tetracyclines. Patients must first try one generic doxycycline IR product, either the hyclate or monohydrate salt and one generic minocycline IR product first, before Seysara.
- Androgens-Anabolic Steroids: Testosterone Replacement Therapies: Applying new manual PA criteria for Xyosted SQ in new and current users. In addition to a trial of the step-preferred testosterone 2% topical gel (Fortesta), patients must also try one injectable testosterone product and meet the Risk Evaluation and Mitigation Strategies (REMS) requirements listed in the Xyosted product label regarding the risk of increases in blood pressure and potential increase in the risk of major adverse cardiovascular events (MACE).
- Applying manual PA criteria to new users of Abilify MyCite, Arakoda, Daurismo, Firdapse, Lorbrena, Oxervate, Talzenna, Tegsedi, Tolsura, Vitrakvi, and Xospata.
- Applying manual PA criteria to new and current users of Aemcolo, Cequa, Nocdurna, Tiglutik, and Yupelri.

D. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***

- **New Drugs Recommended for UF or NF status:** The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1

absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) an effective date upon the first Wednesday 30 days after signing of the minutes in all points of service.

- **New Drugs Recommended for Tier 4 status halobetasol propionate 0.05% foam (Lexette):** The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) for Lexette 1) an effective date of the first Wednesday after a 120-day implementation period at all points of service, and 2) DHA send letters to beneficiaries who are affected by the Tier 4/Not Covered recommendation at 30 days and 60 days prior to implementation. Based on the P&T Committee's recommendation, the effective date is August 28, 2019.

VII. UTILIZATION MANAGEMENT

A. PA Criteria, Step Therapy, and MN Criteria

1. New Manual PA Criteria

a) Antihistamine-1: First generation and combinations – Dexchlorpheniramine 2 mg/5 mL oral solution (Ryclora)

Ryclora is a new liquid formulation of a dexchlorpheniramine, which had previously been removed from the market. The committee reviewed the oral liquid formulations of the non-sedating antihistamines. Cost-effective generic formulations of chlorpheniramine are available on the UF without a PA required, and low-cost OTC liquid formulations for fexofenadine and loratadine are widely available.

COMMITTEE ACTION: ANTIHISTAMINE-1: FIRST GENERATION AND COMBINATIONS DEXCHLORPHENIRAMINE MALEATE LIQUID (RYCLORA) MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for dexchlorpheniramine 2 mg/5 mL oral syrup (Ryclora) in new and current users, due to the significant cost differences and lack of clinically compelling benefits over generic alternatives. See Appendix C for the full criteria.

b) Hepatitis C Agents: Direct-Acting Agents (HCV DAAs): generic ledipasvir/sofosbuvir (authorized generic for Harvoni) and generic sofosbuvir/velpatasvir (authorized generic for Epclusa)

The P&T Committee most recently reviewed the HCV DAAs for formulary status in August 2018. Since the review, authorized generics for Harvoni and Epclusa entered the market in December 2018. An "authorized generic" is the brand company's own product repackaged and marketed as a generic drug. An authorized generic is considered therapeutically equivalent to the name brand drug because it is the same drug. The FDA does not consider authorized generics as AB-rated generic formulations.

COMMITTEE ACTION: GENERIC LEDIPASVIR/SOFOSBUVIR AND GENERIC SOFOSBUVIR/VELPATASVIR MANUAL PA CRITERIA— The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the authorized generic products ledipasvir/sofosbuvir and sofosbuvir/velpatasvir in new users, requiring a trial of the branded Harvoni or Epclusa, due to cost-effectiveness. The PA requirement will be removed when it is no longer cost advantageous. See Appendix C for the full criteria.

c) Skeletal Muscle Relaxants and Combinations: cyclobenzaprine 7.5 mg

Generic formulations of the skeletal muscle relaxant cyclobenzaprine are available in 5 mg, 7.5 mg, and 10 mg tablets. Cyclobenzaprine 7.5 mg tablets are significantly less cost-effective compared to the 5 mg or 10 mg strengths. Cost-effective generic formulations of cyclobenzaprine 5 mg and 10 mg and multiple comparable muscle relaxants (e.g., baclofen, methocarbamol) are available on the UF without PA required. The Committee did note that skeletal muscle relaxants are not considered first-line therapy for musculoskeletal conditions.

COMMITTEE ACTION: CYCLOBENZAPRINE 7.5 MG MANUAL PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for new and current users of cyclobenzaprine 7.5 mg tablets, due to the significant cost differences and lack of clinically compelling benefits compared with administering one and a half of a 5 mg tablet or using other generic muscle relaxants. See Appendix C for the full criteria.

2. Temporary specific Prior Authorization for Drugs Not Subject to 32 CFR 199.21(g)(5)—There are an increasing number of drugs approved by the FDA via Abbreviated New Drug Applications (ANDAs), rather than the traditional New Drug Application (NDA) process. These drugs do not qualify for review by the DoD P&T Committee under 32 CFR 199.219(g)(5) (e.g., innovator reviews or newly approved drug reviews). These ANDA-approved products commonly contain ingredients that are currently available in generic products or were included in formulations previously removed from the market. Additionally, the ANDA-approved products can be less cost-effective than formulary alternatives and provide little to no additional clinical benefit.

In order to respond quickly to market launch of ANDA-approved products where several cost-effective formulary alternatives are available, the DHA Pharmacy Operations Division requested administrative authority to place temporary specific Prior Authorization criteria on select ANDA-approved products. The pre-authorization requirement will help minimize patient impact by decreasing the number of patients potentially initiating treatment on such products.

The "temporary specific" criteria will require documentation by the provider as to why that drug is required rather than the available alternatives. The temporary specific PA

criteria will be implemented at the time of product launch or as soon as operationally possible. All temporary specific PA criteria will be reviewed by the DoD P&T Committee at the next meeting. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes at the next meeting. Letters will be sent to any existing utilizers of the identified drugs, if applicable.

COMMITTEE ACTION: NEWLY APPROVED DRUGS OUTSIDE OF 32 CFR 199.21(g)(5) RECOMMENDED TEMPORARY SPECIFIC PA CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) granting authority to the DHA POD to implement temporary specific PA criteria for those products identified as falling outside of 32 CFR 199.21(g)(5), prior to formal vote by the DoD P&T Committee at the following meeting.

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

   a) **Cardiovascular Agents Miscellaneous: ivabradine (Corlanor)—**The Committee reviewed a request to allow an off-label use for ivabradine (Corlanor). Manual PA criteria have applied to Corlanor since November 2015, limiting use to the FDA indication to decrease the risk of hospitalization in patients with chronic heart failure. The Committee recommended updating the PA criteria to include treatment of patients with symptomatic inappropriate sinus tachycardia (IST) or postural tachycardia syndrome (POTS). The recommendation was based on supporting clinical trial data and the 2015 guidelines from the American College of Cardiology/American Heart Association/Heart Rhythm Society, which state that Corlanor is reasonable for ongoing management in patients with these conditions.

   b) **Cystic Fibrosis Agents: ivacaftor (Kalydeco)**—Kalydeco was first reviewed by the P&T Committee in July 2012, where PA was recommended, based on the package insert labeling. Additional updates were made in May 2014 and November 2018. The FDA has now approved Kalydeco for use in patients as young as 1 year of age, and the PA criteria were updated to reflect the new FDA-approved age range.

   c) **Gastrointestinal-2 Agents: Miscellaneous – rifaximin 200 mg (Xifaxan)—** Manual PA criteria were previously recommended for Xifaxan for Traveler's Diarrhea at the May 2013 P&T Committee meeting. The Xifaxan PA was updated to reflect the most recent update of the 2017 Infectious Diseases Society of America Clinical Practice Guidelines for the Diagnosis and Management of Infectious Diarrhea, requiring a trial of azithromycin or ciprofloxacin.

   d) **Hematological Agents – Platelets: avatrombopag (Doptelet)**—Avatrombopag (Doptelet) and lusutrombopag (Mulpleta) are pre-procedure regimens for patients

with thrombocytopenia associated with liver disease. Mulpleta does not require dose adjustment; therefore, the P&T Committee updated the Doptelet PA criteria to require use of Mulpleta first, to reduce the risk of dosing errors with Doptelet.

e) **Immune Modulators Endocrine Agents: Miscellaneous – Desmopressin nasal spray (Noctiva)**—Noctiva nasal spray was most recently reviewed for formulary placement at the May 2018 DoD P&T Committee meeting. The PA criteria for Noctiva were updated to include a comprehensive list of safety concerns, and to mirror the PA criteria for the new drug desmopressin SL tablets (Nocdurna). The MN criteria were also updated.

f) **Targeted Immunomodulatory Biologics (TIBs): adalimumab (Humira) and anakinra (Kineret)—**The TIBs were most recently reviewed in August 2014, with step therapy requiring a trial of adalimumab (Humira) first. The FDA recently granted new indications for Humira for moderate to severe hidradenitis suppurativa in patients 12 years and older, and for Kineret for systemic juvenile idiopathic arthritis, and the respective PAs were updated for these additional indications.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, STEP THERAPY, AND MN CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Kalydeco, Noctiva nasal spray, Xifaxan, Doptelet, Humira, Kineret, Corlanor; and also recommended updates to the MN criteria for Noctiva. (See Appendices B and C for the full criteria.)

B. Auto-Refill Requirements for Desmopressin (Nocdurna SL tabs and Noctiva nasal spray)

The new formulations of desmopressin, Noctiva and Nocdurna, have significant safety concerns, including hyponatremia, particularly in patients older than 65 years; drug interactions are also common. The 2019 update to the Beers criteria gives a strong recommendation to avoid use of desmopressin for treatment of nocturia and nocturnal polyuria, as safer alternatives are available. The Beers criteria aims to help reduce potentially inappropriate medication use in patients older than 65 years. Due to safety concerns, the P&T Committee recommended removing Noctiva and Nocdurna from the auto-refill program.

1. ***COMMITTEE ACTION: NOCTIVA AND NOCDURNA AUTO-REFILL PROGRAM RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing Nocdurna SL tablets and Noctiva nasal spray from the Auto-Refill program administered by Express Scripts, Inc. at the TRICARE Mail Order Pharmacy.

C. QLs

QLs were reviewed for 7 drugs from drug classes where there are existing QLs, including the oncological agents, GI-2 agents, dry eye disease drugs, and LAMA. QLs were also discussed for 9 drugs where QLs are not currently in place.

1. ***COMMITTEE ACTION: QLs—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Aemcolo, Cequa, Daurismo, Firdapse, Krintafel, Lorbrena, Oxervate, Talzenna, Tegsedi, Tiglutik, Udenyca, Vitrakvi, Xofluza, Xospata, Xyosted, and Yupelri. See Appendix D for the QLs.

D. PA and QLs Implementation Periods

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

   - (18 for, 0 opposed, 0 abstained, 0 absent) New PAs for Ryclora, cyclobenzaprine 7.5 mg, authorized generic ledipasvir/sofosbuvir and authorized generic sofosbuvir/velpatasvir become effective 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for the cyclobenzaprine 7.5 mg and Ryclora if applicable, as new and current users will be subject to the PA.
   - (18 for, 0 opposed, 0 abstained, 0 absent) Updates to the current PA criteria for Kalydeco, Noctiva nasal spray, Xifaxan, Doptelet, Humira, Kineret, and Corlanor in new users, and the MN update to Noctiva nasal spray become effective 30 days after the signing of the minutes.
   - (18 for, 0 opposed, 0 abstained, 0 absent) Removal of Noctiva and Nocdurna from the Auto-Refill program administered by ESI become effective 90 days after the signing of the minutes. Letters will be mailed to patients affected by the decision.
   - (17 for, 0 opposed, 0 abstained, 1 absent) The QLs for the 16 drugs listed in section VII, C, above, and in Appendix D, become effective on the first Wednesday three weeks after the signing of the minutes in all POS.

VIII. BRAND OVER GENERIC AUTHORIZATION FOR DIHYDROERGOTAMINE SPRAY/PUMP (MIGRANAL NASAL SPRAY)

TRICARE Policy requires dispensing of generic products at the Retail Network and Mail Order Pharmacy. However, pricing for the branded Migranal nasal spray product is more cost-effective than the AB-rated generic formulations for dihydroergotamine nasal spray, which were launched in December 2018. Therefore, the branded Migranal Nasal Spray product will continue to be dispensed, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 (generic) copayment will apply to Migranal Nasal Spray. The "brand over generic" requirement for Migranal Nasal Spray will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

A. ***COMMITTEE ACTION: MIGRANAL NASAL SPRAY BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) implementing the requirement to prefer the branded

Migranal Nasal Spray product over generic formulations. Manual PA criteria are required for generic dihydroergotamine mesylate in the Retail Network and Mail Order Pharmacy. The prescriber will provide patient-specific justification as to why the branded Migranal Nasal Spray product cannot be used. (See Appendix C.)

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

IX. LINE EXTENSIONS

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

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

- Basal Insulin Analogs—Insulin degludec (Tresiba) is now available in vials. Insulin degludec in the pen formulation (Tresiba FlexTouch pen) is currently designated as NF and non-step-preferred, requiring a trial of insulin glargine 100 U/mL (Lantus) first. The P&T Committee recommended designating Tresiba vials as NF and non-step-preferred, with the same step therapy and manual PA requirements as the Tresiba FlexTouch pen. Tresiba vials will also be added to the EMMPI program.

- Hematological Agents—eltrombopag (Promacta) is now available in oral suspension packets. Promacta tablets have not yet been reviewed by the Committee for formulary status, and are currently designated as UF, since FDA approval occurred prior to August 2015 with the implementation of the innovator program. The new Promacta formulation will be designated as UF similar to the parent agent.

- TIBs—the new formulation of tocilizumab (Actemra) ACTPen autoinjector pen will be designated as NF and non-step-preferred, with the same MN, PA, and QLs as the Actemra prefilled syringe. See Appendix D for the QLs.

X. RE-EVALUATION OF NF GENERICS/EMMPI REQUIREMENTS

A. Second Generation Antihistamines: levocetirizine (Xyzal)

Antihistamines: levocetirizine (Xyzal, generics)—The P&T Committee reviewed the current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per unit, for generic levocetirizine (Xyzal). The P&T Committee agreed that, while the unit cost of generic levocetirizine has dropped significantly from the previous generic and brand cost, it is still substantially higher than generic OTC formulations of cetirizine and loratadine, both of which are on the Uniform Formulary. The P&T Committee also noted that generic levocetirizine is comparably priced at all 3 points of service and available from at least 13 manufacturers, suggesting stable generic prices or continued price decreases are likely, due to robust market competition.

1. ***COMMITTEE ACTION: LEVOCETIRIZINE FORMULARY STATUS AND IMPLEMENTATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) that levocetirizine (Xyzal, generics) remain NF but be exempted from the mail order requirement on the basis of comparable pricing at mail order versus MTFs or retail, effective the first Wednesday three weeks after the signing of the minutes. See Appendix F.

XI. 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 or UF during the February 2019 P&T Committee Meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs (the Select Maintenance List) under the EMMPI program and the non-formulary to mail requirement. The implementation date for all EMMPI recommendations from the February 2019 meeting, including the newly approved drugs affected by the EMMPI, will be effective upon the first Wednesday three weeks after the signing of the minutes.

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

The P&T Committee recommended (group 1 and group 3: 17 for, 0 opposed, 0 abstained, 1 absent; and group 2: 18 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI program, for the reasons outlined in the table.

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

At the November 2018 meeting, the P&T Committee designated Tobramycin Inhalation Solution Pak (NDC: 70644-0899-99) by Genericus, Inc. as not compliant with Section 703 requirements. After further review and comparison of tobramycin inhalation solution pak with the other available tobramycin inhalation products which do not include the nebulizer, the Committee recommended removing this drug from the Section 703 Non-Compliant Drug List and returning to its previous status of UF on the Uniform Formulary with no POS restrictions.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED UF***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) that the Section 703 non-compliant NDC of the following product return to its former UF status with no POS restrictions:

- Genericus, Inc.: tobramycin inhalation solution pak (*New Drug Application-authorized generic; NDC 70644-0899-99*) 300 mg/5 mL ampule-nebulizer

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

At the retail pharmacy network and mail order pharmacy, OTC medications are limited to those explicitly included in the TRICARE pharmacy benefit (e.g., diabetic supplies, tobacco cessation agents), and those medications added to the Uniform Formulary and covered by TRICARE under provisions of 32 CFR 199.21(h)(5) as being cost-effective and clinically effective compared with other drugs in the same therapeutic class. These covered OTC products currently include omeprazole, loratadine, cetirizine, fexofenadine, levonorgestrel 1.5 mg (Plan B One-Step and its generics), and doxylamine 25 mg. By contrast, MTFs currently dispense a wide variety of OTC medications. A phased process that encompasses standardization across MTFs is underway.

As a first attempt to address standardization, the P&T Committee reviewed 7 low-use, non-FDA-approved products for potential removal from the MHS GENESIS OTC list: niacin, niacinamide, lactase, glucosamine/chondroitin, chlorhexidine/glycerin/he-cell (Maxilube jelly), surgical lubricant (Surgilube), and folic acid 1 mg OTC. The Committee reviewed the utilization of the 7 products at the MTFs and MHS Genesis host sites.

The P&T Committee noted the following:

- Niacin 500 mg tablet is available as a legend product (Niaspan, generics). Almost 90% of MTF OTC niacin prescriptions are for 500 mg tablets or capsules.
- Oral niacinamide is marketed as a food supplement. In addition to niacin deficiency, more than 25 other potential uses have been identified, including acne and rosacea.
- Lactase (e.g., Lactaid) is used for lactose intolerance in the small intestine.

- Glucosamine/chondroitin is marketed as a food supplement and used to slow degeneration of joint cartilage or alleviate joint pain. A number of clinical trials have assessed its efficacy for osteoarthritis (OA), with conflicting results. An assessment from the NIH National Center for Complementary and Integrative Health concludes that 1) evidence suggests chondroitin is not helpful for knee or hip pain; 2) it is unclear if glucosamine is helpful for OA knee pain; 3) it is unclear if either help with pain in other joints. The American College of Rheumatology's 2012 guideline "conditionally recommends" that patients with hip or knee OA not use glucosamine or chondroitin.
- Maxilube is marketed as a personal lubricant, while Surgilube is marketed as a lubricant for surgical and gynecological procedures. It is unclear why Surgilube is being dispensed as an outpatient pharmacy product.
- Folic acid 1 mg is also available as a legend product. Prescription formulations of folic acid 1 mg are available at all three points of service.

A. COMMITTEE ACTION: STATUS OF AGENTS ON THE MHS GENESIS OTC LIST—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing the following products from the MHS GENESIS OTC list: niacin, niacinamide, lactase, glucosamine/chondroitin, chlorhexidine/glycerin/he-cell (Maxilube jelly), surgical lubricant (Surgilube), and folic acid 1 mg.

B. COMMITTEE ACTION: IMPLEMENTATION—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 90 days following signing of the minutes. Letters will be sent to affected patients at MHS GENESIS MTFs.

XIV. BRAND OVERRIDE CRITERIA

Background—The committee reviewed generic over brand mandatory substitution policy. The committee affirmed currently applied appeals criteria.

A. *COMMITTEE ACTION: BRAND OVERRIDE CRITERIA RECOMMENDATION*—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) to maintain current override criteria for brand requests when generic products are available.

XV. DOD SPECIALTY DRUG PROGRAM

The P&T Committee was briefed on various aspects of the DoD Specialty Drug Program. The Committee recommended criteria to identify potential candidates for addition to or removal from the mail order specialty clinical services program. In order to manage the Specialty Drug program more efficiently, the DHA POD requested administrative authority to add or remove drugs or drug classes from the Clinical Services Drug List.

A. COMMITTEE ACTION: ADMINISTRATIVE AUTHORITY RECOMMENDATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) granting administrative authority to the DHA POD to add or remove drugs or drug classes from the Clinical Services Drug List prior to formal vote by the DoD P&T Committee. Any drugs added or removed from the Clinical Services Drug List will subsequently be presented at the next P&T Committee meeting.

XVI. ITEMS FOR INFORMATION

Annual Review of Newly Approved Drugs

The Committee was briefed on the utilization and cost trends for the newly approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. Since the start of the program, a total of 194 drugs have been reviewed, with 101 (52%) designated as UF and 93 (48%) designated as NF. A clinical summary of program to date was also provided. Challenges to maintaining the program include the increasing volume of new drug approvals from the FDA and the increasing number of specialized products, particularly oncology agents, requiring expertise for review. Updates on the metrics for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

XVII. ADJOURNMENT

The meeting adjourned at 1700 hours on February 7, 2019. The next meeting will be in May 2019.

Appendix A—Attendance: February 2019 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary and Nonformulary During the February 2019 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:

After taking into consideration the Beneficiary Advisory Panel non concurrence for Tier 4/Not covered status for Zenpep, and their recommendation to place a stricter PA on Zenpep, the following will occur:

1. Zenpep will retain Non formulary status.
2. New manual PA criteria will apply to all new and current users of Zenpep, to require a trial of all formulary and non formulary Pancreatic Enzyme Replacement Enzymes, with the exception for patients younger than 2 who will only require a trial of Creon.
3. Implementation will occur 90 days after signing, with affected beneficiaries notified via letter

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

25 APR 19
Date

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

FEBRUARY 2019

UPDATED TABLE OF PRIOR AUTHORIZATION CRITERIA FOR ZENPEP AND THE OTHER PANCREATIC ENZYME REPLACEMENT PRODUCTS

Drug / Drug Class	Prior Authorization Criteria
Step-Preferred • Creon **Non-Step-Preferred** • Pancreaze • Pertzye • Viokace **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, and Viokace. 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, and Viokace 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 • Creon **Non-Step-Preferred** • 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 Zenpep. All new and current users of a PERT are required to try Creon first, before receiving one of the non-step-preferred products. Additionally all new and current users of Zenpep are required to try Pertzye, Pancrease, and Viokace. Manual PA criteria—Zenpep is approved if ALL of the following criteria are met: For patients 2 years of age or younger • The patient has had a sufficient trial of Creon and treatment was unsuccessful For patients older than 2 years of age • 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; document the dates tried _____ AND • The patient has failed an adequate trial of Pancreaze, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND • The patient has failed an adequate trial of Pertzye, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND • The patient has failed an adequate trial of Viokace; defined as at least 2 dose adjustments done over a period of at least 4 week; document the dates tried _____. OR the patient is between 2 and 19 years of age and requires a dosage strength that is not available with Viokace. Prior authorization does not expire.

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

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Mr. David Bobb	Chief, DHA Pharmacy Operations Division
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Kevin Roberts, MC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Col Ruben Salinas, MC	Army, Family Medicine Physician
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Shaun Carstairs, MC	Navy, Physician at Large
CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Col Melissa Howard, BSC	Air Force, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
COL Clayton Simon, MC	TRICARE Regional Office Representative
Kelly Echevarria, PharmD for Jennifer Zacher, PharmD	Department of Veterans Affairs
Nonvoting Members Present	
Mr. Brian Wheeler	DHA, Deputy General Counsel
Eugene Moore, PharmD, BCPS for Dean Valibhai, PharmD	DHA Purchased Care Branch
Guests	
Ms. Kimberlymae Wood	DHA Contract Operations Division
Ms. Yvette Dluhos	DHA Contract Operations Division
LCDR Jason Galka	DLA Troop Support
CPT Zachary Leftwich, MSC	Army Medical Department Center and School (AMEDDC&S)
Maj Thomas Robinson	Brooke Army Medical Center (BAMC) Resident

Appendix A—Attendance (continued)

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

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
• aripiprazole tablet with ingestible event marker (Abilify MyCite) **Antipsychotic Agents: Atypical**	• Formulary agents likely to result in therapeutic failure **Formulary Alternatives:** aripiprazole, Abilify Maintena
• clobazam oral film (Sympazan) **Anticonvulsants-Antimania Agents**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • No alternative formulary agent (patient has difficulty swallowing tablets or oral suspension) **Formulary Alternatives:** clobazam tablets and suspension (Onfi)
• cyclosporine 0.09% ophthalmic (Cequa) **Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Immunomodulatory Agents**	• Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** cyclosporine 0.05% (Restasis/multidose), lifitegrast 5% (Xiidra)
• desmopressin sublingual tab (Nocdurna) **Endocrine Agents Miscellaneous**	• Use of formulary agents has resulted in therapeutic failure **Formulary Alternatives:** generic desmopressin nasal, oral desmopressin tab (DDAVP, generics)
• desmopressin nasal spray (Noctiva) **Endocrine Agents Miscellaneous**	**February 2019 updates are in bold** • **Use of formulary agents has resulted in therapeutic failure** • ~~**No alternative formulary agent: Patient is an adult and requires treatment for nocturnal polyuria**~~ • **Formulary Alternatives:** generic desmopressin nasal, oral desmopressin tab (DDAVP, generics)
• filgrastim vials (Granix) **Hematological Agents: WBC Stimulants**	• Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk **Formulary Alternatives:** Granix prefilled syringes, Neupogen, Zarxio
• halobetasol propionate 0.01% lotion (Bryhali) **Corticosteroids-Immune Modulators: High Potency**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Use of formulary agents is contraindicated **Formulary Alternatives:** Topical 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)
• itraconazole 65 mg tabs (Tolsura) **Antifungals**	• Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** itraconazole 100 mg capsules or itraconazole 10 mg/mL solution

Drug / Drug Class	Medical Necessity Criteria
• latanoprost 0.005% ophthalmic emulsion (Xelpros) **Glaucoma Agents**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • All formulary agents resulted in therapeutic failure **Formulary Alternatives:** latanoprost 0.005% ophthalmic solution (generic Xalatan), bimatoprost (generic 0.03% Lumigan)
• omadacycline (Nuzyra) **Antibiotics: Tetracycline**	• Use of formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** doxycycline, linezolid, moxifloxacin, levofloxacin
• revefenacin (Yupelri) **Pulmonary-2: Long Acting Anti-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 Respimat/Handihaler, Tudorza Pressair, Incruse Ellipta, and Seebri Neohaler
• rifamycin (Aemcolo) **Gastrointestinal-2: Miscellaneous**	• Use of formulary agents resulted in therapeutic failure **Formulary Alternatives:** ciprofloxacin, azithromycin, and rifaximin
• sarecycline (Seysara) **Antibiotics: Tetracycline**	• Patient has experienced significant adverse effects from formulary agents – e.g., gastrointestinal adverse events from generic minocycline products **Formulary Alternatives:** minocycline IR 50 mg or 100 mg
• insulin degludec vials (Tresiba) **Insulins: Basal**	• Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control **Formulary Alternatives:** insulin glargine (Lantus), insulin glargine (Toujeo)
• tocilizumab (Actemra ACTPen) **Targeted Immunomodulatory Biologics (TIBs) – Non-tumor Necrosis Factor Inhibitors**	• Use of adalimumab (Humira) is contraindicated • Patient has experienced or is likely to experience significant adverse effects from adalimumab (Humira) • Adalimumab (Humira) has resulted in therapeutic failure • The patient is transitioning from IV tocilizumab (Actemra IV) **Formulary Alternatives:** Humira (BCF)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria

• erenumab-aooe injection (Aimovig)
• fremanezumab-vfrm injection (Ajovy)
• galcanezumab-gnlm injection (Emgality)
 	
Migraine Agents: CGRP Prophylaxis
	February 2019 updates are in BOLD and strikethrough.
	
	Manual PA criteria apply to all new users of Aimovig, Ajovy, or Emgality.
	
	Manual PA Criteria: Aimovig, Ajovy, or Emgality is approved if all criteria are met:
	• Patient ≥ 18 years old and not pregnant
	• Must be prescribed by or in consultation with a neurologist
	• **The patient also meets one of the following:**
	  • **Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR**
	  • Patient has **episodic migraine at a rate** ~~a migraine diagnosis with~~ of at least 8 migraine days per month for 3 months **OR**
	  • **Patient has a diagnosis of chronic migraine**
	• Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes:
	  • Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate
	  • Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, **timolol**
	  • Prophylactic antidepressants: amitriptyline, **duloxetine, nortriptyline,** venlafaxine
	• **Patient is not currently on botulinum toxin or patient must not have received a botulinum toxin injection within the last 2 months**
	• Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed
	• For Emgality, a loading dose will be allowed
	
	Non-FDA-approved uses are NOT approved.
	PA expires after 6 months.
	
	Renewal Criteria: coverage will be approved indefinitely for continuation of therapy if **one of the following apply:**
	• ~~The patient has shown improvement in migraine prevention (e.g., reduced migraine headache days, reduced migraine frequency, reduced use of acute abortive migraine medication)~~
	• **Note that in order to go through renewal criteria, the patient must have satisfied the initial PA criteria**
	• **The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR**
	• **The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures:**
	  • **Migraine Disability Assessment (MIDAS)**
	  • **Reduction of ≥ 5 points when baseline score is 11–20**
	  • **Reduction of ≥ 30% when baseline score is > 20**
	  • **Headache Impact Test (HIT-6)**
	  • **Reduction of ≥ 5 points**
	  • **Migraine Physical Functional Impact Diary (MPFID)**
	  • **Reduction of ≥ 5 points**

Drug / Drug Class	Prior Authorization Criteria

• abiraterone acetate micronized (Yonsa)
 	
Oncological Agents: CYP-17 Inhibitors
	February 2019 updates are in BOLD and strikethrough.
	
	Manual PA criteria apply to all new users of Yonsa.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Age ≥ 18 years**
	• **Prescribed by or in consultation with an oncologist or urologist**
	• Provider is aware that Yonsa may have different dosing and food effects than other abiraterone acetate products (medication errors and overdose warning)
	~~• Patient has documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)~~
	~~• Patient has documented diagnosis of metastatic high-risk castration-sensitive prostate cancer (mCSPC)~~
	• **Patient has documented diagnosis of non-localized disease including:**
	  • **Metastatic castration-resistant prostate cancer (mCRPC)**
	  • **Metastatic castration-sensitive prostate cancer (mCSPC)**
	  • **Regional disease (T_xN1M0) OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	  • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
	• Patient must receive concomitant therapy with methylprednisolone
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	
	Other non-FDA-approved uses are NOT approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• abiraterone acetate (Zytiga, generics)
 	
Oncological Agents: CYP-17 Inhibitors
	February 2019 updates are in BOLD and strikethrough.
	
	Manual PA criteria apply to **all new and current users** of Zytiga and generics.
	
	***DoD will allow the clinical PA to provide information for the 250 mg or 500 mg tablets. Currently, the 250 mg tablets are the preferred agent, so if the provider is willing to write for the 250 mg tablets, then a new prescription will need to be written – but the PA will not need to be filled out more than once.**
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Yonsa is the Department of Defense's preferred CYP-17 Inhibitor agent.**
	  • **Has the patient tried Yonsa?**
	  OR
	  • **Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Yonsa that is not expected to occur with the requested agent?**
	• **Age ≥ 18 years**
	• **Prescribed by or in consultation with an oncologist or urologist**
	• ~~Patient has documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)~~
	• ~~Patient has documented diagnosis of metastatic high-risk castration-sensitive prostate cancer (mCSPC)~~
	• **Patient has documented diagnosis of non-localized disease including:**
	  • **Metastatic castration-resistant prostate cancer (mCRPC)**
	  • **Metastatic castration-sensitive prostate cancer (mCSPC)**
	  • **Regional disease (T_xN1M0) OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	  • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
	• Patient must receive concomitant therapy with prednisone
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	• **Zytiga 250 mg is the DoD's preferred strength. Is the prescription for Zytiga 250 mg OR will the prescription be changed to the 250 mg?**
	  • **Note: If the prescription is being changed to the 250 mg strength, please submit a new prescription with this PA form**
	  OR
	  • **Please state why the patient cannot take multiple 250 mg tablets to achieve the patient's daily dose (fill-in blank)**
	
	Other non-FDA-approved uses are NOT approved.
	PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• enzalutamide (Xtandi)
 	
Oncological Agents: 2nd-Gen Antiandrogens
	February 2019 updates are in BOLD.
	
	Manual PA criteria apply to all new users of Xtandi.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Age ≥ 18 years**
	• **Prescribed by or in consultation with an oncologist or urologist**
	• Patient has documented diagnosis of **metastatic OR non-metastatic** castration-resistant prostate cancer (CRPC)
	  • If used in non-metastatic castration-resistant prostate cancer (nmCRPC), patient must have: prostate specific antigen doubling time **(PSADT) ≤ 10 months OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	  • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	
	Other non-FDA-approved uses are NOT approved.
	PA does not expire.

• apalutamide (Erleada)
 	
Oncological Agents: 2nd-Gen Antiandrogens
	February 2019 updates are in BOLD.
	
	Manual PA criteria apply to all new users of Erleada.
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• **Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen agent.**
	  • **Has the patient tried Xtandi?**
	  OR
	  • **Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Xtandi that is not expected to occur with Erleada**
	• **Age ≥ 18 years**
	• Prescribed by or in consultation with an oncologist or urologist
	• Patient has documented diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND**
	  • Negative CT scan of abdomen/pelvis and/or negative bone scan, **AND**
	  • **PSADT ≤ 10 months OR**
	• **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND**
	• **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.**
	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy
	
	Other non-FDA-approved uses are NOT approved.
	PA expires in 1 year.
	
	Renewal PA Criteria: Coverage will be approved for 1 year for continuation of therapy if:
	• Patient continues to be metastases-free
	• No toxicities have developed
	• Patient has not progressed onto subsequent therapy (such as abiraterone ~~[Zytiga]~~)

Drug / Drug Class	Prior Authorization Criteria
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	Manual PA applies to all new users of Firdapse. Manual PA Criteria: Firdapse is approved if: • Age ≥ 18 years old • Drug is prescribed by an oncologist or neurologist • Has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS) Non-FDA-approved uses are NOT approved. PA does not expire.
• aripiprazole tablet with ingestible event marker (Abilify MyCite) **Antipsychotic Agents: Atypical**	Manual PA criteria apply to all new users of Abilify MyCite. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient must have documented attempt to use generic aripiprazole tablets, with non-compliance documented in prescriber notes. Prescriber notes must also document the prescriber's attempted medication adherence counseling. • Patient must have documented trial of at least 12 weeks of Abilify Maintena first • Provider acknowledges that FDA labeling states the ability of Abilify MyCite to improve patient compliance or modify aripiprazole dosage has not been established. Non-FDA-approved uses are NOT approved. PA does not expire.
• cenegermin-bkbj ophthalmic solution (Oxervate) **Anti-inflammatory Immunomodulatory Ophthalmic Agents**	Manual PA criteria apply to all new users of Oxervate. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 2 years • Patient has a documented diagnosis of neurotrophic keratitis • Drug is prescribed by a cornea specialist or ophthalmologist • Patient does not wear contact lenses during treatment course Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• cyclosporine 0.09% ophthalmic (Cequa) **Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Immunomodulatory Agents**	**February 2019 criteria for Cequa are in BOLD.** PA criteria apply to all **new and current** users. A new user is defined as a patient who has not filled a prescription for **Cequa** in the past 120 days. • If there is no Restasis, **Cequa**, or Xiidra prescription in the past 120 days, a manual PA is required. <u>Manual PA Criteria:</u> Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • **For Cequa: the patient is ≥ 18 years old** • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: • Positive symptomatology screening for moderate to severe dry eye disease from an appropriate measure • At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • Concomitant use of Restasis, **Cequa**, or Xiidra is NOT allowed. **Non-FDA-approved uses for Cequa are NOT approved.** PA expires in one year. <u>Renewal Criteria:</u> Coverage will be approved indefinitely if all criteria are met: • The drug is prescribed by an ophthalmologist or optometrist. • The patient must have documented improvement in ocular discomfort. • The patient must have documented improvement in signs of dry eye disease.

• desmopressin sublingual (SL) tab (Nocdurna) • desmopressin nasal spray (Noctiva) **Endocrine Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Nocdurna. **Manual PA criteria apply to all new users of Noctiva Nasal Spray; Noctiva Nasal Spray updates are in BOLD** Manual PA Criteria: Coverage is approved if all criteria are met: • For Nocdurna: Age ≥ 18 years old • For Nocdurna: For females: must use 27.7 mcg dosage; for males: must use 55.3 mcg dosage • For Noctiva Nasal Spray: Age ≥ 50 years old (Only the low dose is allowed for pts > 65 years old) • Patient has nocturia defined as having ≥ 2 nocturnal voids nightly for ≥ 6 months • Causes of nocturia have been evaluated and nocturnal polyuria is confirmed with a 24-hour urine collection • **Patient has tried non-pharmacologic techniques or lifestyle interventions to manage the nocturia (e.g., nighttime fluid restriction, avoidance of caffeine and alcohol, earlier timing of medications, leg elevation and/or use of compression stockings)** • **The patient has tried oral desmopressin acetate tablets (DDAVP tablets, generics)** • Patient is not currently taking any of the following medications: – Loop diuretics, alpha$_1$-adrenoceptor antagonists, 5-alpha reductase inhibitors (ARIs), thiazide diuretics, anticholinergics, antispasmodics, sedative/hypnotic agents, NSAIDs, SSRIs, SNRIs, antidepressants, anti-epileptics, opioids, or SGLT2s – Systemic or inhaled corticosteroids or lithium • Prescribed by a urologist, a geriatrician, an endocrinologist, or a **nephrologist** • **Provider must supply most recent serum sodium and date** – **Sodium _____mEq/mL Date_____** • Patient has normal sodium (135-145 meq/L) prior to initiation, recheck sodium after one week of therapy, and another sodium recheck at 1 month • **Provider acknowledges that patients over 65 years old are at greater risk of hyponatremia and has advised the patient about this significant safety concern** • Patient does not have the following conditions for both Noctiva Nasal Spray and Nocdurna: – **Renal impairment (eGFR < 50 mL/min)** – **Hyponatremia or history of hyponatremia** – **Polydipsia** – **Nocturnal enuresis** – **SIADH** – **Congestive heart failure** – **Uncontrolled hypertension or uncontrolled diabetes mellitus** – **Interstitial cystitis** – **Chronic prostatitis/chronic pelvic pain syndrome** – **Suspicion of bladder outlet obstruction (BOO) or urine flow <5 mL/sec** – **Surgical treatment, including transurethral resection, for BOO or benign prostatic hyperplasia within the past 6 months** – **Urinary retention or a post-void residual volume in excess of 250 mL as confirmed by bladder ultrasound performed after suspicion of urinary retention** – **Current or a history of urologic malignancies (e.g., urothelium, prostate, or kidney cancer)** – **Genitourinary tract pathology (e.g., infection or stone in the bladder and urethra causing symptoms)** – **Neurogenic detrusor activity (detrusor overactivity)** – **Suspicion or evidence of cardiac failure** – **History of obstructive sleep apnea** – **Hepatic and/or biliary diseases** – **Treatment with another investigational product within 3 months prior to initiating therapy** – **Known alcohol or substance abuse** – **Work or lifestyle that may have interfered with regular nighttime sleep**

Drug / Drug Class	Prior Authorization Criteria
	AND • **Patient does not have the following conditions for Noctiva Nasal Spray** – **acute or chronic rhinitis (for Noctiva nasal spray only)** – **atrophy of nasal mucosa (for Noctiva nasal spray only**) Non-FDA-approved uses are NOT approved. PA expires ~~in 6 months~~ **4 months.** Renewal Criteria: Coverage will be approved for an additional 6 months if all of the following apply: • **Note that in order to go through renewal criteria, the patient must have satisfied the initial PA criteria** • Patient has not developed any of the conditions above • **Patient is not taking any of the medications mentioned above** • Patient has shown a reduction in nocturia episodes
• gilteritinib (Xospata) **Oncological Agents: Acute Myelogenous Leukemia**	Manual PA criteria apply to all new users of Xospata. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 18 • Has laboratory evidence of relapsed or refractory acute myeloid leukemia with a Ferline McDonough Sarcoma (FMS)-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test • The patient will be monitored for posterior reversible encephalopathy syndrome (PRES), prolonged QTc, and pancreatitis • Patient is not pregnant or actively trying to become pregnant • Prescribed by or in consultation with a hematologist/oncologist Non-FDA-approved uses are NOT approved. PA does not expire.
• glasdegib (Daurismo) **Oncological Agents: Acute Myelogenous Leukemia**	Manual PA criteria apply to all new users of Daurismo. Manual PA Criteria: Coverage is approved if all criteria are met: • Treatment of newly diagnosed acute myeloid leukemia (in combination with low-dose cytarabine) in adult patients who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy. • Provider acknowledges and patient has been informed that limitations of use include that this drug has not been studied in patients with severe renal impairment or moderate to severe hepatic impairment. • Patient is not pregnant or actively trying to become pregnant • Patient will be monitored for febrile neutropenia and QTc prolongation • Prescribed by or in consultation with a hematologist/oncologist Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• inotersen injection (Tegsedi) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of Tegsedi. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 18 and has genetically confirmed transthyretin mutation resulting in familial amyloidotic polyneuropathy (FAP) stage 1 or 2 hereditary transthyretin-mediated amyloidosis (hTTRA) • Has polyneuropathy secondary to hereditary transthyretin-mediated amyloidosis with either 1) a polyneuropathy disability (PND) score ≤ IIIB or 2) a Neuropathy Impairment Score between 10 and 130 • Provider and patient are both registered and enrolled with the Tegsedi Risk Evaluation and Mitigation Strategies (REMS) program • Patient has no evidence of thrombocytopenia • Patient does not have chronic kidney disease (CKD) stage 3b and has no history of glomerulonephritis • The provider will monitor the patient's platelet counts and renal and hepatic function • Patient will take an oral Vitamin A supplement at the recommended daily allowance • Provider is aware and patient is informed of the following potential adverse drug reactions: stroke, encephalitis, carotid arterial dissection, hypercoagulability and thrombosis (venous and arterial), QRS prolongation and other arrhythmias, elevated liver-associated enzymes, autoimmune hepatitis, primary biliary cirrhosis, biliary obstruction, glomerulonephritis, nephrotic syndrome, interstitial nephritis, thrombocytopenia, idiopathic thrombocytopenia (ITP), antineutrophil cytoplasmic antibody-associated (ANCA) vasculitis, and hypersensitivity • Prescribed by or in consultation with a specialist that manages hereditary transthyretin amyloidosis (e.g., cardiologist, geneticist, neurologist) • Concomitant use of Onpattro and Tegsedi is not allowed Non-FDA-approved uses are NOT approved. PA does not expire.
• itraconazole 65 mg caps (Tolsura) **Antifungals**	Manual PA applies to all new users of Tolsura. Manual PA Criteria: Tolsura is approved if: • Patient has one of the following diagnoses: ▪ Histoplasmosis ▪ Pulmonary or Extrapulmonary Blastomycosis ▪ Pulmonary or Extrapulmonary Aspergillosis AND • For histoplasmosis or blastomycosis: ▪ Patient has had serious side effects with generic itraconazole 100 mg tablets/capsules OR ▪ Patient has failed drug treatment with generic itraconazole 100 mg tabs/capsules • For aspergillosis ▪ Patient has had serious side effects with generic itraconazole 100 mg tablets/capsules and amphotericin B OR ▪ Patient has failed drug treatment with generic itraconazole 100 mg tabs/capsules and amphotericin B Non-FDA-approved uses are NOT approved including onychomycosis. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• larotrectinib (Vitrakvi) capsules and oral solution **Oncological Agents**	Manual PA criteria apply to all new users of Vitrakvi capsules and oral solution. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient diagnosed with a solid tumor that: ▪ has a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, ▪ is metastatic **OR** where surgical resection is likely to result in severe morbidity, AND ▪ has no satisfactory alternative treatments OR that has progressed following such treatment(s). • Larotrectinib (Vitrakvi) is prescribed by or in consultation with a hematologist/oncologist • For Vitrakvi oral solution: in addition to the above criteria, the patient has difficulty swallowing the capsules Non-FDA-approved uses are NOT approved. PA does not expire.
• lorlatinib (Lorbrena) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of Lorbrena. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by or in consultation with hematologist or oncologist • Patient has a diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer • Patient has experienced disease progression on one of the following treatments: – crizotinib (Xalkori) and at least one other ALK inhibitor – alectinib (Alecensa) as a first-line agent – ceritinib (Zykadia) as a first-line agent **OR** • **If patient has a diagnosis other than those listed above, list the diagnosis: _____. AND** • **The diagnosis is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation** Non-FDA-approved uses are NOT approved. PA does not expire.
• revefenacin (Yupelri) **Pulmonary-2: Long Acting Anti-Muscarinic Agents (LAMAs)**	Manual PA is required for all new and current users of Yupelri. Manual PA Criteria: Yupelri is approved if all criteria are met: • The patient has a diagnosis of chronic obstructive pulmonary disease • The patient has tried and failed an adequate course of a nebulized Short-Acting Muscarinic Antagonist (e.g., ipratropium) • The patient has tried and failed an adequate course of Spiriva Respimat • The patient has tried and failed an adequate course of therapy with 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. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rifamycin (Aemcolo) **GI-2: Miscellaneous**	Manual PA criteria apply to all new and current users of Aemcolo. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 18 • Patient has a diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* • Patient does not have diarrhea complicated by fever and/or bloody stool • Patient does not have diarrhea due to pathogens other than noninvasive strains of *E. coli* • Patient has tried and failed a 3-day trial of ciprofloxacin unless a contraindication exists or patient has tried and failed azithromycin unless a contraindication exists Non-FDA-approved uses are NOT approved including but not limited to diarrhea-predominant irritable bowel syndrome (IBS-D), non-alcoholic steatohepatitis (NASH), small intestine bacterial overgrowth (SIBO), and inflammatory bowel disease (IBD). PA renewal not allowed. A new prescription will require a new PA to be submitted.
• riluzole oral suspension (Tiglutik) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new and current users of Tiglutik. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is diagnosed with amyotrophic lateral sclerosis • Patient has dysphagia/swallowing dysfunction Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• sarecycline (Seysara)
 	
Antibiotics: Tetracycline
	February 2019 criteria specific to Seysara are in BOLD.
	
	PA applies to both new and current users of Seysara.
	
	Automated PA Criteria:
	• Patient has filled a prescription for one generic IR doxycycline (either hyclate or monohydrate salt; does not include doxycycline monohydrate 40 mg IR/DR) AND one generic minocycline IR product at any Military Treatment Facility (MTF), retail network pharmacy, or the mail order pharmacy in the previous 180 days
	
	Manual PA Criteria: If automated PA criteria are not met, the non-step-preferred product is allowed if:
	
	Acne Vulgaris or Rosacea
	• For Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Mondoxyne NL, or Okebo: The patient has tried and had an inadequate response to or failed to tolerate the following:
	  ◦ one generic immediate-release doxycycline product (hyclate or monohydrate salt) AND
	  ◦ one generic immediate-release minocycline product
	
	• For Solodyn or generic minocycline ER, Minolira, **or Seysara:** The patient has acne with inflammatory lesions AND
	  ◦ the patient cannot tolerate generic minocycline IR due to gastrointestinal adverse events
	
	Susceptible Infections
	• For Doryx, Doryx MPC, Acticlate, and Okebo: if used for susceptible infections, the patient has failed or had clinically significant adverse events to generic IR doxycycline
	
	Non-FDA-approved uses are NOT approved.
	PA expires in 1 year.
	
	Renewal Criteria:
	• Acticlate, Doryx, Doryx MPC, Targadox, Monodox, Morgidox, Mondoxyne NL, Okebo, Solodyn or generic minocycline ER, or Minolira will be approved for an additional year, if:
	  ▪ The patient's therapy has been re-evaluated within the last 12 months
	  ▪ The patient is tolerating treatment, and there is continued medical need for the medication
	  ▪ The patient has had disease stabilization or improvement in disease on therapy
	• **Seysara: PA renewal is not allowed; repeat courses will require a new PA to be submitted**

Drug / Drug Class	Prior Authorization Criteria
• tafenoquine (Arakoda) **Antimalarials**	Manual PA criteria apply to all new users of tafenoquine (Arakoda). Manual PA Criteria: Coverage will be approved for tafenoquine (Arakoda) if all criteria are met: • Age ≥ 18 and Arakoda is being prescribed for malaria chemoprophylaxis • Patient has a contraindication or intolerance to both atovaquone-proguanil (Malarone) and doxycycline (e.g., pregnancy) • Patient does not have a major psychiatric disorder to include but not limited to: – Active or recent history of depression – Generalized anxiety disorder – Psychosis or schizophrenia – Post-Traumatic Stress Disorder or Traumatic Brain Injury • Patient does not have a history of seizures or vestibular disorders • Patient does not have a cardiac conduction abnormality • Patient has been tested and is negative for glucose 6 phosphate dehydrogenase (G6PD) deficiency • The above information must be documented in the patient's medical record, and the patient must be educated on Arakoda adverse effects and dosing Non-FDA-approved uses are NOT approved. PA expires after 2 years. PA renewal is not allowed; repeat courses will require a new PA to be submitted.
• talazoparib (Talzenna) **Oncological Agents: Breast Cancer**	Manual PA criteria apply to all new users of Talzenna. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by or consultation with a hematologist or oncologist • Patient has a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) and human epidermal growth factor receptor 2-negative (HER2-) breast cancer Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria

• testosterone enanthate SQ injection (Xyosted)
 	
Androgens-Anabolic Steroids: Testosterone Replacement Therapies
	February 2019 criteria specific to Xyosted are in BOLD
	
	Manual PA criteria apply to all new and current users of Xyosted.
	
	Manual PA for Xyosted requires a trial of the step-preferred product, Fortesta **and one injectable testosterone product**
	
	Manual PA Criteria: Coverage is approved if all criteria are met:
	• Age ≥ 18 years and male
	• Patient has documentation of experiencing signs and symptoms usually associated with hypogonadism
	• **Xyosted is prescribed for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies**
	• Diagnosis of hypogonadism is confirmed and evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions
	• Patient has one of the following criteria:
	  • Patient has tried Fortesta (testosterone 2% gel) **AND an injectable testosterone formulation for a minimum of 90 days AND** failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after Fortesta application or the injectable testosterone formulation) **AND** without improvement in symptoms
	  – OR –
	  • **Patient has a contraindication to or has experienced a clinically significant adverse reaction to Fortesta that is not expected to occur with the Xyosted autoinjector**
	• **The provider has considered the patient's baseline cardiovascular risk and ensured blood pressure is adequately controlled before initiating Xyosted and periodically during the course of treatment (based on the product's boxed warning of increased risk of major adverse cardiovascular events and hypertension).**
	• **Patient does not have any of the following:**
	  • **Carcinoma of the breast or suspected carcinoma of the prostate**
	
	Non-FDA-approved uses are NOT approved.
	Not approved for concomitant use with other testosterone products.
	PA does not expire.

• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**February 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Doptelet. Manual PA Criteria: Avatrombopag (Doptelet) is approved if all criteria are met: • Age ≥ 18 years • **The patient has tried and failed, or has a contraindication to, or is expected to have an intolerance to lusutrombopag (Mulpleta)** • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet count less than 50 x 10^9/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • The drug is prescribed by or in consultation with a gastroenterologist Non-FDA-approved uses are NOT approved. PA expires in 60 days.

Drug / Drug Class	Prior Authorization Criteria
• cyclobenzaprine 7.5 mg (generic) **Skeletal Muscle Relaxants and Combinations**	Manual PA criteria apply to all new and current users of cyclobenzaprine 7.5 mg tablets or capsules. Manual PA Criteria: Coverage will be approved for cyclobenzaprine 7.5 mg tablets if all criteria are met: • Cyclobenzaprine 7.5 mg tablets have been identified as having cost-effective alternatives. The provider must describe why cyclobenzaprine 7.5 mg is required as opposed to available alternatives, including generic cyclobenzaprine 5 mg tablets and cyclobenzaprine 10 mg tablets • (blank write in) Non-FDA-approved uses are NOT approved. PA does not expire.
• dexchlorpheniramine 2 mg/5 mL oral syrup (Ryclora) **Anthistamine-1: First Generation and Combinations**	Manual PA criteria apply to all new and current users of dexchlorpheniramine liquid (Ryclora). Manual PA Criteria: Coverage will be approved for dexchlorpheniramine liquid if all criteria are met: • Ryclora liquid has been identified as having cost-effective alternatives. The provider must describe why Ryclora is required as opposed to available alternatives (chlorpheniramine liquid, loratadine liquid, cetirizine liquid and fexofenadine liquid). Non-FDA-approved uses are NOT approved. PA does not expire.
• dihydroergotamine nasal spray/pump **Migraine Agents**	Manual PA criteria apply to all new users of generic dihydroergotamine (DHE) nasal spray. Note that brand Migranal nasal spray is the preferred product in the DoD. Manual PA Criteria—Coverage for generic DHE nasal spray is approved if the following criteria is met: • The provider has provided patient-specific justification as to why the brand Migranal nasal spray cannot be used.
• insulin degludec vials (Tresiba) **Basal Insulins**	Manual PA criteria apply to all new users of Tresiba vials. Manual PA Criteria: Tresiba is approved if ALL criteria are met: • Patient is age ≥ 1 year • The provider must explain why the patient cannot use Lantus (fill in the blank) • The provider must explain why the patient cannot use Toujeo (fill in the blank) Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• ivabradine (Corlanor) **Miscellaneous Cardiovascular Agents**	Manual PA criteria apply to all new users of Corlanor. **Updates from the February 2019 meeting are in bold.** Manual PA Criteria: Corlanor is approved **if all of the following criteria are met:** **For Heart Failure with reduced ejection fraction** • The drug is prescribed by a cardiologist or heart failure specialist. • The patient has a diagnosis of stable, symptomatic heart failure with left ventricular ejection fraction ≤ 35%, is in sinus rhythm, and has a resting heart rate > 70 beats per minute. • The patient has heart failure symptoms despite maximal therapy of a beta blocker therapy that has been shown to have survival benefit in heart failure. ▪ Note that acceptable heart failure beta blockers and target doses include the following: metoprolol succinate ER 200 mg QD; carvedilol 25 mg BID or 50 mg BID if > 85 kg; carvedilol ER 80 mg QD; bisoprolol 10 mg QD (bisoprolol is not FDA-approved for heart failure but has proven efficacy in a large clinical trial) • OR the patient has a contraindication to beta blocker use ▪ Note that the contraindication must be listed on the Prior Authorization form. • **OR the patient has tried and experienced intolerance to a heart failure beta blocker (metoprolol succinate, carvedilol, carvedilol, bisoprolol)** **For inappropriate sinus tachycardia or postural tachycardia syndrome** • **The drug is prescribed by a cardiologist** • **The patient has a diagnosis of postural orthostatic tachycardia syndrome (POTS) and/or inappropriate sinus tachycardia (IST)** **Non-FDA-approved uses other than IST or POTS are NOT approved.** Prior authorization does not expire.
• ivacaftor (Kalydeco) **Cystic Fibrosis Agents**	**February 2019 updates are in BOLD and strikethrough.** Manual PA criteria apply to all new users of Kalydeco. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient ~~is 24 months~~ **has a diagnosis of cystic fibrosis and is being prescribed for an age appropriate population according to the FDA indication** • Patient is not homozygous for the F508del mutation in the CFTR gene • The patient has a specific CF-related gene mutation that has been detected by an FDA-approved test • **Kalydeco will not be used concomitantly or at the same time as Orkambi or Symdeko** • What is the gene mutation? (fill in the blank) Non-FDA-approved uses are NOT approved. PA does not expire.

Drug / Drug Class	Prior Authorization Criteria
• rifaximin 200 mg (Xifaxan) **Gastrointestinal-2 Agents: Miscellaneous**	**February 2019 updates for the indication of Traveler's Diarrhea are in BOLD. No changes were made for the indications of hepatic encephalopathy or diarrhea-predominant irritable bowel syndrome (IBS-D).** Manual PA criteria apply to all new users of Xifaxan 200 mg for TD. Manual PA Criteria: Coverage is approved if all criteria are met: • Age ≥ 12 years • Patient has a diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* • Patient does not have diarrhea complicated by fever and/or bloody stool • Patient does not have diarrhea due to pathogens other than noninvasive strains of *E. coli* • Patient has tried and failed a 3-day trial of ciprofloxacin unless a contraindication exists **or patient has tried and failed azithromycin unless a contraindication exists** **Non-FDA-approved uses are NOT approved including: small intestinal bacterial overgrowth (SIBO), non-alcoholic steatohepatitis (NASH) or non-alcoholic fatty liver disease (NAFLD), spontaneous bacterial peritonitis (SBP), functional dyspepsia, diabetes, cirrhosis (ascites/alcohol-related), graft vs host disease, primary sclerosing cholangitis, Celiac disease, ulcerative colitis, Crohn's disease, diverticular disease, bowel preparation, constipation, colorectal cancer prevention, opioid-induced constipation, chronic abdominal pain, or other disease states.** **PA renewal is not allowed; no refills allowed**
• ledipasvir/sofosbuvir (Harvoni authorized generic) **Hepatitis C Virus - Direct Acting Antivirals Subclass (HCV DAAs)**	**Manual PA criteria apply to all new users of ledipasvir/sofosbuvir (authorized generic for Harvoni).** Manual PA Criteria: Ledipasvir/sofosbuvir authorized generic products are approved if all of the following criteria are met: • The brand Harvoni formulation is preferred over the authorized generic product. Please provide a patient-specific justification as to why the brand Harvoni product cannot be used in this patient. (Fill in the blank) AND the patient must meet the following criteria for a HCV DAA product: • ≥ 18 years of age • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of hepatitis C virus infection • The HCV genotype is documented. (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires in 1 year.

Drug / Drug Class	Prior Authorization Criteria
• sofosbuvir/velpatasvir (**Epclusa** authorized generic) **Hepatitis C Virus - Direct Acting Antivirals Subclass (HCV DAAs)**	**Manual PA criteria apply to all new users of sofosbuvir/velpatasvir (authorized generic for Epclusa).** Manual PA Criteria: sofosbuvir/velpatasvir authorized generic products are approved if all of the following criteria are met: • The brand Epclusa formulation is preferred over the authorized generic product. Please provide a patient-specific justification as to why the brand **Epclusa** product cannot be used in this patient. (Fill in the blank) AND the patient must meet the following criteria for a HCV DAA product: • ≥ 18 years of age • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of hepatitis C virus infection • The HCV genotype is documented. (Check box – GT1a, GT1b, GT2, GT3, GT4, GT5, GT6) Coverage for the HCV DAA is only allowed for the FDA-approved indications or as outlined in the AASLD/IDSA HCV guidelines. PA expires in 1 year.

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

Drug / Drug Class	Prior Authorization Criteria
• anakinra (Kineret) **Targeted Immunomodulatory Biologics (TIBs) – Non-Tumor Necrosis Factor (TNF) Inhibitors**	**February 2019 updates are in BOLD.** Manual PA criteria apply to all new users of Kineret. <u>Manual PA Criteria:</u> Coverage is approved for Kineret if: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis Coverage approved for pediatric patients (all ages) with (Trial of Humira not required.): • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) • Cryopyrin Associated Period Syndrome (CAPS) or • **Systemic Juvenile Idiopathic Arthritis (sJIA)** • Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications. Has the patient tried Humira? • The patient has a contraindication to Humira (adalimumab) OR • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are NOT approved. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (**Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).**

Drug / Drug Class	Prior Authorization Criteria
• tocilizumab (Actemra ACTPen) **Targeted Immunomodulatory Biologics (TIBs) – Non-tumor Necrosis Factor Inhibitors**	Manual PA criteria apply to all new users of Actemra ACTPen, similar to other Actemra formulations. <u>Manual PA Criteria</u>: If automated criteria are not met: Coverage approved for patients ≥ 18 years with: • Moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response to ≥ 1 disease modifying anti-rheumatic drugs (DMARDs). • Giant cell arthritis (GCA) (Trial of Humira not required.) Coverage approved for pediatric patients ≥ 2 years with: • Active polyarticular juvenile idiopathic arthritis (PJIA) • Systemic juvenile idiopathic arthritis (SJIA) • Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications. • The patient has a contraindication to Humira (adalimumab) OR • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent. • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • Patient has been stable on an IV Actemra with continuous use in the last 3 months and needs to transition to the SQ formulation of Actemra. • Patient's platelet count is ≥ 100,000 per mm³ AND ALT/AST ≤ 1.5 times ULN • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed). Non-FDA-approved uses are NOT approved. Prior Authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya).

Appendix D—Table of Quantity Limits (QLs)

Drug / Drug Class	Quantity Limits
• fremanezumab-vfrm (Ajovy) **CGRP Prophylaxis Subclass**	▪ Retail: 1 syringe per fill (allow multiple copays for multiple refills) ▪ MTF/Mail: 3 syringes per fill Note that the QL changes will be implemented when the PA is implemented 30 days after signing of the minutes.
• galcanezumab-gnlm (Emgality) **CGRP Prophylaxis Subclass**	▪ Retail: 1 syringe or pen per fill; 2 syringes allowed for loading dose in PA (allow multiple copays for multiple refills) ▪ MTF/Mail: 3 syringes or pens per fill Note that the QL changes will be implemented when the PA is implemented 30 days after signing of the minutes.
• erenumab-aooe (Aimovig) 70 mg and 140 mg **CGRP Prophylaxis Subclass**	▪ Retail: 1 syringe or pen per fill (allow multiple copays for multiple refills) ▪ MTF/Mail: 3 syringes per fill Note that the QL changes will be implemented when the PA is implemented 30 days after signing of the minutes.
• abiraterone acetate micronized (Yonsa) • abiraterone acetate (Zytiga, generics) **Oncological Agents: CYP-17 Inhibitors**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply Note that the QL changes will be implemented when the PA is implemented 90 days after signing of the minutes.
• enzalutamide (Xtandi) • apalutamide (Erleada) **Oncological Agents: 2nd-Generation Antiandrogens**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply
• baloxavir marboxil (Xofluza) **Antivirals**	▪ MTF/Mail/Retail: 1 package per fill ▪ No refills allowed
• cenegermin-bkbj (Oxervate) **Anti-inflammatory Immunomodulatory Ophthalmic Agents**	▪ MTF/Mail/Retail: 56-day supply

Drug / Drug Class	Quantity Limits
• cyclosporine 0.09% ophthalmic (Cequa) **Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Immunomodulatory Agents**	▪ Retail: 60 vials (1 carton) per fill ▪ MTF/Mail: 180 vials (3 cartons) per fill
• gilteritinib (Xospata) **Oncological Agents: Acute Myelogenous Leukemia**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• glasdegib (Daurismo) **Oncological Agents: Acute Myelogenous Leukemia**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• inotersen injection (Tegsedi) **Neurological Agents Miscellaneous**	▪ MTF/Mail/Retail: 30-day supply
• ivacaftor (Kalydeco) tablets **Cystic Fibrosis Agents**	▪ MTF/Mail/Retail: 30-day supply
• larotrectinib (Vitrakvi) capsules **Oncological Agents**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• larotrectinib (Vitrakvi) oral solution **Oncological Agents**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• lorlatinib (Lorbrena) **Oncological Agents: Lung Cancer**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• pegfilgrastim-cbqv (Udenyca) **Hematological Agents: White Blood Cell Stimulants**	▪ Retail: 1 syringe per fill and 21-day supply ▪ MTF/Mail: 2 syringes per fill and 45-day supply
• revefenacin (Yupelri) **Pulmonary-2: Long Acting Muscarinic Antagonists (LAMAs)**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply

Drug / Drug Class	Quantity Limits
• rifamycin (Aemcolo) **Gastrointestinal-2 Agents: Miscellaneous**	▪ MTF/Mail/Retail: 12 tabs per fill ▪ No refills allowed
• riluzole oral suspension (Tiglutik) **Neurological Agents Miscellaneous**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• testosterone enanthate (Xyosted) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	▪ Retail: 4 syringes per fill and 28-day supply ▪ MTF/Mail: 12 syringes per fill and 84-day supply
• talazoparib (Talzenna) **Oncological Agents: Breast Cancer**	▪ Retail: 30-day supply ▪ MTF/Mail: 60-day supply
• tafenoquine (Krintafel) **Antimalarials**	▪ MTF/Mail/Retail: 2 tabs per fill

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
amifampridine (Firdapse)	Neurological Agents Miscellaneous	• None	Lambert-Eaton myasthenic syndrome (LEMS)	• Firdapse is the first FDA-approved drug for the treatment of LEMS in the United States. • Amifampridine was previously approved by the European Commission as an orphan drug in December of 2002. • The active ingredient was previously available as a compounded formulation, which is no longer available, given the FDA approval of Firdapse. • Firdapse may cause seizures, including in patients with no prior history. • Use Firdapse with caution in patients with uncontrolled asthma and in patients with congenital QT syndromes or a prolonged QT interval. • Firdapse is the first-line option for a very rare disorder, but should be only be prescribed with a diagnosis of LEMS by an oncologist or neurologist.	• UF • Do not add to EMMPI list
aripiprazole tablet with ingestible event marker (Abilify MyCite)	Antipsychotic Agents: Atypical	• Aripiprazole oral tab • Abilify Maintena ER monthly depot	Bipolar I disorder, irritability with autistic disorder, major depressive disorder, schizophrenia, Tourette's	• Abilify MyCite is a new formulation of aripiprazole that contains an ingestible event marker (IEM) to monitor adherence and a patch to collect the data. • This is the first drug approved using the IEM technology. • Despite its marketing strategy to improve patient adherence, no studies assessing patient adherence were conducted with Abilify MyCite. • Aside from the ability to send data to HCPs, Abilify MyCite provides no compelling advantage over existing formulary agents.	• NF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
baloxavir (Xofluza)	Antivirals	• oseltamivir (Tamiflu)	Influenza	• Xofluza is the first polymerase acidic endonuclease inhibitor and fourth FDA-approved agent for Influenza virus strains A and B. • It is given as a single dose given within 48 hours for the treatment of acute, uncomplicated influenza in patients 12 years and older. • Approval occurred via an expedited 505(b) pathway. • In 2 clinical efficacy trials, Xofluza treatment at the recommended dose resulted in a statistically significant shorter time to alleviation of symptoms compared with placebo by about 24 hours (50 hrs with Xofluza vs. 78 hrs with placebo). • In 1 clinical efficacy trial, there was no difference in the time to alleviation of symptoms between subjects who received Xofluza and oseltamivir; both drugs alleviated symptoms by 54 hours. • Compared to placebo, Xofluza does not produce an increased adverse event profile. • Xofluza reduces flu symptoms for the same duration as Tamiflu, is administered as a single dose, and has a mild side effect profile, but is lacking data regarding pediatric efficacy and prophylactic studies.	• UF • Do not add to EMMPI list
cenegermin-bkbj ophthalmic solution (Oxervate)	Antiinflammatory Immunomodulatory Ophthalmic Agents	• None	Neurotrophic keratitis	• Oxervate is a biologic ophthalmic solution that is recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis (NK). • Oxervate is the first drug approved for NK. • Clinical trials were conducted in relatively small numbers of patients; however, rates of complete corneal healing were statistically significant compared to vehicle. • Long-term safety has not been established. • Most common ADRs include eye pain, ocular hyperemia, eye inflammation, and increased lacrimation. • Oxervate demonstrated superior healing rates and has a unique place in therapy for this rare ocular condition.	• UF • Do not add to EMMPI list
clobazam oral film (Sympazan)	Anticonvulsants-Antimania Agents	• clobazam (Onfi) tablets and suspension	Indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older	• Clobazam (as a tablet, oral suspension, or film) is one option for adjunctive treatment of patients with Lennox-Gastaut Syndrome. • Sympazan is a new oral film formulation that has comparable bioavailability to clobazam tablets (Onfi) and oral suspension. • Approved based on bioequivalence with Onfi tablets and two adjunctive treatment studies showing statistically significant improvement in drop seizures. • Sympazan provides no compelling advantage over clobazam tablets and suspension.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
cyclosporine 0.09% ophthalmic solution (Cequa)	Antiinflammatory Immuno-modulatory Ophthalmic Agents: Ophthalmic Immuno-modulatory Agents	• cyclosporine 0.05% ophthalmic emulsion (Restasis unit dose and multidose) • lifitegrast 5% ophthalmic solution (Xiidra)	Dry eye disease	• Cequa is the third medication approved for the treatment of dry eye disease and the second cyclosporine ophthalmic for dry eye disease after Restasis. • Although Cequa is statistically superior to placebo based on the Schirmer Tear Test, it did not meet the minimal clinically important difference (MCID) for this endpoint versus placebo. • Similar safety profile to Restasis and Xiidra. • No compelling advantages over existing medications.	• NF • Add to EMMPI list
desmopressin acetate SL tablet (Nocdurna)	Endocrine Agents Miscellaneous	• desmopressin oral tab • desmopressin nasal • Noctiva nasal	Nocturia due to nocturnal polyuria	• Nocdurna is a new sublingual formulation of desmopressin indicated for nocturia due to nocturnal polyuria in adults. • Nocdurna was evaluated in a 4-week and two 12-week placebo-controlled, phase III studies. • Sex-specific dosing of Nocdurna was statistically superior to placebo in reducing the average number of nocturic episodes per night from baseline; however, clinical relevance is questionable. • Significant placebo effect. • Three initial studies submitted to the FDA did not lead to approval. • Significant safety concerns exist, including a black box warning for risk of hyponatremia and drug interactions; there is an increased risk of serious AEs with increased age. • There is little to no clinical benefit of Nocdurna and significant safety concerns exist.	• NF • Add to EMMPI list
elapegademase-lvlr IM injection (Revcovi)	Metabolic Replacement Agents Miscellaneous	• pegademase bovine (Adagen) IM solution	Adenosine deaminase severe combined immune deficiency (ADA-SCID)	• Revcovi is the second drug available to treat ADA-SCID. • Two small, open-label studies showed improvements in disease severity and immune function. • Revcovi provides an additional option to treat a very rare disorder.	• UF • Do not add to EMMPI list
tbo-filgrastim (Granix vials)	Hematological Agents: WBC stimulants	• Granix syringes • Neupogen • Zarxio • Nivestym	Neupogen Biosimilar	• Granix is a biosimilar to Neupogen. • The vials are a new formulation in addition to the previously available pre-filled syringes. • No new clinical data was submitted for approval of the vials. • Provides no compelling clinical advantages over existing filgrastim formulary agents.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
gilteritinib (Xospata)	Oncological Agents: Acute Myelogenous Leukemia	• midostaurin (Rydapt)	AML, FLT3 mutation	• Second kinase inhibitor indicated for AML with an FLT3 mutation, but first for relapsed/remitting AML. • Three trials supporting efficacy with interim analysis of phase III RCT, ADMIRAL, showing superior efficacy to salvage chemo regimens. • Extensive safety profile but not significantly different from other kinase inhibitors. • Overall well tolerated with rare serious adverse events requiring discontinuation.	• UF • Do not add to EMMPI list
glasdegib (Daurismo)	Oncological Agents: Acute Myelogenous Leukemia	• None	AML	• First-in-class agent for AML inhibiting Sonic Hedgehog (SHH) pathway. • Approved for use in newly diagnosed AML alongside low-dose cytarabine in select populations including patients ≥ 75 years old and those who cannot tolerate intensive standard-of-care induction regimens, e.g. 7+3 (cytarabine + daunorubicin). • Limitations include insufficient data to determine impact of severe renal impairment (50% renal clearance) and moderate to severe hepatic impairment (83% metabolized primarily via CYP3A4).	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
halobetasol propionate 0.01% lotion (Bryhali)	Corticosteroids-Immune Modulators: High Potency	• clobetasol 0.05% cream & ointment • fluocinonide 0.05% cream & oint (Lidex) • betamethasone dipropionate augmented 0.05% cream, ointment, **gel,** & **lotion** (Diprolene, Diprolene AF, generics) • clobetasol 0.05% **solution**, **foam**, **gel**, **shampoo**, **lotion,** & spray (Clobex, Olux) • **halobetasol propionate 0.05%** cream, ointment, **foam,** & combinations (Halonate, Ultravate, generics)	Plaque psoriasis	• Bryhali is another formulation of halobetasol propionate in a lotion formulation. • There are 28 other high-potency topical corticosteroid options on the BCF and UF and at least 12 other agents that are appropriate for scalp use. • Topical steroids are highly interchangeable within potency classes (e.g., high, medium and low) and vehicle (e.g., lotion, foam, shampoo). • Bryhali has little to no clinical benefit relative to similar drugs on the formulary.	• NF • Add to EMMPI list
halobetasol propionate 0.05% foam (Lexette)	Corticosteroids-Immune Modulators: High Potency	• Same comparators as Bryhali	Plaque psoriasis	• Lexette is another formulation of halobetasol propionate in a foam vehicle. • There are 28 other high-potency topical corticosteroid options on the BCF and UF and at least 12 other agents that are appropriate for scalp use. • Topical steroids are highly interchangeable within potency classes (e.g., high, medium, low) and vehicle. • Lexette has little to no clinical benefit relative to similar drugs on the formulary.	• Tier 4 (Not covered)

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
inotersen injection (Tegsedi)	Neurological Agents Miscellaneous	• patisiran (Onpattro) – medical benefit	Hereditary Transthyretin Amyloidosis	• Second siRNA treatment for hereditary transthyretin (hTTR) amyloidosis; first pharmacy benefit agent. • Indicated for neuropathy secondary to hTTR amyloidosis. • Statistically and clinically meaningful efficacy in lowering transthyretin levels. • Significant safety concerns include a disproportionate death rate in the Tegsedi arm, numerous serious ADRs, and a black box warning and REMS program.	• UF • Do not add to EMMPI list
itraconazole 65 mg capsules (Tolsura)	Antifungals	• itraconazole 100 mg caps and 200 mg tablets (Sporanox)	Fungal infections in adults including blastomycosis, histoplasmosis, and aspergillosis.	• Tolsura is the third itraconazole formulation available currently on the US market including one suspension and 100 mg capsule. • Administration of Tolsura (2 x 65 mg capsules) with food results in exposures similar to those achieved when itraconazole 2 x 100 mg capsule is administered with food. • No new efficacy studies were submitted for Tolsura FDA approval. • Tolsura carries traditional itraconazole warnings and precautions and provides little to no clinical benefit relative to similar drugs on the formulary.	• NF • Do not add to EMMPI list
larotrectinib (Vitrakvi)	Oncological Agents	• None	Kinase inhibitor for solid tumors	• New multi-kinase inhibitor designated as first-in-class agent. • First oncologic agent approved for molecular target absent a cancer subtype. • Promising results but studies are limited. • Overall, well tolerated with favorable safety profile relative to many intensive chemotherapeutic regimens.	• UF • Do not add to EMMPI list
latanoprost 0.005% ophthalmic emulsion (Xelpros)	Glaucoma Agents	• latanoprost 0.005% ophthalmic solution (Xalatan) • latanoprostene bunod 0.024% ophthalmic solution (Vyzulta)	Glaucoma or ocular hypertension (HTN)	• Third prostaglandin analog without benzalkonium chloride (BAK) as its preservative. • Xelpros was approved through the 505(b)(2) pathway and is the third latanoprost-like agent approved by the FDA. • No new efficacy data was published, and the package insert suggests similar efficacy and safety compared with Xalatan. • This is another option for patients with BAK allergy or sensitivity. Other BAK-free agents are tafluprost and travoprost. • Despite being BAK-free, Xelpros provides no compelling advantages over current available therapy.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
lorlatinib (Lorbrena)	Oncological Agents: Lung Cancer	• alectinib (Alecensa) • crizotinib (Xalkori) • ceritinib (Zykadia) • brigatinib (Alunbrig)	Anaplastic lymphoma kinase (ALK)-positive, metastatic, non-small cell lung cancer (NSCLC) patients who have progressed after one of the following: 1. crizotinib and one other ALK inhibitor 2. alectinib as first-line ALK inhibitor therapy 3. ceritinib as first-line ALK inhibitor therapy	• Fifth ALK inhibitor (ALK-I) available to treat NSCLC. • First third-generation ALK-I indicated for patients with ALK inhibitor resistance. • Indicated for patients who have progressed after second-generation ALK-I treatment, with or without prior crizotinib. • Evaluated for efficacy in 1 single-arm, open-label study, NCT01970865. • As second-line therapy, lorlatinib provided an objective response in 47% of patients. • When used as a third-line agent, lorlatinib demonstrated a 38.7% objective response. • There are currently no head-to-head studies with other ALK inhibitors. • Has a higher risk of weight gain (16%), hypercholesterolemia (66%), and hypertriglyceridemia (45%) and a lower risk of interstitial lung disease (< 1%), compared to other ALK inhibitors. • Lorlatinib provides an additional treatment option for ALK+ NSCLC and is the first agent approved for third-line care or second-line after a second-generation ALK inhibitor.	• UF • Do not add to EMMPI list
loteprednol 1% ophthalmic suspension (Inveltys)	Anti-inflammatory Immunomodulatory Ophthalmic Agents: Ophthalmic Anti-inflammatory Agents	• loteprednol 0.5% (Lotemax) • prednisolone 1% (Pred Forte)	For the treatment of post-operative inflammation and pain following ocular surgery	• Inveltys is another formulation of loteprednol for post-surgery pain and inflammation. • Clinical trials showed superiority at decreasing inflammation and pain compared to placebo at day 15. • Inveltys is the only BID formulation in the ophthalmic anti-inflammatory subclass. All others are typically dosed QID. • No compelling clinical advantage over available agents, other than less frequent dosing.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
omadacycline (Nuzyra)	Antibiotics: Tetracycline	• doxycycline 100 mg tablets	Community-acquired bacterial pneumonia (CABP)/acute bacterial skin and skin structure infections (ABSSSI)	• Nuzyra is a novel tetracycline with potent broad-spectrum activity against infectious pathogens that cause CABP or ABSSSI. • Like doxycycline, omadacycline's pharmacokinetic profile allows for once-daily dosing and lung penetration and lacks requirements for renal dose adjustments. • Requires administration on an empty stomach similar to other tetracyclines/doxycycline. • Three Phase III non-inferiority trials: OASIS, OASIS-2, and OPTIC studies compared Nuzyra in head-to-head vs standard-of-care agents for CABP and ABSSSI. • Similar safety profile to doxycycline with nausea and vomiting occurring most frequently. • Nuzyra coverage mimics other tetracyclines: no *C. diff.*-associated diarrhea was observed in clinical trials; coverage includes gram-positive, gram-negative, atypical, aerobic, and anaerobic bacteria. • In the OPTIC trial, omadacycline was associated with a higher mortality rate (n=8; 2%) compared to moxifloxacin (n=4; 1%). The FDA is requiring additional postmarketing studies regarding mortality difference. • There are numerous cost-effective antibiotics available on the formulary that do not carry additional safety risk.	• NF • Do not add to EMMPI list
pegfilgrastim-cbqv injection (Udenyca)	Hematological Agents: WBC Stimulants	• Neulasta • Fulphila	Biosimilar to Neulasta	• Udenyca is a biosimilar to Neulasta. • No new clinical data was submitted for approval of Udenyca. • Provides no compelling clinical advantages over existing formulary pegfilgrastims.	• UF • Add to EMMPI list
revefenacin nebulized solution (Yupelri)	Pulm-2: LAMAs	• tiotropium soft mist inhaler (Spiriva Respimat) • glyco-pyrrolate nebulized solution (Lonhala Magnair)	For the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)	• Sixth LAMA and the second nebulized LAMA but provides no advantage over Spiriva Respimat, a soft mist inhaler (SMI), which does not require inspiratory flow of ≥ 60 L/min. • In RCTs, the increases in trough FEV_1 with Yupelri were superior to the increases seen with placebo. • Yupelri provides no compelling clinical advantages over other agents in the class.	• NF • Add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
rifamycin (Aemcolo)	GI-2: Miscellaneous	• ciprofloxacin 500 mg BID x 3 days or 750 mg once • azithromycin 1 gm once • rifaximin 200 mg TID x 3 days	Traveler's diarrhea	• Aemcolo is a new non-systemically absorbed oral antibiotic indicated for the treatment of traveler's diarrhea caused by non-invasive strains of *E. coli* in adults. Mechanism is similar to rifaximin (Xifaxin), which is also indicated for traveler's diarrhea. • Available in an enteric-coated tablet that delivers the active ingredient to the distal small bowel and colon. • Dosing is 2 x 194 mg tablets given twice daily for 3 days. • One placebo-controlled study showed the time to last unformed stool was about 24 hours sooner with Aemcolo versus placebo (26 hours vs. 68 hours). Clinical cure was seen in 81.4% of Aemcolo-treated subjects compared to 56.9% with placebo. Both endpoints were statistically significant. • Has not been compared head-to-head with other agents indicated for traveler's diarrhea. • ADR profile is benign. • IDSA guidelines currently recommend use of either a fluoroquinolone or azithromycin, depending on susceptibility patterns and travel history. • Aemcolo offers an additional treatment option for traveler's diarrhea; however, it provides no compelling clinical advantages over existing formulary agents.	• NF • Do not add to EMMPI list
riluzole oral suspension (Tiglutik)	Neurological Agents Miscellaneous	• riluzole oral tablets	Amyotrophic lateral sclerosis (ALS)	• Tiglutik is a new formulation of riluzole in an oral suspension approved for ALS. • No new clinical trials were conducted on riluzole oral suspension; pharmacokinetics demonstrated equivalence with oral tablets. • Riluzole has the potential for off-label use, including in psychiatric disorders. • Riluzole oral suspension provides an option other than crushing tablets for patients with dysphagia/swallowing difficulties.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
sarecycline (Seysara)	Antibiotics: Tetracycline	• doxycycline 100 mg • minocycline 100 mg	Acne	• Sarecycline is a narrow spectrum tetracycline-derived antibiotic approved for the treatment of moderate to severe acne. • Doxycycline IR generics and minocycline IR generics are step-preferred in this class. • 21st tetracycline agent approved for moderate to severe acne vulgaris studied in patients aged 9–45 years. • Once-daily dosing, pregnancy restrictions, and dose adjustments are similar to doxycycline or minocycline; Seysara has less gram-negative coverage. • There are no head-to-head trials of sarecycline vs other tetracycline agents to show improved efficacy, safety, or clinical importance of surpassing bacterial resistance mechanisms. • Use beyond 12 weeks and safety beyond 12 months have not been established. • Although Seysara may provide a theoretical benefit, acne vulgaris is rarely cultured to investigate resistance, and there are many cost-effective alternatives on the formulary. • Seysara provides little to no clinical benefit over formulary alternatives.	• NF • Add to EMMPI list
tafenoquine 100 mg tablet (Arakoda)	Antimalarials	• doxycycline • atovaquone/ proguanil (Malarone) • mefloquine	Antimalarial for chemoprophylaxis	• New formulation of tafenoquine approved for chemoprophylaxis of malaria that is dosed once weekly. • Arakoda was evaluated in 2 trials. In a phase III trial, Arakoda was non-inferior to mefloquine in 615 patients. In a phase IIb trial, Arakoda was more effective at treating malaria compared to placebo. • The most common ADRs include dizziness, GI complications, headache, psychiatric events, and decreased hemoglobin. • Arakoda-specific ADR includes increased alanine aminotransferase (ALT). • Arakoda showed non-inferiority in a head-to-head trial vs mefloquine, allows for weekly dosing, and no cases of resistance have been seen to date; however, it has a similar lead time to doxycycline and Malarone, both which have a mild side effect profile. • Arakoda offers a compelling clinical advantage in terms of weekly dosing and its ability to kill all types of plasmodium, but there is insufficient data regarding adverse events, particularly surrounding psychiatric adverse events.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
tafenoquine 150 mg tablet (Krintafel)	Antimalarials	• primaquine	Antimalarial for prevention of relapse/radical cure	• Krintafel is a new formulation of tafenoquine indicated for radical cure of *P. vivax* malaria in combination with a second antimalarial agent; it is NOT approved for malaria prophylaxis. • Krintafel has a higher relapse-free rate than chloroquine plus primaquine or primaquine alone. • The most common ADRs include dizziness, GI complications, headache, psychiatric events, and decreased hemoglobin. • The tafenoquine resistance profile is unknown; however, some multidrug-resistant strains of malaria have been successfully treated with tafenoquine in combination with another agent. • Krintafel currently provides an additional option for curing of malaria relative to other drugs on the formulary.	• UF • Do not add to EMMPI list
talazoparib (Talzenna)	Oncological Agents: Breast Cancer	• olaparib (Lynparza)	Treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer	• Talzenna is the fourth available PARP inhibitor and the second PARP inhibitor indicated for breast cancer; however, it is the only PARP inhibitor option that can be used regardless of chemotherapy history. • The primary endpoint of progression-free survival was statistically significant in comparison to standard chemotherapy treatment in the EMBRACA trial. • The secondary endpoint of overall survival was not statistically significant compared to chemotherapy. • No head-to-head studies with other PARP inhibitors were conducted. • Most common ADRs (> 20% occurrence) include: anemia, neutropenia, thrombocytopenia, decreased appetite, headache, nausea, vomiting, diarrhea, alopecia, and fatigue. • Talazoparib provides a minimal improvement to progression-free survival, without a statistically significant mortality benefit. • The PARP inhibitor appeared to be very effective at enhancing quality of life; however, the quality of life metrics were exploratory and not designed to appropriately detect significance. • This drug offers minimal advantages in clinical efficacy relative to existing treatment options.	• UF • Do not add to EMMPI list

Generic (Trade)	UF Class	Comparators	Indications	Clinical Summary	Recommended UF Status
testosterone enanthate, SQ injection (Xyosted)	Androgens-Anabolic Steroids: Testosterone Replacement Therapies	**Injectables (vial):** •T. enanthate •T. cypionate •T. undecanoate (Med benefit) **Non-injectables:** •Fortesta gel •Androderm patch •Androgel •Natesto nasal spray	Male testosterone replacement therapy	• Xyosted is the fourth testosterone replacement therapy (TRT) injection on the market and first autoinjector for subcutaneous use. • Xyosted is dosed once weekly for subcutaneous administration in the abdominal region. • Unlike the other TRTs, Xyosted requires monitoring for HTN due to boxed warnings of: ↑ risk of HTN and ↑ risk for major adverse CV events (MACE). • Other than being a self-injectable drug, it provides no compelling advantage over other injectable and non-injectable testosterone products available on the formulary.	• UF and non-step-preferred • Add to EMMPI list

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

DoD P&T Meeting	ADD to the Mail Order Requirement (NOT Excepted from Mail Order Requirement)	Do NOT Add to the Mail Order Requirement (Excepted from Mail Order Requirement)
February 2019	**Basal Insulins:** ▪ insulin degludec (Tresiba) vials **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Assuming mail order availability:* ▪ testosterone enanthate SQ injection (Xyosted) ▪ pegfilgrastim injection (Udenyca) **Designated NF:** *No reason to exempt from EMMPI requirement:* ▪ sarecycline (Seysara) ▪ revefenacin (Yupelri) ▪ desmopressin acetate sublingual (Nocdurna) ▪ filgrastim (Granix) vials ▪ halobetasol propionate 0.01% lotion (Bryhali) ▪ clobazam oral film (Sympazan) ▪ latanoprost 0.005% ophthalmic emulsion (Xelpros) ▪ cyclosporine 0.09% ophthalmic solution (Cequa)	**2nd-generation antihistamines** *Comparable pricing at mail order vs MTFs or retail:* ▪ levocetirizine (Xyzal; generics) **Newly Approved Drugs per 32 CFR 199.21(g)(5)** **Designated UF:** *Not yet clear if feasible to provide through mail order:* ▪ elapegademase (Revcovi) ▪ cenegermin ophthalmic solution (Oxervate) ▪ talazoparib (Talzenna) ▪ lorlatinib (Lorbrena) ▪ larotrectinib (Vitrakvi) ▪ glasdegib (Daurismo) ▪ gilteritinib (Xospata) ▪ inotersen (Tegsedi) ▪ tafenoquine (Arakoda) for malaria prophylaxis ▪ amifampridine (Firdapse) limited distribution ▪ riluzole oral suspension (Tiglutik) *Drugs for acute or limited duration use*: ▪ baloxavir (Xofluza) for influenza ▪ tafenoquine (Krintafel) for radical cure of *Plasmodium vivax* malaria ▪ loteprednol ophthalmic (Inveltys), for inflammation and pain after ocular surgery **Drugs designated NF:** *Acute use exception applies:* ▪ rifamycin (Aemcolo) for traveler's diarrhea ▪ omadacycline (Nuzyra) for CABP and ABSSSI ▪ itraconazole 65 mg capsules (Tolsura) for invasive fungal infections *Existing exception applies:* ▪ aripiprazole tablet with ingestible event marker (Abilify MyCite), antipsychotic exception

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2019	**Migraine Agents – Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass**	UF Class Review	▪ None. Note that a CGRP was not selected for the BCF. ▪ Sumatriptan and rizatriptan are currently on the BCF for treatment of migraines.	▪ erenumab-aooe injection (Aimovig) ▪ fremanezumab-vfrm injection (Ajovy) ▪ galcanezumab-gnlm injection (Emgality)	▪ None	Pending signing of the minutes / 30 days The effective date is May 29, 2019.	▪ Manual PA criteria applies to all new users	▪ See Appendix C for PA criteria.
Feb 2019	**Prostate Cancer Agents: CYP-17 Inhibitors Subclass and 2nd-Generation Antiandrogen Subclass**	UF Class Review Class previously reviewed in Feb 2015	▪ None. Note that no BCF selection was made for the 2 subclasses. ▪ bicalutamide (Casodex, generics) are currently on the BCF for prostate cancer. (Feb 2015)	CYP-17 Inhibitors *Step-preferred* ▪ abiraterone acetate micronized (Yonsa) *Non-step-preferred* ▪ abiraterone acetate (Zytiga, generics) 2nd-Generation Antiandrogens *Step-preferred* ▪ enzalutamide (Xtandi) *Non-step-preferred* ▪ apalutamide (Erleada)	▪ None	Pending signing of the minutes / 90 days The effective date is July 31, 2019.	▪ Manual PA required ▪ QLs apply	▪ Yonsa and Xtandi will be Tier 1 copay/cost-shared. ▪ See Appendix C for full PA criteria and step therapy requirements.

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

Appendix H—Table of Abbreviations

Term	Definition	Term	Definition
AA	Antiandrogen	CKD	chronic kidney disease
AASLD	American Association for the Study of Liver Diseases	CMA	cost minimization analysis
ABSSSI	acute bacterial skin and skin structure infection	COPD	chronic obstructive pulmonary disease
ADA-SCID	adenosine deaminase severe combined immune deficiency	CV	cardiovascular
ADR	adverse reaction	CYP 17	cytochrome P450 17α−hydroxylase/17,20-lyase enzyme
AE	adverse event	DAA	direct-acting antiviral
AHS	American Headache Society	DHA	Defense Health Agency
ALK	anaplastic lymphoma kinase	DHE	dihydroergotamine
ALS	amyotrophic lateral sclerosis	DMARD	disease-modifying anti-rheumatic drug
ALT	alanine aminotransferase	DoD	Department of Defense
AML	Acute Myelogenous Leukemia	DR	delayed release
ANCA	antineutrophil cytoplasmic antibody-associated	ECF	Extended Core Formulary
ANDA	abbreviated new drug application	EGFR	epidermal growth factor receptor
ARI	alpha reductase inhibitor	EMMPI	The Expanded MTF/Mail Pharmacy Initiative
AS	ankylosing spondylitis	ER	extended release
AST	aspartate aminotransferase	ESI	Express Scripts, Inc.
AUA	American Urological Association	FAP	familial amyloid polyneuropathy
BAK	benzalkonium chloride	FDA	U.S. Food and Drug Administration
BCF	Basic Core Formulary	FEV_1	forced expiratory volume in one second
BIA	budget impact analysis	FMB	Formulary Management Branch
BOO	bladder outlet obstruction	FMS FLT3	Ferline McDonough Sarcoma-like tyrosine kinase 3 mutation
CABP	community-acquired bacterial pneumonia	FY	fiscal year
CAPS	Cryopyrin Associated Period Syndrome	G6PD	glucose-6-phosphate dehydrogenase
CD	Crohn's Disease	gBRCAm	germline BRCA-mutated
CF	cystic fibrosis	GCA	giant cell arthritis
CFR	Code of Federal Regulations	GI	gastrointestinal
CFTR	cystic fibrosis transmembrane conductor regulator	GnRH	gonadotropin-releasing hormone
CGRP	calcitonin gene-related peptide	HCP	health care provider
CHF	chronic heart failure	HCV	hepatitis C virus

Term	Definition	Term	Definition
HER2-	human epidermal growth factor receptor 2 negative	NAFLD	non-alcoholic fatty liver disease
HIT-6	Headache Impact Test	NASH	non-alcoholic steatohepatitis
HS	hidradenitis suppurativa	NCCN	National Comprehensive Cancer Network
HSPC	hormone-sensitive prostate cancer	NDA	New drug application
HTN	hypertension	NDAA	National Defense Authorization Act
hTTRA	hereditary transthyretin amyloidosis	NDC	National Drug Code
IBD	inflammatory bowel disease	NF	nonformulary
IBS-D	diarrhea-predominant irritable bowel syndrome	NIH	National Institutes of Health
ICER	Institute for Clinical and Economic Review	NK	neurotrophic keratitis
IDSA	Infectious Diseases Society of America	nmCRPC	non-metastatic castration-resistant prostate cancer
IEM	ingestible event marker	NOMID	Neonatal-Onset Multisystem Inflammatory Disease
IM	intramuscular	NSAID	nonsteroidal anti-inflammatory drug
IR	immediate release	NSCLC	non-small cell lung cancer
IST	inappropriate sinus tachycardia	NTRK	neurotrophic tropomyosin receptor kinase
ITP	immune thrombocytopenic purpura	OA	osteoarthritis
IV	intravenous	OTC	over-the-counter
LAMA	long-acting muscarinic antagonist	P&T	Pharmacy and Therapeutics
LEMS	Lambert-Eaton myasthenic syndrome	PA	prior authorization
LGS	Lennox-Gastaut syndrome	PARP	poly ADP-ribose polymerase
MACE	major adverse cardiovascular events	PERT	Pancreatic Enzymes Replacement Therapy drug class
MCID	minimal clinically important difference	PJIA	polyarticular juvenile idiopathic arthritis
mCRPC	metastatic castration-resistant prostate cancer	PND	polyneuropathy disability
mCSPC	metastatic castration-sensitive prostate cancer	POD	Pharmacy Operations Division
MFS	metastasis-free survival	POS	point of service
MHS	Military Health System	POTS	postural tachycardia syndrome
MIDAS	Migraine Disability Assessment	PPI	proton pump inhibitor
MMD	monthly migraine days	PRES	posterior reversible encephalopathy syndrome
MN	medical necessity	Ps	plaque psoriasis
MPFID	Migraine Physical Functional Impact Diary	PsA	psoriatic arthritis
MTF	Military Treatment Facility	PSA	prostate-specific antigen

Term	Definition	Term	Definition
PSADT	prostate-specific antigen doubling time	SNRI	serotonin and norepinephrine reuptake inhibitor
QL	quantity limit	SQ	subcutaneous
RA	Rheumatoid arthritis	SSRI	selective serotonin reuptake inhibitor
RCT	randomized controlled trial	TB	tuberculosis
REMS	Risk Evaluation and Mitigation Strategies	TD	traveler's diarrhea
SBP	spontaneous bacterial peritonitis	TIBs	targeted immunomodulatory biologics
SGLT2	sodium-glucose cotransporter-2 inhibitor	TNF	tumor necrosis factor
SHH	Sonic Hedgehog	TRT	testosterone replacement therapy
SIADH	syndrome of inappropriate antidiuretic hormone secretion	UC	Ulcerative colitis
SIBO	small intestinal bacterial overgrowth	UF	Uniform Formulary
siRNA	small interfering Ribonucleic Acid	ULN	upper limit normal
SJIA	systemic juvenile idiopathic arthritis	WBC	White blood cell
SL	sublingual	XR	extended release
SMI	soft mist inhaler		