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

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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

<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">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		