**DEPARTMENT OF DEFENSE**
**PHARMACY AND THERAPEUTICS COMMITTEE**

**MINUTES AND RECOMMENDATIONS**

**November 2021**

## I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on November 3 and 4, 2021. Due to the COVID-19 pandemic, the meeting was held via teleconference.

## II. ATTENDANCE

The attendance roster is listed in Appendix A.

**Review Minutes of Last Meetings**

1. **Status of February, May 2021 and August 2021 Committee meeting Minutes—**The February 2021, May 2021 and August 2021 Committee meeting minutes have not been signed yet by the Director, DHA, due to the delay caused by the Secretary of Defense's zero based review of the TRICARE Beneficiary Advisory Panel (BAP).

2. **Clarification of Previous Minutes**

**a) August 2021 Meeting**

- **Miscellaneous Insulin Devices: Omnipod, Omnipod DASH and VGo PA and QLs:** Quantity Limits (QLs) for these products will be implemented 2 weeks after signing of the minutes, with the PA implementation remaining at 90 days.
- **Migraine Drugs:** The PA and QL update for **rimegepant (Nurtec ODT)** allowing for the new preventive indication will be implemented at 30 days after signing, rather than 60 days after signing.
- **Prenatal Vitamins: Neonatal DHA, Neonatal FE**: The PA will apply to new users, as there have been no patients currently receiving these products prior to implementation of the PA in August 2021.

**b) May 2021 Meeting**

- **Updated PA criteria for new indications or age ranges:** Due to the delay in the August P&T Committee minutes' signing, several PA updates that expand the criteria for patient access due to either new FDA-approved indications for oncology drugs or expanded age ranges were implemented in September, 2021. PAs where recommended updates to criteria that are not due to the above reasons are awaiting the BAP meeting and Director's signature

**c) February 2021 Meeting**

- **Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors: Updated PA criteria for abemaciclib (Verzenio): Utilization Management:** On October 14, 2021, Verzenio received a new indication for use in patients with early stage breast cancer. The February 2021 CDK inhibitor drug class review did discuss the data supporting this new indication. The February 2021 minutes were updated to reflect this new indication.
- **Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors: empagliflozin (Jardiance) PA**: Updates to the PA criteria for the SGLT-2 inhibitors for non-diabetic indications were recommended at the February 2021 meeting. On August 18, 2021 the FDA-approved package labeling for empagliflozin was updated to include heart failure with reduced ejection fraction. Updates to the PAs for the SGLT-2 inhibitors await the BAP meeting and signing by the Director.

## 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. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms. When applicable, patient-oriented outcomes are assessed, in accordance with the Final Rule. 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 NF medication.

NF 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. Continuous Glucose Monitoring Systems (CGMs)

*Background*—The P&T Committee evaluated the relative clinical effectiveness of the CGMs. CGMs are minimally-invasive medical devices that continuously monitor and provide real-time results and recording of glucose levels. This allows the patient and provider to have immediate feedback for making treatment decisions.

The devices consist of a subcutaneously placed sensor, an external receiver/reader, and/or an external transmitter. Therapeutic CGMs or integrated CGMs (iCGMs) are part of an integrated system with other compatible medical devices and are designed to replace traditional finger sticks. Two devices currently meet the definition of a therapeutic or iCGM: Dexcom G6 and Abbott FreeStyle Libre 2.

CGMs were not previously covered under the TRICARE pharmacy benefit. They have been available through the TRICARE medical benefit as durable medical equipment (DME). Medical devices are not part of the TRICARE pharmacy benefit, with limited exceptions, such as some diabetic supplies including self-monitoring blood glucose (SMBG) test strips and lancets. Commercial health care plans have shown a movement toward pharmacy benefit coverage of the CGMs to improve access for patients. As a result of this class review, Dexcom G6 and FreeStyle Libre 2 will be available under the TRICARE pharmacy benefit, and may continue to have coverage under the medical benefit.

The clinical and cost effectiveness review focused on the safety and efficacy of Dexcom G6 and FreeStyle Libre 2. The literature review centered on professional clinical practice guidelines (CPGs) and clinical trial data conducted in patients with type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), and gestational diabetes. Information from manufacturer-provided dossiers was also analyzed. Reviewed studies included those reporting outcomes of hemoglobin A1c (A1c), glucose time in range, hypoglycemia events, or maternal and fetal endpoints. Data evaluating earlier versions of Dexcom or FreeStyle Libre were also included in the review.

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

*Clinical Practice Guidelines (CPGs)*

- Several CPGs from professional organizations in the US, Canada, the UK and Europe were evaluated. Overall, the guidelines support use of CGMs for different patient populations, including T1DM and T2DM, however there were varying levels of evidence to support the recommendations.

*Efficacy and Safety*

- *T1DM:* The majority of available clinical evidence supporting CGM use is in patients with T1DM.
    - A systematic review *(Benkhadra 2017)* and data from several individual randomized controlled trials (RCTs) with Dexcom or FreeStyle Libre systems reported significant decreases in A1c.

- In several randomized controlled trials, use of CGMs produced a significant decrease in the number of hypoglycemic events or time spent below-glucose levels of <70 mg/dL.

- *T2DM:* For patients with T2DM using CGMs, the majority of the evidence is in patients receiving multiple daily insulin injections.
  - Overall, there are fewer studies and more variable results reported in terms of A1c reductions or glucose time in range, compared to the data in patients with T1DM. For the T2DM patient population, higher baseline A1c values may predict better response to CGM use.
  - There is minimal safety data to guide use in T2DM populations.
  - Further research in T2DM patients is needed, particularly in those patients receiving soleoy oral medications or those on basal insulin alone.

- *Gestational Diabetes:* Several professional diabetes societies endorse CGMs for pregnant patients. Guidelines from the UK National Institute for Health and Care Excellence *(NICE 2020)* recommend real-time-CGM for all pregnant women with T1DM. Studies in this patient population show that a 5% increase in the glucose time in range can significantly reduce adverse outcomes such as large-for-gestational age (LGA) infants, neonatal intensive care unit admissions, and neonatal hypoglycemia episodes.
  - The UK NICE pregnancy guidelines also state that real-time CGM can be considered in pregnant women with T2DM receiving insulin therapy who have problematic hypoglycemia or unstable blood glucose levels. However, randomized controlled trial data is inconclusive in this area.

*Dexcom G6 vs. FreeStyle Libre 2*

- There were no head-to-head trials available evaluating outcomes to assess whether there are clinically relevant differences in efficacy or safety between the Dexcom G6 or FreeStyle Libre 2 CGMs.
- Similarities between the Dexcom G6 and FreeStyle Libre 2 include that both devices have programmable voluntary additional alerts for a variety of high or low readings; both allow healthcare provider access to patient data to aid in treatment decisions; finger stick calibration is not required with either system; and both allow self-insertion and removal of the sensor.
- *Dexcom G6*: The Dexcom G6 provides real-time data sharing, as it updates results continuously every 5 minutes via Bluetooth capability. The sensors must be replaced every 10 days, and require a 2 hour warm-up time. Dexcom G6 is approved for patients as young as 2 years of age. This system

has a mandatory alarm, the "urgent low soon," which detects downward trends in glucose; this alert cannot be adjusted or disabled. Several insulin pumps are compatible with the Dexcom G6 system.

- *FreeStyle Libre 2*: The FreeStyle Libre 2 is an intermittently scanned system, since scanning of the sensor is required every 8 hours. The data is updated every 15 minutes via RFID or Bluetooth. The sensors are replaced every 14 days, with the sensors requiring a 1 hour warm up time. FreeStyle Libre 2 is approved for use in children as young as 4 years of age. All alarms are optional. The FreeStyle Libre 2 is currently not compatible with any insulin pump. The receiver has a built-in glucometer for finger sticks.

*Other Factors*

- Since the iCGMs are intended to replace the need for finger sticks, they ideally will result in a corresponding reduction in overall MHS utilization and subsequent cost of self-monitoring blood glucose test (SMBG) strips.
- The Committee agreed that any newly FDA-approved iCGM platforms would first be evaluated as to whether they would be included on the TRICARE pharmacy benefit, prior to reviewing them as part of the innovator program.

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

- CMA results showed that the Dexcom G6 and FreeStyle Libre 2 were comparable in cost.
- BIA and a sensitivity analysis were performed to evaluate the potential impact of designating the two iCGMS as UF, NF, or Tier 4 on the formulary. BIA results showed that designating both Dexcom G6 and FreeStyle Libre 2 as UF and included as part of the TRICARE pharmacy benefit demonstrated significant cost avoidance to the MHS, when compared to their costs under the TRICARE medical benefit.

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

        - Dexcom G6
        - Abbott FreeStyle Libre 2
    - NF/Tier 4
        - None
    - Note that with the recommendation to include CGMs on the TRICARE pharmacy benefit, local MTF commands are encouraged to adjust pharmacy budgets accordingly.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) PA criteria for Dexcom G6 and Freestyle Libre 2. All patients currently receiving Dexcom G6 or FreeStyle Libre 2 under the TRICARE medical benefit will require PA to receive coverage under the pharmacy benefit. Coverage for both Type 1 and Type 2 diabetes is allowed, provided that the patient is receiving basal and prandial insulin, or if the patient is using an insulin pump. There is no requirement for a minimal number of SMBG test strips to be used daily, in order to receive Dexcom G6 or Freestyle Libre 2. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) quantity limits for all components (e.g. readers, receivers, sensors, and transmitters) associated with the Dexcom G6 and Freestyle Libre 2 CGMs. See Appendix D for the full criteria.

4. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) exempting Dexcom G6 and Freestyle Libre 2 from the EMMPI requirement since there is no cost advantage to including them on the program.

5. ***COMMITTEE ACTION: AUTO-REFILL PROGRAM RECOMMENDATION—***The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1 absent) excluding Dexcom G6 and Freestyle Libre 2 from the Auto-Refill program administered by Express Scripts, Inc at the TRICARE Mail Order Pharmacy, to reduce the potential for wastage.

6. ***COMMITTEE ACTION: UF, PA, QUANTITY LIMITS, AUTO REFILL PROGRAM AND EMMPI IMPLEMENTATION PERIOD—*** The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 1

absent) an effective date of the first Wednesday 60-days after signing of the minutes in all points of service (POS). Based on the P&T Committee's recommendation, the effective date is April 20, 2022.

**B. Subcutaneous Immunoglobulins (SCIG)**

*Background*—The P&T Committee evaluated the relative clinical effectiveness of the immunoglobulin replacement agents used for treating a variety of primary immunodeficiency disorders and other conditions. They are used to prevent serious bacterial infection and modulate immune function. The products in the class all contain polyvalent immunoglobulin G (IgG) obtained from pooled donors. Differences between agents are due to variances in the manufacturing process, IgG concentration, stabilizer, and vehicle, and are not due to the active IgG ingredient.

Eight products are available as part of the TRICARE pharmacy benefit, however three agents, Gammaked, Gammagard Liquid and Gamunex can be administered either intravenously (IV) or subcutaneously (SC). The five exclusively SC administered products include Cutaquig, Cuvitru, Hizentra, Hyqvia, and Xembify. The exclusively SC administered formulations provide an option for patients with poor vascular access and those with numerous reactions to the intravenous infusions. Subcutaneous preparations with concentrations higher than 10% or which contain hyaluronidase cannot be given IV.

The exclusively IV administered products (e.g., Gammaplex, Octagam) are part of the TRICARE medical benefit and were not included in the formulary review.

*Relative Clinical Effectiveness Conclusion*—The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 3 absent) the following:

*Efficacy*

- Professional treatment guidelines from the Immune Deficiency Foundation Diagnostic and Clinical Care Guidelines (3rd edition) do not make any distinction between an individual SCIG product, manufacturer, concentration, formulation, stabilizer, or quality control method in their recommendations.
- A comprehensive evidence review shows that efficacy of the SCIG products is a function of dose (which correlates to IgG serum levels), rather than a specific SCIG preparation or administration route.
- No one SCIG product is superior (or inferior) to any other. Practical considerations may limit use of one preparation over another, (e.g., patient body size vs. volume to be administered).

*Safety*

- Safety is a class effect for the SCIG formulations. Common adverse reactions include local infusion site reactions, headache, fever, diarrhea, dermatitis, nausea, vomiting, fatigue and pyrexia.

- SCIG products administered by IV routes have higher rates of systemic adverse events, including systemic hypersensitivity reactions. In contrast products administered by the SC routes have higher rates of local administration site reactions.
- Unique factors of the individual SCIG products may apply to specific patient populations. Lower concentration products can preclude use in patients with minimal subcutaneous tissue (e.g. small children or cachectic patients). Additionally, patients with IgA hypersensitivity should not use preparations with higher thresholds of IgA. Patients at risk of volume overload should avoid higher sodium-containing and higher osmolality products.

*Products*

- *Gammagard Liquid, Gammaked, and Gamunex-C* have concentrations of 10% and when administered IV can treat conditions requiring greater quantities of IgG. These products are administered once per four weeks. Gammagard 10% is an IgA depleted product. There is currently high utilization of Gamunex-C in the MHS.
- *Cutaquig 16.5%* contains maltose as a stabilizer and could potentially interfere with blood glucose monitoring in diabetic patients, due to the risk of falsely elevated blood glucose readings. Since Cutaquig has the highest threshold concentration of IgA, it should be avoided in patients with IgA hypersensitivity. It also is a high osmolality product and should be avoided in patients with renal dysfunction or heart failure. It is administered weekly.
- *Cuvitru 20%* requires weekly administration.
- *Hizentra 20%* is administered weekly. Patients with hyperprolinemia should avoid Hizentra due to the proline stabilizer. It is also a high osmolality product and is administered weekly. It is an IgA depleted product.
- *Hyqvia 10%* contains hyaluronidase which allows for less frequent administration; it is given every 4 weeks. Patients with hypersensitivity or antibodies to hyaluronidase should avoid Hyqvia. Hyqvia is an IgA depleted product.
- *Xembify 20%* requires weekly administration and has a risk of venous thromboembolism.

*Overall Clinical Conclusion*

- The SCIG products are highly therapeutically interchangeable, after accounting for differences in dosing and concentrations. There may be niche patient populations where individual preparations are relatively contraindicated.
- In order to meet the needs of MHS patients, at least three SCIG products are required on the formulary, including one formulation that can be given both by the

IV and SC routes, and a product which is IgA depleted. Potential manufacturer shortages preclude having only one SCIG agent on the formulary.

*Relative Cost Effectiveness Analysis and Conclusion*—CMA and BIA were performed. The P&T Committee concluded (14 for, 0 opposed, 0 abstained, 3 absent) the following:

- CMA results showed that Hyqvia, Cuvitru, Gammagard Liquid, Hizentra, Cutaquig, Gammaked, Gamunex-C, and Xembify were all cost effective agents.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF, or Tier 4. BIA results showed that designating Cutaquig and Gamunex-C as UF and step-preferred, with Cuvitru, Gammagard Liquid, Gammaked, Hizentra, Hyqvia, and Xembify as UF non-step-preferred demonstrated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) the following:
    - **UF Step-preferred**
        - Cutaquig
        - Gamunex-C
    - **UF non-step-preferred**
        - Gammagard Liquid
        - Gammaked
        - Cuvitru
        - Hizentra
        - Hyqvia
        - Xembify
        - Note that as part of the recommendation, a trial of either Cutaquig or Gamunex-C is required in new patients, before patients can try Gammagard, Gammaked, Cuvitru, Hizentra, Hyqvia, or Xembify.
        - The SCIG products are not included on the EMMPI program.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for the non-step preferred products, Gammagard Liquid, Gammaked, Cuvitru, Hizentra, Hyqvia, and Xembify. Patients with clinical factors such as a

contraindication, intolerance to, or an adverse reaction to the step-preferred SCIG products Gamunex-C or Cutaquig can receive one of the non-step-preferred products. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: CUTAQUIG TIER 1 STATUS***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) lowering the current Tier 2 cost-share for Cutaquig to the generic Tier 1 cost-share.

   The authority for this recommendation is codified in 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020 which states "in implementing this rule, the Committee will not only evaluate drugs for exclusion from coverage, but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending, and better patient outcomes." Lowering the cost-share for Cutaquig will provide a greater incentive for beneficiaries to use the most cost-effective SCIG, in the purchased care points of service.

4. ***COMMITTEE ACTION: UF, PA, AND TIER 1 COPAY IMPLEMENTATION PERIOD***—The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday 90 days from signing of the minutes in all POS. Based on the P&T Committee's recommendation, the effective date is May 18, 2022.

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions*—The P&T Committee agreed (group 1: 15 for, 0 opposed, 0 abstained, 2 absent; group 2: 14 for, 0 opposed, 0 abstain, 3 absent; Loreev XR 15 for, 0 opposed, 0 abstained, 2 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 2021 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 group 1: (15 for, 0 opposed, 0 abstained, 2 absent) and group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and for lorazepam ER capsules (Loreev XR) (15 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF:
    - belumosudil (Rezurock) – Immunosuppressive for chronic graft-vs-host disease
    - belzutifan (Welireg) – Oncological agent for von Hippel Lindau disease
    - mobocertinib (Exkivity) – Oncological agent for non-small cell lung cancer (NSCLC)
    - naloxone nasal 8 mg (Kloxxado) – Narcotic antagonist for opioid overdose
    - serdexmethylphenidate/dexmethylphenidate (Azstarys) – Stimulant ADHD agent
- NF:
    - finerenone (Kerendia) – Miscellaneous cardiovascular agent for chronic kidney disease associated with diabetes
    - ibrexafungerp (Brexafemme) – Antifungal for vulvovaginal candidiasis
    - mirabegron extended release granules for oral suspension (Myrbetriq Granules) – Overactive bladder agent for neurogenic detrusor overactivity (NDO)
    - odevixibat (Bylvay) – Miscellaneous metabolic agent for progressive familial intrahepatic cholestasis (PFIC)
    - olanzapine/samidorphan (Lybalvi) – Combination atypical antipsychotic for schizophrenia and bipolar I disorder
    - ruxolitinib 1.5% cream (Opzelura) – Topical corticosteroid immune modulator for atopic dermatitis
- Tier 4 (Not covered): See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
    - lorazepam extended-release capsules (Loreev XR) – Antianxiety Agent – benzodiazepines: extended release lorazepam capsules for anxiety in adults already stabilized on three times a day dosing of lorazepam tablets
        - Loreev XR was recommended for Tier 4/Not Covered status as it has little to no clinical benefit relative to other lorazepam formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives to Loreev XR include lorazepam immediate-release tablets and alprazolam IR and XR tablets.

- dihydroergotamine mesylate nasal spray (Trudhesa) – Migraine drugs - another DHE nasal spray for acute treatment of migraine in adults with or without aura
    - Trudhesa was recommended for Tier 4 as it has little to no clinical benefit relative to other DHE products, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include DHE nasal spray, sumatriptan nasal and oral, and other triptans, including rizatriptan, zolmitriptan, and eletriptan.

**B.** ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent) MN criteria for Brexafemme, Bylvay, Kerendia, Lybalvi, Myrbetriq Granules, and Opzelura. See Appendix B for the full criteria.

**C.** ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent)the following (see Appendix C for the full criteria):

- Oncologic drugs: Applying manual PA criteria to new users of Exkivity and Welireg.
- Applying manual PA criteria to new users of Azstarys, Lybalvi, Myrbetriq Granules, and Rezurock.
- Applying manual PA criteria to new and current users of Opzelura, Kerendia, and Bylvay.

**D.** ***COMMITTEE ACTION: NALOXONE NASAL 8 MG (KLOXXADO) TIER 1 STATUS***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 2 absent) lowering the current Tier 2 cost-share for Kloxxado to the generic Tier 1 cost-share, with an effective date of the first Wednesday two weeks after signing of the minutes at all points of service, on March 2, 2022. (See p 9 for the Final Rule comments on Tier 1 selections). Lowering the cost-share for Kloxxado will provide a greater incentive for beneficiaries to use a cost-effective naloxone formulation in the purchased care points of service.

**E.** ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended for group 1: (15 for, 0 opposed, 0 abstained, 2 absent); group 2: (14 for, 0 opposed, 0 abstained, 3 absent); and for Loreev XR (15 for, 0 opposed, 0 abstained, 2 absent) an effective date of the following:

- **New Drugs Recommended for UF or NF Status:** an effective date of the first Wednesday two weeks after signing of the minutes in all points of service, on March 2, 2022.

- **New Drugs Recommended for Tier 4 Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in 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, on June 15, 2022.

## VI. UTILIZATION MANAGEMENT

### A. PA Criteria

#### 1. New Manual PA Criteria

Manual PA criteria were recommended for several recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. These drugs all have numerous cost effective formulary alternatives available that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users, requiring a trial of cost effective generic formulary medications first.

a) **Antihistamine-1s: First Generation and Combinations—clemastine 0.5 mg/mL oral syrup—**Clemastine syrup is manufactured by a single company and requires a prescription prior to dispensing. Clemastine tablets and other antihistamines are available via prescription that do not require prior authorization criteria or are available over-the-counter (OTC).

b) **Pain Agents: NSAID – diclofenac potassium 25 mg tablet (Lofena)—**A new diclofenac 25 mg tablet that is manufactured by a single company is markedly not cost-effective relative to other formulary NSAIDs. All other strengths of diclofenac potassium, diclofenac sodium, and various other NSAIDs are included on the TRICARE pharmacy benefit and do not require prior authorization criteria. OTC NSAIDs are also widely available.

c) **Anti-Emetic/Anti-Vertigo Agents – meclizine 50 mg tablet (Antivert)—** Meclizine is an older antiemetic widely available in 12.5 mg and 25 mg tablets in prescription and over-the-counter formulations. A new expensive 50 mg tablet has come to market manufactured by a single company which requires a prescription prior to dispensing.

d) **Antilipidemics-1 – niacin 500 mg tablet—**Niacin is available in several formulations, including Niaspan 500 mg, 750 mg and 1,000 mg ER tablets, and Niacor 500 mg tablets. Niacin 500 mg by a sole manufacturer is not cost-effective relative to other niacin formulations.

e) **Vitamins: Prenatal – Prenatal Multivitamin (Neonatal Complete)—**Neonatal Complete is a prenatal dietary supplement manufactured by a single company which requires a prescription prior to dispensing. The primary ingredients of Neonatal Complete are similar to that found in Azesco, Zalvit, Trinaz, Neonatal-

DHA, and Neonatal FE, which require manual PA and are very expensive. Several cost-effective prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria.

f) **Antidepressant and Non-Opioid Pain Syndrome Agents: Selective serotonin reuptake inhibitors (SSRIs) – sertraline 150 mg and 200 mg capsules—** Sertraline 25 mg, 50 mg and 100 mg tablets have been on the UF long-term, and do not require prior authorization. A new sertraline capsule formulated in 150 mg and 200 mg is not cost effective relative to the other sertraline formulations and other formulary SSRIs.

g) **Skeletal Muscle Relaxants and Combinations—tizanidine 2 mg, 4 mg, 6 mg capsules (Zanaflex, generics)—**Tizanidine is an alpha2-adrenergic agonist indicated to treat spasticity and is available in tablet and capsule formulations. The 2 mg, 4 mg and 6 mg capsule formulations (available from several manufacturers) are significantly more costly than the tablets. Manual PA criteria were recommended for all new users of tizanidine capsules, to require a trial of the cost-effective tizanidine tablet formulation and other formulary muscle relaxants first.

***COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PLAN—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for clemastine 0.5 mg/mL oral syrup, diclofenac potassium 25 mg tablet, meclizine 50 mg tablet, niacin 500 mg tablet, Neonatal Complete (regardless of the woman's age) and sertraline 150 mg and 200 mg capsules in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 90 days after the signing of the minutes, and DHA will send letters to affected patients.

The PA Committee also recommended (14 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for tizanidine capsules (Zanaflex) in new users, which will be effective the first Wednesday 60 days after signing of the minutes. See Appendix C for the full criteria.

**2. Updated PA Criteria for New FDA-Approved Indications**

The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

a) **Antilipidemics-1: PCSK9–inhibitors: evolocumab (Repatha)—**The manual PA criteria were updated for Repatha, allowing use in children as young as 10 years of age with homozygous- or heterozygous familial hypercholesterolemia. Additionally, for patients with atherosclerotic cardiovascular disease (ASCVD),

the qualifying LDL for treatment is now lowered to less than 70 mg/dL, rather than 100 mg/dL, corresponding with data from the FOURIER outcomes trial and the updated American Heart Association/America College of Cardiology/National Lipid Association guidelines.

b) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors–zanubrutinib (Brukinsa)**—Includes the new indication for adult patients with the following: Waldenström's macroglobulinemia (WM), a rare non-Hodgkin lymphoma; and relapsed or refractory marginal zone lymphoma (MZL) in patients who have received at least 1 anti-CD20-based regimen.

c) **Oncological Agents: Acute Myelogenous Leukemia–ivosidenib (Tibsovo)**—Includes the new indication for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a FDA-approved test.

d) **Respiratory Interleukins–mepolizumab injection (Nucala)**—Includes the new indication for adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) as add-on maintenance therapy who have had an inadequate response to nasal corticosteroids.

e) **Sleep Disorders: Wakefulness Promoting Agents–sodium oxybate/calcium/magnesium/potassium oral solution (Xywav)**—Includes the new indication for adult patients with idiopathic hypersomnia.

f) **Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors–adalimumab (Humira)**—New guidelines from the American College of Rheumatology recommend a trial of Humira first, before small molecule immunomodulators, in patients with psoriatic arthritis. The current Humira PA requires a trial of methotrexate, aminosalicylates (sulfasalazine, mesalamine), corticosteroids, or immunosuppressants (azathioprine) prior to allowing Humira. Manual PA criteria was updated to allow Humira as first-line therapy in patients for psoriatic arthritis, and not require prior non-biologic systemic therapy.

***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the manual PA criteria for Tibsovo, Brukinsa, Nucala, Xywav, Humira, and Repatha in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix C for the full criteria

**3. Updated PA Criteria for Safety Information**

a) **Targeted Immunomodulatory Biologics (TIBs): Janus Kinase (JAK) inhibitors: baricitinib (Olumiant) and upadacitinib (Rinvoq)**—In September 2021, the FDA published results of a large RCT with the oral JAK inhibitor tofacitinib (Xeljanz and Xeljanz XR). Xeljanz and Xeljanz XR were associated with an increased risk of serious cardiovascular-related events, cancer,

thrombosis, and death; subsequently there were revisions to the product labeling. Since Olumiant and Rinvoq have a similar mechanism of action, the FDA also required updates to the package inserts for these products, due to the potential for similar risks as Xeljanz. The revised labeling cautions providers to evaluate the risk vs. benefit of the JAK inhibitors, and to use these products as 2nd line therapy.

***COMMITTEE ACTION: OLUMIANT AND RINVOQ UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria for Olumiant and Rinvoq, requiring provider acknowledgment of the safety alerts and boxed warnings. Implementation will occur the first Wednesday 30 days after signing of the minutes. See Appendix C for the full criteria.

## B. Quantity Limits

QLs were reviewed for the newly approved drugs where there are existing QLs for the class, including the narcotic antagonists, antifungals, metabolic agents-miscellaneous, immunosuppressive, oncological agents, overactive bladder drugs, and atopic dermatitis products.

***COMMITTEE ACTION: QLs AND IMPLEMENTATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) QLs for Kloxxado, Brexafemme, Bylvay, Rezurock, Exkivity, Welireg, Myrbetriq Granules, and Opzelura, with implementation occurring the first Wednesday two weeks after signing of the minutes. See Appendix D for the QLs.

## C. Line Extensions

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

a) **Respiratory Interleukins—**designating **dupilumab (Dupixent) 200 mg pen** as UF, with the same manual PA criteria requirements, QL, EMMPI List status, and specialty status as Dupixent 300 mg pen.

b) **Thyroid and Antithyroid Agents—**designating **levothyroxine sodium (Tirosint-Sol) 37.5 mcg/mL, 44 mcg/mL, and 62.5 mcg/mL** as UF, with the same manual PA criteria, and EMMPI List status similar to the various other strengths of Tirosint-Sol.

c) **Antivirals—**designating **baloxavir marboxil (Xofluza) 80 mg x 1** as UF and same QL similar to original strengths of 20 mg x 2 and 40 mg x 2 formulations.

***COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION—***The P&T Committee recommended (14 for, 0 opposed, 0 abstained, 3 absent) clarifying the formulary status of the line extension products, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

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

**Newly Approved Drugs per 32 CFR 199.21(g)(5)**
See Appendix F for the mail order status of medications designated UF or NF during the November 2021 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 2021 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.

***COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—***
The P&T Committee recommended (for group 1: 15 for, 0 opposed, 0 abstained, 2 absent; group 2: 14 for, 0 opposed, 0 abstained, 2 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. See Appendix F.

## VIII. ITEMS FOR INFORMATION

### A. Annual MHS Prescribing and Cost Trends

The Committee was briefed on various aspects of MHS prescribing and cost trends, including overall trends and spends, the top 25 drug classes, increasing specialty spend, new 2022 pharmacy copays, and the impact of the Beneficiary Advisory Panel delay on the cost avoidance projections from the previous 2021 quarterly meetings.

### B. Ivermectin PA

Quantity limits for ivermectin were recommended at the August 2021 P&T Committee meeting, as MHS data showed a large increase in the number of dispensed ivermectin prescriptions. Continued increasing DoD usage was noted, likely correlating with the widespread publicity of ivermectin's unproven use for COVID-19. Several requests were received from the field to add PA criteria.

After consultation with several MHS Infectious Disease specialists and the DoD P&T Committee Chair, PA for ivermectin was implemented in September 2021, limiting use to the FDA-approved indications, or if prescribed by or in consultation with an ID specialist. The P&T Committee administrative authorities document which was updated at the August 2021 meeting allow implementation of PAs and QL, in the setting of national emergencies or shortages.

## IX. ADJOURNMENT

The meeting adjourned at 1500 hours on November 4, 2021. The next meeting will be in February 2022.

**Appendix A—Attendance: November 2021 DoD P&T Committee Meeting:**
**Appendix B—Table of Medical Necessity Criteria**
**Appendix C—Table of Prior Authorization Criteria**
**Appendix D—Table of Quantity Limits**
**Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)**
**Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the November 2021 DoD P&T Committee Meeting**
**Appendix G—Table of Implementation Status of Uniform Formulary Recommendations/Decisions Summary**
**Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives**
**Appendix I—Table of Abbreviations**

## DECISION ON RECOMMENDATIONS

**SUBMITTED BY:**

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

**The Director, DHA:**

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

Brian C. Lein, MD
Assistant Director,
Healthcare Administration
*for* Ronald J. Place
LTG, MC, USA
Director

14 Jul 2022
Date

**Appendix A—Attendance: November 2021 P&T Committee Meeting**

| **Voting Members Present** | |
|---|---|
| John Kugler, COL (Ret.), MC, USA | DoD P&T Committee Chair |
| Col Paul Hoerner BSC, for Col Markus Gmehlin BSC | Chief, DHA Pharmacy Operations Division (POD) |
| CDR Scott Raisor | Acting Chief, Formulary Management Branch (Recorder) |
| MAJ Sebastian Welsh, MC | Army, Physician at Large |
| COL Aatif Sheikh, MSC | Army, Pharmacy Officer |
| LTC Rosco Gore, MC | Army, Internal Medicine Physician |
| Ruben Salinas, COL (Ret.) MC, USA | Army, Family Medicine Physician |
| LCDR Sean Stuart, MC | Navy, Physician at Large |
| CAPT Bridgette Faber, MSC | Navy, Pharmacy Officer |
| CDR Austin Parker, MC | Navy, Internal Medicine Physician |
| CDR Christopher Janik for CAPT Paul Michaud, USCG Day #1 | Coast Guard, Pharmacy Officer |
| CAPT Paul Michaud, USCG Day #2 | Coast Guard, Pharmacy Officer |
| Lt Col Jeffrey Colburn, MC | Air Force, Internal Medicine Physician |
| Maj Jennifer Dunn, MC | Air Force, Physician at Large |
| Lt Col Larissa Weir, MC | Air Force, OB/GYN Physician |
| Col Corey Munro, BSC | Air Force, Pharmacy Officer |
| LCDR Joseph An, MC | Navy, Oncologist |
| Beth Days, RPh | Oncology Pharmacist |
| **Nonvoting Members Present** | |
| Bryan Wheeler, DHA | Associate General Counsel, DHA |
| Megan Gemunder, DHA | Attorney Advisor, Contract Law |
| Eugene Moore, PharmD | COR TRICARE Pharmacy Program |
| LCDR William Agbo | DLA Troop Support |

**Appendix A—Attendance: November 2021 P&T Committee Meeting**

| **Guests** | |
|---|---|
| Lt Col John Oberlin, MC | Chief, Pediatric Endocrinology & Diabetes<br>San Antonio Military Health System |
| Lt Col Francisco Boral | DLA Troop Support |
| Ms. Marsha Peterson | DHA Contracting Officer |
| Ms. Tracy Banks | DHA Contracting |
| Ms. Madison Northern | DHA Contracting |
| Mr. Hudson Tompkins | DHA Contracting |
| Mr. Monroe Porter | DHA Contracting |
| Capt Stefanie Johnson, MSC | DHA Healthcare Optimization Fellow |
| **Others Present** | |
| MAJ Adam Davies, MSC | Chief, P&T Section, DHA Formulary Management Branch |
| Angela Allerman, PharmD, BCPS | DHA Formulary Management Branch |
| Shana Trice, PharmD, BCPS | DHA Formulary Management Branch |
| Amy Lugo, PharmD, BCPS | DHA Formulary Management Branch |
| LCDR Todd Hansen, MC | DHA Formulary Management Branch |
| LCDR Elizabeth Hall, BCPS | DHA Formulary Management Branch |
| Maj Angelina Escano, MC | DHA Formulary Management Branch |
| LCDR Giao Phung, MSC | DHA Formulary Management Branch |
| Ellen Roska, PharmD, MBA, PhD | DHA Formulary Management Branch |
| Julia Trang, PharmD | DHA Formulary Management Branch |
| Maj Gregory Palmrose, BSC | DHA Market Management Branch |
| Mr. David Folmar | DHA Formulary Management Branch Contractor |
| Mr. Kirk Stocker | DHA Formulary Management Branch Contractor |
| Mr. Michael Lee | DHA Formulary Management Branch Contractor |
| Ms. Samantha Valliant | University of North Carolina at Chapel Hill PharmD student |

## Appendix B—Table of Medical Necessity Criteria

| Drug / Drug Class | Medical Necessity Criteria |
|---|---|
| • finerenone (Kerendia)<br><br>**Cardiovascular Agents: Miscellaneous** | • Use of formulary agents is contraindicated<br>• Patient has experienced significant adverse effects from formulary agents<br>• Formulary agents resulted in therapeutic failure<br><br>• **Formulary alternatives:** empagliflozin |
| • ibrexafungerp (Brexafemme)<br><br>**Antifungals** | • Use of formulary agents is contraindicated<br>• Patient has experienced significant adverse effects from formulary agents<br>• Formulary agents resulted in therapeutic failure<br><br>**Formulary alternatives:** oral generic fluconazole, OTC clotrimazole vaginal cream, OTC miconazole vaginal cream |
| • mirabegron extended release granules for oral suspension (Myrbetriq Granules)<br><br>**Overactive Bladder Agents** | • Patient has experienced or is likely to experience significant adverse effects from formulary agents<br>• Formulary agents resulted in therapeutic failure<br><br>**Formulary alternatives:** oxybutynin |
| • odevixibat (Bylvay)<br><br>**Metabolic Agents-Miscellaneous** | • All five formulary agents (ursodiol, cholestyramine, rifampin, naltrexone, and at least 1 antihistamine) have resulted in therapeutic failure<br><br>• **Formulary alternatives:** ursodiol, cholestyramine, diphenhydramine, hydroxyzine, rifampin, naltrexone |
| • olanzapine/ samidorphan (Lybalvi)<br><br>**Antipsychotic Agents: Atypical** | • Patient has experienced significant adverse effects from two formulary agents<br><br>**Formulary alternatives:** olanzapine/fluoxetine, olanzapine, aripiprazole, ziprasidone |
| • ruxolitinib 1.5% cream (Opzelura)<br><br>**Corticosteroids-Immune modulators: Atopic dermatitis** | • Use of formulary agents are contraindicated<br>• Patient has experienced or is likely to experience significant adverse effects from formulary agents<br>• Formulary agents resulted in therapeutic failure<br><br>**Formulary alternatives:** topical corticosteroids (various); tacrolimus (generic); pimecrolimus (Elidel) |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| **Drug Class Review PAs** | |
| • Dexcom G6<br>• FreeStyle Libre 2<br><br>**Continuous Glucose Monitoring (CGM) Systems** | Manual PA criteria apply to all new and current users of Dexcom G6 or Abbott FreeStyle Libre 2.<br><br>Patients who have previously received Dexcom G6 or FreeStyle Libre 2 under the TRICARE medical benefit (e.g., DME) must still fill out the prior authorization criteria below in order to receive these CGMs under the TRICARE pharmacy benefit.<br><br>Note: other CGM systems are not part of the TRICARE pharmacy benefit but may be covered through the TRICARE DME process.<br><br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• The patient has a diagnosis of Type 1 diabetes mellitus OR Type 2 diabetes mellitus<br>• One of the following situations applies:<br>  • Patient is using basal and prandial insulin injections; OR<br>  • Patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR<br>  • Patient has Type 2 diabetes mellitus and is receiving insulin therapy and has a history of severe hypoglycemia episodes requiring medical intervention<br>• Dexcom G6 or FreeStyle Libre 2 is prescribed by an endocrinologist or diabetes specialist<br>• Documentation from the patient record must be submitted with all of the following:<br>  • Diagnosis<br>  • Medication history, including use of insulin<br>  • Completion of a comprehensive diabetes education program for the patient<br>  • Patient agrees to wear CGM as directed<br>  • Patient agrees to share device readings with managing healthcare professional for overall diabetes management<br>• Patient meets the following age requirements<br>  • Dexcom G6: Patient is 2 years of age or older<br>  • FreeStyle Libre 2: Patient is 4 years of age or older<br>• Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips, with the goal of minimizing/discontinuing use<br><br>Initial prior authorization expires in 1 year<br>PA renewal will be required annually<br><br>Renewal criteria: Coverage will be approved on a yearly basis if all of the following apply (Note that initial TRICARE PA approval is required for renewal)<br><br>• Confirmation that the patient has seen an endocrinologist or diabetes specialist at least once within the past year<br>• Confirmation that the patient has utilized CGM daily<br>• Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips at every visit, with the goal of minimizing/discontinuing use<br>• Patients with T2DM continue to require daily basal and prandial insulin injections<br>• Patient continues to agree to share data with managing healthcare professional for the purposes of clinical decision making |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| • Gammagard Liquid<br>• Gammaked<br>• Xembify<br>• Hizentra<br>• Cuvitru<br>• Hyqvia<br><br>**Subcutaneous Immunoglobulins (SCIG)** | Manual PA that apply to all new users of Gammagard Liquid, Gammaked, Xembify, Hizentra, Cuvitru, and Hyqvia.<br><br>Manual PA criteria—Coverage is approved if all of the following criteria are met:<br>• The provider acknowledges that Cutaquig and Gamunex-C do not require a PA.<br>• Patient is 2 years of age or older<br>• One of the following situations applies:<br>  • Patient has primary immunodeficiency disease (any)<br>  • Patient has a chronic inflammatory demyelinating polyneuropathy (any)<br>  • Patient has another diagnosis not listed above for which chronic immunoglobulin replacement therapy is a guideline-recommended therapeutic option<br>  Name of Guideline:_____<br>  Guideline Recommendation Strength:_____<br>• Patient has not tolerated, has had an adverse reaction to, and/or has a contraindication to Gamunex-C that is not anticipated with the chosen product (to include intolerance to increased volumes associated with subcutaneous delivery)<br>• Patient has not tolerated, has had an adverse reaction to, or has a contraindication to Cutaquig that is not anticipated with the chosen product (to include known or increased risk for IgA hypersensitivity, inability to accurately monitor blood sugars, and/or increased risk from a higher osmolality product)<br>• If immunoglobulin replacement therapy will be administered subcutaneously, and this is the first time this product will be used, provider has followed package label directions for converting from intravenous dose (by mass)<br>• Patient agrees to be monitored at indicated intervals to establish therapeutic immunoglobulin levels<br><br>Other Non-FDA-approved uses are NOT approved<br>Prior authorization does not expire. |
| **Newly Approved Drugs PAs** | |
| • belumosudil (Rezurock)<br><br>**Immunosuppressives** | Manual PA criteria apply to all new users of Rezurock<br><br>Manual PA criteria: Rezurock is approved if all criteria are met:<br>• Patient is12 years of age and older<br>• Rezurock is prescribed by or in consultation with a hematologist/oncologist<br>• Patient has chronic graft-versus-host disease (cGVHD) and has failed treatment with steroids alone and at least two prior lines of systemic therapy<br>• Female patients of childbearing age are not pregnant confirmed by (-) HCG<br>• Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment<br>• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.<br>• The diagnosis IS NOT listed above but IS cited in a nationally accredited guideline with a moderate strength or higher recommendation. If so, the guideline society is _____, the strength of recommendation is _____, and the diagnosis is: _____.<br><br>Non-FDA-approved uses are not approved except as noted above.<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| • belzutifan (Welireg)<br><br>**Oncological Agents** | Manual PA criteria apply to all new users of Welireg<br><br>Manual PA criteria: Welireg is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Welireg is prescribed by or in consultation with an oncologist<br>• The patient has von Hippel-Landau disease and requires therapy for associated renal cell carcinoma (RCC), CNS hemangioblastomas or pancreatic neuroendocrine tumors (pNET) not requiring surgery<br>• Patient does not have metastatic disease<br>• Female patients of childbearing age are not pregnant, confirmed by (-) HCG<br>• Female patients will not breast feed during treatment and for at least 3 weeks after the cessation of treatment<br>• Both male and female patients of childbearing potential agree to use effective non-hormonal contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male<br>• Male patients have been informed of the risk of infertility<br>• The diagnosis is NOT listed above, but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so the provider must list the diagnosis<br><br>Non-FDA-approved uses are not approved, other than noted above<br>Prior authorization does not expire. |
| • finerenone (Kerendia)<br><br>**Cardiovascular Agents: Miscellaneous** | Manual PA criteria apply to all new and current users of Kerendia.<br><br>Manual PA criteria: Kerendia is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Kerendia is prescribed by or in consultation with a nephrologist<br>• The patient has a diagnosis of type 2 diabetes mellitus (T2DM)<br>• The patient has documented diabetic kidney disease with albuminuria, defined as one of the following<br>  • An estimated glomerular filtration rate (eGFR) of 25-75 with albuminuria >300mg/g OR<br>  • eGFR 25-60 with albuminuria > 30mg/g plus diabetic retinopathy<br>• Patient has been taking max-dose ACE inhibitor or ARB for at least 4 weeks<br>• Patient tried DoDs preferred sodium-glucose-co-transporter 2 (SGLT-2) inhibitor empagliflozin (Jardiance)<br>• The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease<br>• Patient does not have uncontrolled hypertension (>170/110 mmHg) at initiation of Kerendia therapy<br>• Patient does not have renal artery stenosis<br>• Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc)<br>• Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception<br><br>Non-FDA approved uses are not approved including patients renal transplants<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| • mirabegron extended release granules for oral suspension (Myrbetriq Granules)<br><br>**Overactive bladder agents** | Manual PA criteria apply to all new users of Myrbetriq Granules<br><br>Note that the previous automation for Myrbetriq granules and tablets has been removed<br><br>Manual PA criteria: Myrbetriq Granules are approved if all criteria are met:<br>• Myrbetriq granules for oral suspension are prescribed by or in consultation with a urologist or nephrologist<br>• The prescription is written for neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele, and not for overactive bladder<br>• Provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization<br>• Patient has tried and failed or has a contraindication to oxybutynin<br>• Patient requires Myrbetriq granules for oral suspension for one of the following reasons:<br>  • The patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, etc) and not convenience. OR<br>  • The patient weighs less than 35 kg<br>• Provider acknowledges that Myrbetriq granules for suspension are not bioequivalent to and cannot be substituted on a mg to mg basis to the Myrbetriq tablets<br>• Provider acknowledges that Myrbetriq granules for suspension and the Myrbetriq tablets will not be combined to achieve a specific dose<br>• Provider acknowledges the detailed renal and hepatic dosing adjustments in the package labeling and agrees to consult this before prescribing the granules in these special populations<br><br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |
| • mobocertinib (Exkivity)<br><br>**Oncological Agents: Lung Cancer** | Manual PA criteria apply to all new users of Exkivity<br><br>Manual PA criteria: Exkivity is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Exkivity is prescribed by or in consultation with a hematologist/oncologist<br>• Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy<br>• The patient will be monitored for QTc prolongation, interstitial lung disease, pneumonitis, decreased cardiac function, and diarrhea<br>• If the patient develops diarrhea, he/she will be prescribed an anti-diarrheal agent<br>• Female patients of childbearing age are not pregnant, confirmed by (-) HCG<br>• Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment<br>• Both male and female patients of childbearing potential will use effective non-hormonal contraception during treatment and for one month after cessation of therapy if female, and for one week after cessation of therapy if male<br>• 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: _____.<br><br>Non-FDA-approved uses are not approved except as noted above.<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| • odevixibat (Bylvay)<br><br>**Metabolic agents-miscellaneous** | Manual PA criteria apply to all new and current users of Bylvay.<br><br>Manual PA criteria: Bylvay is approved if all criteria are met:<br>• Patient is 3 months of age or older and weighs 5 kg or greater<br>• Patient has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus<br>• The prescription is written by a pediatric gastroenterologist, or pediatric hepatology transplant specialist<br>• Patient has been evaluated for possible orthotopic liver transplant (OLT)<br>• Patient has previously tried and failed all of the following:<br>  • ursodiol<br>  • cholestyramine<br>  • rifampin<br>  • naltrexone<br>  • At least one antihistamine (e.g. Atarax, Benadryl, etc.)<br><br>Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), progressive familial intrahepatic cholestasis (PFIC2), Alagille syndrome, Biliary atresia are not approved.<br>Prior authorization expires after 6 months. Bylvay will be approved for an additional 6 months if the following criteria are met:<br><br>Renewal criteria (initial TRICARE PA approval is required for renewal) AND<br>• Patient must demonstrate significant improvement in pruritus symptoms. |
| • olanzapine/ samidorphan (Lybalvi)<br><br>**Antipsychotic Agents: Atypical** | Manual PA criteria apply to all new users of Lybalvi.<br><br>Manual PA criteria: Lybalvi is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Patient has a documented diagnosis of schizophrenia or bipolar 1 disorder<br>• Patient has tried for at least 6 months and had an adverse event to at least 2 antipsychotic agents<br>• Provider must indicate the drug, date of initiation, duration of therapy, and whether the patient had an adverse reaction or failure to therapy of other therapies tried<br>  • Drug: Date_____ Duration of therapy _____<br>  Adverse Reaction _____ Therapeutic Failure _____<br>  • Drug: Date_____ Duration of therapy _____<br>  Adverse Reaction _____ Therapeutic Failure _____<br><br>Non-FDA-approved uses are not approved including major depressive disorder, fibromyalgia, or other mood disorders.<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| • ruxolitinib 1.5% cream (Opzelura)<br><br>**Corticosteroids-Immune modulators: Atopic dermatitis** | Manual PA criteria apply to all new and current users of Opzelura.<br><br>Manual PA criteria: Opzelura is approved if all criteria are met:<br>• Patient is 12 years of age and older<br>• Opzelura is prescribed by a dermatologist, allergist, or immunologist<br>• The patient has mild to moderate uncontrolled atopic dermatitis<br>• The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories:<br>  • Topical Corticosteroids:<br>  – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream)<br>  – For patients 12 to 17 years of age: any topical corticosteroid<br>  AND<br>  • Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)<br>• The patient is not using other immuno-biologics (e.g.; Humira, Stelara etc) , other JAK inhibitors (e.g., Xeljanz, Olumiant, Rinvoq), or potent immunosuppressants such as azathioprine or cyclosporine<br><br>Non-FDA-approved uses are not approved.<br>Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely.<br><br>Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND<br>• The patient has had a positive response to therapy, e.g., an Investigator's Static Global Assessment (ISGA) score of clear (0) or almost clear<br>• The patient's disease severity has improved and stabilized to warrant continued therapy |
| • serdexmethylphenidate/ dexmethylphenidate (Azstarys)<br><br>**ADHD Agents: Stimulants** | Manual PA criteria apply to all new users of Azstarys<br><br>Manual PA Criteria: Azstarys is approved if all criteria are met:<br>• Patient is 6 years of age or older<br>• Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record<br>• Patient has tried for at least two months and failed, had an inadequate response, or has a contraindication to methylphenidate OROS (Concerta, generic) or other long-acting methylphenidate<br>• Patient has tried for at least two months and failed, had an inadequate response, or has a contraindication to amphetamine mixed salts XR (Adderall XR generic) or other long-acting amphetamine<br>• Patient has tried for at least two months and failed, had an inadequate response, or has a contraindication to another long-acting MPH (methylphenidate ER/CD/LA, Quillivant XR, Aptensio XR)<br>• Patient has tried, for at least two months, an immediate release formulation methylphenidate product in conjunction with generic Concerta or another long-acting methylphenidate<br>• Please explain why the patient needs Azstarys: *(fill-in blank question)*<br>Non-FDA-approved uses are NOT approved<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| **New PAs** | |
| • clemastine 0.5 mg/mL syrup<br><br>**Antihistamine-1: First Generation and Combinations** | Manual PA criteria applies to new and current users of clemastine syrup.<br><br>Note: clemastine tablets and other antihistamines are available without a PA; providers are encouraged to consider changing the prescription to one of the drugs listed: clemastine tablets or other antihistamines (i.e., chlorpheniramine, cyproheptadine, diphenhydramine or the 2nd generation antihistamines – loratadine, fexofenadine, cetirizine).<br><br>Manual PA Criteria: clemastine syrup is approved if all criteria are met:<br>• Provider is aware and acknowledges that clemastine tablets and other antihistamines are available to DoD beneficiaries without the need of prior authorization<br>• The provider must explain why the patient requires clemastine syrup and cannot take one of the cost effective formulary alternatives. (fill-in blank)<br><br>Non-FDA approved uses are NOT approved.<br>Prior Authorization does not expire. |
| • diclofenac potassium 25 mg tablet (Lofena)<br><br>**Pain Agents: NSAID** | Manual PA criteria applies to new and current users of diclofenac potassium 25 mg tablet.<br><br>Note: other strengths of diclofenac potassium, generic diclofenac sodium, and other formulary NSAIDs are available without a PA; providers are encouraged to consider changing the prescription to one of the alternatives listed.<br><br>Manual PA Criteria: diclofenac 25 mg tablet is approved if all criteria are met:<br>• Provider acknowledges that other strengths of diclofenac potassium, generic diclofenac sodium, or other formulary NSAIDs are available to DoD beneficiaries without the need of prior authorization<br>• The provider must explain why the patient requires diclofenac potassium 25 mg tablet and cannot take the cost-effective generic diclofenac potassium, generic diclofenac sodium, or other formulary NSAIDs (fill-in blank)<br><br>Non-FDA-approved uses are NOT approved.<br>Prior authorization does not expire. |
| • meclizine 50 mg tablet (Antivert)<br><br>**Anti-Emetic/Anti-Vertigo Agents** | Manual PA criteria applies to new and current users of meclizine 50 mg tablet (Antivert).<br><br>Note: meclizine 25 mg tablets are available without a PA; providers are encouraged to consider changing the prescription to meclizine 25 mg tablets.<br><br>Manual PA Criteria: meclizine 50 mg tablet (Antivert) is approved if all criteria are met:<br>• Provider is aware and acknowledges that meclizine 25 mg tablet is available to DoD beneficiaries without the need of prior authorization, and is encouraged to consider changing the prescription to the preferred meclizine 25 mg tablet<br>• The provider must explain why the patient requires meclizine 50 mg tablet (Antivert) and cannot take the cost-effective meclizine 25 mg tablet (fill-in blank)<br><br>Non-FDA-approved uses are NOT approved.<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| • niacin 500 mg tablet<br><br>**Antilipidemics-1** | Manual PA criteria applies to new and current users of Niacin 500 mg tablet.<br><br>Note: other formulations of niacin, including Niaspan and Niacor, are available without a PA; providers are encouraged to consider changing the prescription to another niacin formulation.<br><br>Manual PA Criteria: Niacin 500 mg tablet is approved if all criteria are met:<br>• Provider acknowledges that other formulations of niacin, including Niaspan and Niacor, are available to DoD beneficiaries without the need of prior authorization<br>• Patient has tried AND cannot take at least two other prescription or over-the-counter (OTC) niacin-containing products due to a significant allergy to an inactive ingredient (for example dyes, fillers, etc.) or due to significant adverse reactions to the other niacin-containing products<br>• The provider must explain what differences are in the inactive ingredient(s) which leads to an allergy to the other niacin-containing products or provide what serious adverse reactions to the other niacin-containing products are of concern (fill-in blank)<br><br>Non-FDA-approved uses are NOT approved.<br>Prior authorization does not expire. |
| • prenatal MVI (Neonatal Complete)<br><br>**Vitamins: Prenatal** | Manual PA criteria applies to new and current users of prenatal MVI (Neonatal Complete).<br><br>Note: Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, **and Neonatal Complete** and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant.<br><br>Manual PA Criteria: Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, or **Neonatal Complete** is approved if all criteria are met:<br>• Provider acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, and Neonatal Complete and are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant. Please consider changing the prescription to one of these agents<br>• The provider must explain why the patient requires Neonatal Complete and cannot take one of the cost effective formulary alternatives. (fill-in blank)<br><br>Non-FDA approved uses are NOT approved.<br>Prior Authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| • sertraline 150 mg and 200 mg capsules<br><br>**Antidepressant and Non-Opioid Pain Syndrome Agents: SSRIs** | Manual PA criteria applies to new and current users of sertraline 150 mg and 200 mg capsules.<br><br>Note: other strengths of sertraline and other formulary SSRIs are available without a PA; providers are encouraged to consider changing the prescription to another strength of sertraline or another formulary SSRI.<br><br>Manual PA Criteria: Sertraline 150 mg or 200 mg capsules are approved if all criteria are met:<br>• Provider acknowledges that other strengths of sertraline and other formulary SSRIs are available to DoD beneficiaries without the need of prior authorization<br>• The provider must explain why the patient cannot take a combination of lower sertraline strengths to achieve the desired dose: (fill-in blank)<br><br>Non-FDA-approved uses are NOT approved.<br>Prior authorization does not expire. |
| • tizanidine capsules (Zanaflex)<br><br>**Skeletal Muscle Relaxants and Combinations** | Manual PA criteria applies to new users of tizanidine capsules (Zanaflex).<br><br>Note: tizanidine tablets and other formulary muscle relaxants are available without a PA; providers are encouraged to consider changing the prescription to one the tizanidine tablets or another formulary muscle relaxant.<br><br>Manual PA Criteria: tizanidine capsules (Zanaflex) is approved if all criteria are met:<br>• Provider is aware and acknowledges that tizanidine tablets and other formulary muscle relaxants are available to DoD beneficiaries without the need of prior authorization<br>• The provider must explain why the patient requires tizanidine capsules and cannot take tizanidine tablets or one of the other cost effective formulary alternatives. (fill-in blank)<br><br>Non-FDA approved uses are NOT approved.<br>Prior Authorization does not expire. |
| **Updated PAs** | |

## Appendix C—Table of Prior Authorization (PA) Criteria

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| • evolocumab (Repatha)<br><br>**Antilipidemics 1' Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors** | **Changes from November 2021 meeting are in BOLD and strikethrough**<br>Manual PA criteria apply to all new users of evolocumab (Repatha).<br><br>Manual PA criteria—Evolocumab is approved if:<br>• A cardiologist, lipidologist, or endocrinologist initially prescribes the drug.<br>• The patient is at least 18 years of age for ~~**HoFH and**~~ clinical ASCVD. For **HeFH** HoFH, patients as young as **10 years**~~**13 years**~~ of age can receive the drug.<br>• The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol.<br>• The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.<br>• The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL **>70 mg/dL** >~~**100 mg/d**~~L despite statin therapy at maximally-tolerated doses, according to the criteria below:<br>  • The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR<br>  • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR<br>  • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants), AND<br>  • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.<br>• For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:<br>  • Intolerance<br>  ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND<br>  ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR<br>  ▪ The patient has had a creatinine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use.<br>  • Contraindication to statin<br>  ▪ The contraindication must be defined.<br>• Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD.<br>• Repatha is not approved for patients who are pregnant or lactating.<br>• The dosage must be documented on the PA Form as either:<br>  • 140 mg every 2 weeks, or<br>  • 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose.<br>• PA expires in one year.<br>• PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, and lipidologist. Continued use of Repatha will be approved for the following:<br>  • The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND<br>  • The patient has documented adherence |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| • zanubrutinib (Brukinsa)<br><br>**Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors** | **Updates from the November 2021 Meeting are in bold.**<br>Manual PA criteria apply to all new users of zanubrutinib (Brukinsa).<br><br>Manual PA Criteria: Brukinsa is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Prescribed by or in consultation with a hematologist/oncologist<br>• Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL)<br>• **Patient has Waldenström's macroglobulinemia (WM), a rare non-Hodgkin lymphoma**<br>• **Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen**<br>• Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias<br>• Patient will use sun protection in sun-exposed areas<br>• Female patients of childbearing age and are not pregnant confirmed by (-) HCG.<br>• Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment<br>• Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment<br>• 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: _____.<br>Other non-FDA-approved uses are not approved.<br>Prior Authorization does not expire. |
| • ivosidenib (Tibsovo)<br><br>**Oncological Agents: Acute Myelogenous Leukemia** | **Updates from the November 2021 Meeting are in bold.**<br><br>Manual PA criteria apply to all new users of ivosidenib (Tibsovo).<br><br>Manual PA Criteria: Tibsovo is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Patient has a diagnosis of:<br>▪ Relapsed/refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by a FDA-approved test OR<br>▪ Patient has newly diagnosed AML and is aged 75 years of age or older OR has comorbidities that preclude use of intensive induction chemotherapy with a susceptible IDH1 mutation as detected by a FDA-approved test OR<br>▪ **Patient has previously treated, locally advanced, or metastatic cholangiocarcinoma with an IDH1 mutation as detected by a FDA-approved test OR**<br>▪ 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: _____.<br>• The patient will be monitored for differentiation syndrome<br>• The patient will be monitored for Guillain-Barre syndrome<br>• Prescribed by or in consultation with a hematologist/oncologist<br>Other Non-FDA-approved uses are not approved.<br>Prior Authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

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| • mepolizumab (Nucala)<br><br>**Respiratory Interleukins** | **Updates from the November 2021 Meeting are in bold.**<br>Manual PA is required for all new users of mepolizumab (Nucala).<br><br>Manual PA Criteria: Nucala coverage will be approved for initial therapy for 12 months if all criteria are met:<br><br>*For eosinophilic asthma:*<br>• The patient has a diagnosis of severe persistent eosinophilic asthma<br>• The drug is prescribed by an allergist, immunologist, or pulmonologist<br>• The patient must have an eosinophilic phenotype asthma as defined as either<br>▪ Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR<br>▪ Eosinophils ≥ 300 cells/mcL<br>• The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following:<br>▪ Hospitalization for asthma in past year OR<br>▪ Two courses of oral corticosteroids in past year OR<br>▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids<br>• The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid:<br>▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi),<br>▪ Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or<br>▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo)<br>*For eosinophilic granulomatosis with polyangiitis (EGPA):*<br>• The patient has a diagnosis of EGPA<br>• The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist<br>• The patient is 18 years of age or older<br>• A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication<br>*For Hypereosinophilic Syndrome (HES):*<br>• The patient has a diagnosis of HES<br>• The patient has had eosinophil levels > 1,000 cells/mcL in the past year<br>• The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist<br>• The patient is 12 years of age or older<br>• A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the HES indication<br>***For chronic rhinosinusitis with nasal polyps (CRSwNP):***<br>• **The patient has a diagnosis of CRSwNP**<br>• **Nucala is being prescribed as add-on maintenance therapy due to patient having inadequate response to nasal corticosteroid**<br>AND<br>• For all indications, the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], dupilumab [Dupixent] or omalizumab [Xolair])<br><br>Non-FDA-approved uses are not approved<br>Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| | Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND<br>• Eosinophilic asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use<br>• EGPA, HES: The patient's disease severity has improved and stabilized to warrant continued therapy<br>• Chronic rhinosinusitis with nasal polyposis (CRSwNP): There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| • sodium oxybate/calcium/ magnesium/potassium oral solution (Xywav)<br><br>**Sleep Disorders: Wakefulness Promoting Agents** | **Updates from the November 2021 Meeting are in bold.**<br>Manual PA criteria apply to all new users of sodium oxybate/calcium/magnesium/potassium oral solution (Xywav).<br><br>Manual PA Criteria: Coverage of Xywav is approved if all criteria are met:<br>• Patient is 18 years of age or older AND<br>• The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND<br>• Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND<br>• Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy<br>▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR<br>• **Xywav is prescribed for idiopathic hypersomnia OR**<br>• Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy &<br>▪ The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND<br>▪ Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) OR<br>• Patient is a child 7 years of age or older AND<br>• The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND<br>• Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND<br>• Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy.<br>▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR<br>• Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND<br>▪ The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND<br>• Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders)<br>Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy<br><br>Prior Authorization expires after 1 year.<br>Renewal PA criteria; Renewal not allowed. A new prescription will require a new PA to be submitted |

## Appendix C—Table of Prior Authorization (PA) Criteria

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| • adalimumab (Humira)<br><br>**Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors** | **<u>Updates from the November 2021 meeting are in bold</u>.**<br><br>Manual PA criteria applies to all new users of adalimumab (Humira).<br><br><u>Manual PA Criteria</u>: Humira is approved if all criteria are met:<br><br>Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication:<br>• Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS)<br>• Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy<br>• Moderate to severely active Crohn's disease (CD)<br>• Moderate to severely active ulcerative colitis (UC)<br>• Moderate to severe hidradenitis suppurativa (HS)<br>• Non-infectious intermediate, posterior, and panuveitis<br>• Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation<br>• Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids<br>OR<br>Coverage approved for pediatric patients 12-17 years of age with diagnosis of:<br>• Moderate to severe hidradenitis suppurativa (HS)<br>OR<br>Coverage approved for pediatric patients 6-17 years of age with diagnosis of:<br>• Moderate to severely active Crohn's disease (CD)<br>OR<br>Coverage approved for pediatric patients 5-17 years of age with diagnosis of:<br>• Moderately to severely active ulcerative colitis (UC)<br>OR<br>Coverage approved for pediatric patients 4-17 years of age with diagnosis of:<br>• Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate<br>OR<br>Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication:<br>• Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA)<br>• Non-infectious intermediate, posterior, and panuveitis<br>Below criteria applies to AS indication only:<br>• Patient has had an inadequate response to at least two NSAIDs over a period of at least two months<br>Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease, ankylosing spondylitis (AS), and pyoderma gangrenosum (PG), **psoriatic arthritis (PsA)** and applies to pediatric patients with plaque psoriasis or Crohn's disease:<br>• Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])<br>Below criteria applies to all patients (regardless of age):<br>• Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this?<br>• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)<br>Coverage for non-FDA-approved uses not listed above. Please provide a diagnosis and rationale for treatment. Supportive evidence will be considered.<br><br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
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| | Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER). |
| • baricitinib (Olumiant)<br><br>**Targeted Immunomodulatory Biologics (TIBs): Miscellaneous** | **Updates from the November 2021 meeting are in bold.**<br><br>Note that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis.<br><br>Step therapy and manual PA criteria apply to all new users of baricitinib (Olumiant).<br><br>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.<br><br>AND<br><br>Manual PA Criteria:<br>If automated criteria are not met, coverage for Olumiant is approved if all criteria are met:<br>• Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND:<br>• The patient had an inadequate response to Humira OR<br>• The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent<br>OR<br>• The patient has a contraindication to Humira<br>• Patient is 18 years of age or older<br>• Patient has a diagnosis of:<br>o Moderate to severe active rheumatoid arthritis (RA)<br>• 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.)<br>• The patient will not be receiving other biologic DMARDs or potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly<br>• Patient has no history of thromboembolic disease<br>• **Provider is aware of the FDA safety alerts AND Boxed Warnings**<br>• Patient hemoglobin (Hgb) must be > 9 g/dL<br>• Patient absolute neutrophil count (ANC) < 1,000/$mm^3$<br>• Patient absolute lymphocyte count (ALC) < 500/ $mm^3$<br>• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)<br>• May not be used concomitantly with other TIBs agents except for Otezla<br><br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |

## Appendix C—Table of Prior Authorization (PA) Criteria

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| • upadacitinib (Rinvoq)<br><br>**Targeted Immunomodulatory Biologics (TIBs): Miscellaneous** | **Updates from the November 2021 meeting are in bold.**<br><br>Note that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis.<br><br>Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq).<br><br>Manual PA Criteria: Rinvoq is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Patient has diagnosis of active rheumatoid arthritis<br>• Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs)<br>• Patient has had an inadequate response to Humira OR<br>• Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR<br>• Patient has a contraindication to Humira AND<br>• Patient has had an inadequate response to Xeljanz or Olumiant OR<br>• Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with the requested agent OR<br>• Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq AND<br>• Patient has no evidence of active TB infection within the past 12 months<br>• Patient has no history of venous thromboembolic (VTE) disease<br>• **Provider is aware of the FDA safety alerts AND Boxed Warnings**<br>• Patient has no evidence of neutropenia (ANC < 1000)<br>• Patient has no evidence of lymphocytopenia (ALC < 500)<br>• Patient has no evidence of anemia (Hgb < 8)<br>• Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine).<br><br>Non-FDA-approved uses are not approved.<br>PA does not expire. |

## Appendix D—Table of Quantity Limits (QL)

| Drug / Drug Class | Quantity Limits |
|---|---|
| • Dexcom G6<br>• Abbott FreeStyle Libre 2<br><br>**Continuous Glucose Monitoring (CGM) Systems** | **Dexcom G6**<br>▪ Sensors<br>o Retail: 3 sensors in 30 days<br>o MTF/Mail: 9 sensors in 90 days<br>▪ Transmitters: Retail/MTF/Mail: 1 transmitter in 90 days<br>▪ Receivers: Retail/MTF/Mail: 1 receiver in 365 days<br><br>**Abbott FreeStyle Libre 2**<br>▪ Sensors<br>o Retail: 2 sensors in 28 days<br>o MTF/Mail: 6 sensors in 84 days<br>▪ Readers: Retail/MTF/Mail: 1 reader in 365 days |
| • belumosudil (Rezurock)<br><br>**Immunosuppressive** | ▪ Retail/MTF/Mail: 30 day supply |
| • mobocertinib (Exkivity)<br><br>**Oncological Agents: Lung Cancer** | ▪ Retail/MTF/Mail: 30 day supply |
| • belzutifan (Welireg)<br><br>**Oncological Agents** | ▪ Retail/MTF/Mail: 30 day supply |
| • odevixibat (Bylvay)<br><br>**Metabolic Agents-Miscellaneous** | ▪ Retail/MTF/Mail: 30 day supply |
| • naloxone nasal 8 mg (Kloxxado)<br><br>**Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists** | ▪ Retail/MTF/Mail: 2 cartons (2 nasal spray devices per carton) per fill |
| • mirabegron extended release granules for oral suspension (Myrbetriq Granules)<br><br>**Overactive bladder agents** | ▪ Retail/MTF/Mail: 2 bottles per fill |
| • ruxolitinib 1.5% cream (Opzelura)<br><br>**Corticosteroids-Immune modulators: Atopic dermatitis** | ▪ Retail: 30 day supply<br>▪ MTF/Mail: 60 day supply |
| • ibrexafungerp (Brexafemme)<br><br>**Antifungals** | ▪ Retail/MTF/Mail: 1 blister (4 tablets) per fill |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| belumosudil (Rezurok)<br><br>Immuno-suppressive | • abatacept (Orencia)<br>• etanercept (Enbrel)<br>• ibrutinib (Imbruvica) | • 200 mg oral tabs<br>• Take 1 tab once daily with food | Chronic graft-versus-host disease | • Infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension | • Rezurock is a first-in-class ROCK2 inhibitor indicated for chronic Graft vs Host Disease<br>• Based on pivotal trial structure, efficacy only established after the failure of steroids and 2 systemic therapies<br>• Clinically meaningful durability (time before death or new treatment initiation)<br>• High rate of adverse events – especially infections – and discontinuations<br>• Rezurock is another treatment option for cGVHD | • UF<br>• Do not add to EMMI list |
| belzutifan (Welireg)<br><br>Oncological Agents | • pazopanib (Votrient) | • 40 mg oral tabs<br>• Recommended dosing = 120 mg once daily | Treatment of adults with von- Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery | • Common ADRS: decreased hemoglobin, fatigue, increased creatinine, nausea, increased glucose<br>• Warnings: severe anemia, severe hypoxia, may cause fetal harm | • VHL disease causes cancer in kidneys, pancreas, and CNS<br>• Welireg is the 1st hypoxia-inducible factor 2 alpha (HIF-2α) inhibitor approved for VHL<br>• Welireg reduces transcription and expression of HIF-2 α target genes associated with cellular proliferation, angiogenesis and tumor growth<br>• Approval based on one single-arm, open label unpublished trial in 61 patients. Results showed an overall response rate of 49% for renal cell carcinoma; all responses were partial responses (no complete responses)<br>• NCCN kidney cancer guidelines recommend Welireg as a preferred regimen for VHL disease as a category 2A recommendation<br>• FDA reviewers considered Welireg to have a "good response rate with what appears to be a good duration of response and an acceptable safety profile" | • UF<br>• Do not add to EMMI list |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| dihydro-ergotamine mesylate nasal spray (Trudhesa)<br><br>Migraine Agents | • DHE nasal spray generic<br>• Migranal<br>• ergotamine/ caffeine | • Dosing: One spray (0.725 mg) into each nostril (Total dose is1.45 mg) | Acute treatment of migraine with/without aura in adults | • Same warning, C/I, precautions, drug interactions as Migranal | • Trudhesa is another DHE nasal spray<br>• No new studies conducted; efficacy based on bioavailability to DHE nasal spray<br>• Maintains all of the same warnings, contraindications, drug interactions, and ADRs as generic DHA nasal spray<br>• Trudhesa provides little to no clinical benefit relative to existing formulary agents | • Tier 4/Not covered |
| finerenone (Kerendia)<br><br>Cardiovascular Agents: Miscellaneous | • empagliflozin | • Oral Tablets: 10 mg, 20mg<br>• eGFR 25-59: 10 mg<br>• eGFR > 60: 20 mg | Reduce the risk of sustained eGFR decline in adult patients with chronic kidney disease associated with type 2 diabetes (T2DM) | • Common ADRs: hyperkalemia, hypotension, and hyponatremia<br>• Warnings: Hyperkalemia - Patients with decreased kidney function and higher baseline potassium levels are at increased risk<br>• Monitor serum potassium levels and adjust dose as needed | • Kerendia is the first non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline in adult patients with chronic kidney disease associated with T2DM<br>• Kerendia was evaluated in two studies (Fidelio-DKD and Figaro-DKD) compared to placebo<br>• Reduction of GFR was statistically significant for finerenone vs placebo however clinical significance is unclear<br>• Currently, there are no head-to-head studies of Kerendia with other agents such as MRAs or SGLT-2 inhibitors<br>• Most common ADRs include hyperkalemia, hypotension, hyponatremia<br>• Kerendia offers another option in the treatment of CKD in T2D patients however place in therapy is currently unclear | • NF<br>• Do not add to EMMI list |
| ibrexafungerp (Brexafemme)<br><br>Antifungals | • fluconazole tablets<br>• OTC clotrimazole cream<br>• OTC miconazole cream | • Packaging: 4 x 150 mg oral tablets<br>• Two 150 mg tablets taken every 12 hours x 1 day (4 doses total) with or without food<br>• If used with strong CYP3A inhibitor: 1x 150 mg tablet every 12 hours x 1 day | For the treatment of vulvovaginal candidiasis (VVC) in post-menarchal females | Most commonly reported ADRs:<br>• diarrhea (16.7%)<br>• nausea (11.7%)<br>• abdominal pain (11.4%)<br>• dizziness (3.3%)<br>• vomiting (2%) | • First triterpenoid antifungal drug for VVC tx<br>• Statistically significant results in in reaching key efficacy endpoints; well-tolerated compared to placebo<br>• In a non-pivotal phase IIb trial, Brexafemme and fluconazole appeared equally efficacious<br>• Guidelines strongly recommend topical antifungals and oral fluconazole for the treatment of VVC; Brexafemme not yet addressed<br>• Disadvantages compared to fluconazole: greater pill burden; not available as a single dose | • NF<br>• Do not add to EMMI list |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| | | | | | • Further research is needed to determine if there are any comparative efficacy or safety advantages over azole antifungals<br>• Despite Brexafemme's novel mechanism of action and fungicidal activity, there do not appear to be any compelling clinical advantages over existing formulary options at this time | |
| lorazepam ER capsule (Loreev XR)<br><br>Antianxiety Agents: Benzo-diazepines | • lorazepam tablets<br>• alprazolam IR<br>• alprazolam ER | • Formulations: 1 mg, 2 mg, and 3 mg ER capsules | Treatment of anxiety disorders in adults who are receiving stable, evenly divided, TID dosing with lorazepam tablets | • Same as generic lorazepam | • Loreev XR is a new extended-release formulation of lorazepam<br>• Lorazepam (Ativan) originally approved in 1977<br>• No new studies<br>• Advantage of Ativan is its short-acting duration<br>• Provides no clinical benefit relative to existing formulary agents | • Tier 4/Not covered |
| mirabegron extended release granules for oral suspension (Myrbetriq Granules)<br><br>Overactive Bladder Agents | • oxybutynin syrup<br>• Vesicare LS<br>• Toviaz | • Granules for ER oral suspension<br>• For patients < 35 kg: doses of 24 - 64 mg/day<br>• For patients ≥ 35 kg: doses up to 80 mg/day<br>• Renal and hepatic dose adjustments<br>• Tablets and granules not substitutable | For treatment of neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 3 years old | • Most commonly reported adverse reactions (≥ 3%): UTI, headache, nasopharyngitis, constipation, | • New formulation of mirabegron for use in NDO patients ≥ 3 years old<br>• 3rd pharmacy-benefit drug approved for NDO, 1st β-3 adrenergic agonist for NDO<br>• Convenient once daily dosing compared to up to three times a day dosing with oxybutynin syrup<br>• Guidelines do not yet address the role of Myrbetriq Granules; they strongly encourage the use of antimuscarinic medications for NDO<br>• Pivotal trial was open-label and did not directly compare Myrbetriq Granules to other NDO drugs, although indirect comparison suggests that Myrbetriq Granules may be more effective<br>• Short shelf-life after reconstitution (28 days) is a disadvantage compared to other available agents<br>• Myrbetriq granules are another option for the treatment of NDO in pediatric patients; it's place in therapy is still to be determined | • NF<br>• Add to EMMI list |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| mobocertinib (Exkivity)<br><br>Oncological Agents: Lung Cancer | • amvantinib (Rybrevant) – medical benefit agent | • 40 mg caps<br>• Dosing: 4 caps once daily with or without food | NSCLC with EGFR exon 20 mutation | • Most common (>20%) ADRs: diarrhea, rash, nausea, stomatitis, vomiting, decreased appetite, paronychia, fatigue, dry skin, and musculoskeletal pain<br>• Most common (≥2%) Grade 3/4 lab abnormalities: decreased lymphocytes, potassium, and magnesium; increased amylase, lipase, and creatinine; anemia | • Exkivity is FDA-approved to treat adults with EGFR Exon20 insertion mutated Non-Small Cell Lung Cancer (NSCLC)<br>• While it is the first small molecule inhibitor of EGFR with an Exon 20 insertion, it is not the only agent recommended by guidelines to treat this mutation.<br>• Exkivity received accelerated approval based on overall response rate (ORR) and duration of response (DoR) in setting of a difficult-to-treat disease state but no long term survival data has been published<br>• Exkivity is poorly tolerated with ~40% of population requiring dose-reduction or discontinuation.<br>• Exkivity is an important addition to the treatment of EGFR Exon 20 insertion-mutated NSCLC able to be sequenced with its comparator | • UF<br>• Do not add to EMMI list |
| naloxone nasal 8 mg (Kloxxado)<br><br>Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists | • naloxone nasal 4 mg/o.1 mL (Narcan)<br>• naloxone autoinjector (Evzio) - discontinued | • Nasal Spray: 8 mg of naloxone hydrochloride in 0.1mL<br>• 2 vials per package<br>• 1 spray (8mg) intranasally into 1 nostril<br>• May repeat every 2-3 minutes prn until EMS arrival | Emergency treatment of known or suspected opioid overdose | • Abdominal pain, asthenia, dizziness, headache, nasal irritation, precipitation of severe opioid withdrawal, risk of recurrent respiratory and CNS depression | • Kloxxado is a new formulation of naloxone nasal spray for acute opioid overdose<br>• First 8 mg ready to use nasal spray (vs standard Narcan 4 mg)<br>• Both Narcan and Kloxxado have same indication<br>• No new clinical studies or administration studies to demonstrate efficacy, tolerability, or superiority to Narcan<br>• Two small pharmacokinetic studies available with bioavailability of Kloxxado vs IM and IV naloxone<br>• Kloxxado provides another nasally administered naloxone that is more concentrated for treatment of opioid overdose | • UF<br>• Do not add to EMMI list |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| odevixibat (Bylvay)<br><br>Metabolic Agents-Miscellaneous | • ursodiol<br>• cholestyramine<br>• naltrexone<br>• rifampin<br>• phenobarbital<br>• antihistamines | • Oral Pellets: 200 mcg, 600 mcg<br>• Oral Capsules: 400 mcg, 1200 mcg<br>• 40 mcg/kg once daily in the morning with a meal.<br>• Can be increased in 40 mcg/kg increments up to 120 mcg/kg once daily after 3 months of minimal improvement.<br>• Do not exceed 6 mg/day | Pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC) | • Liver enzyme elevation<br>• Diarrhea<br>• Fat-soluble vitamin deficiency | • Bylvay is a new ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus secondary to PFIC in patients 3 months or older<br>• May not be effective in PFIC Type 2 patients with ABCB11 variants that result in non-functional or absent BSEP-3 protein<br>• Guidelines recommend initial treatment with ursodeoxycholic acid, followed by cholestyramine as second line alternative<br>• Evaluated in one small (n=62), unpublished study compared to placebo (long term efficacy and safety study ongoing)<br>• Bylvay achieved little to no scratching in a significantly greater proportion of patients compared to placebo (30-35% vs 13%)<br>• Only 1/3 of Bylvay treated patients achieved primary endpoint<br>• Greater difference seen using 40 mcg/kg/day dosing<br>• Higher dosing did not achieve greater effectiveness<br>• Most common AEs (incidence ≥ 2%) include liver enzyme elevation, diarrhea, vomiting, abdominal pain, fat soluble vitamin deficiencies<br>• 14.2% (n=6) of Bylvay-treated patients dropped out due to lack of efficacy compared to 25% (n=5) with placebo<br>• Bylvay has only been studied and approved to treat pruritus related to PFIC, cannot validate efficacy of treating underlying disease process<br>• Bylvay provides an additional treatment option for pruritus secondary to PFIC, however place in therapy is unclear | • NF<br>• Do not add to EMMI list |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| olanzapine/ samidorphan (Lybalvi)<br><br>Antipsychotic Agents: Atypical | • olanzapine<br>• olanzapine/ fluoxetine<br>• aripiprazole<br>• ziprasidone | • olanzapine/ samidorphan 5mg/10mg, 10mg/10mg, 15mg/10mg, or 20mg/10mg<br>• Once daily tablet with or without food | • Schizophrenia in adults<br>• Bipolar I in adults; Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate; Maintenance monotherapy treatment | Schizophrenia: weight gain, somnolence, dry mouth, headache<br><br>Bipolar I disorder, manic, or mixed episodes: asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor | • Lybalvi is another formulation of olanzapine combined with an opioid antagonist (samidorphan)<br>• The addition of samidorphan is designed to mitigate weight gain associated with olanzapine<br>• Efficacy and safety of Lybalvi in schizophrenia was established in 2 placebo-controlled studies with olanzapine as an active comparator. Similar efficacy between Lybalvi and olanzapine was demonstrated, with both superior to placebo.<br>• In one study, less weight gain was seen with Lybalvi vs. olanzapine however, the olanzapine-subtracted difference in weight gain was -2.4%, which equates to a difference of ~5-pounds.<br>• Differences with Lybalvi vs. olanzapine on related metabolic parameters have not been adequately studied<br>• No new bipolar studies were conducted<br>• All of the same warnings and contraindications of olanzapine exist, with the addition of potential opioid withdrawal or overdose when using opioid analgesics.<br>• While offering a unique combination, other atypical antipsychotics (AAP) have less propensity for weight gain (e.g. aripiprazole, ziprasidone) compared to olanzapine. The addition of metformin has also been studied in the setting of minimizing AAP weight gain.<br>• Lybalvi provides no compelling advantage over existing formulary agents. | • NF<br>• Do not add to EMMI list |

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

| Generic (Trade) Name UF Class | Comparators | Dosage Form/ Dosing | Indications | Adverse Events (AEs) | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| ruxolitinib 1.5% cream (Opzelura)<br><br>Corticosteroids-Immune Modulators: Atopic Dermatitis | • tacrolimus (Protopic) 0.1% ointment<br>• pimecrolimus (Elidel) 1% cream<br>• crisaborole (Eucrisa) 2% ointment | • 1.5% Cream in 60 gm tube<br>• Dosing: AAA twice daily up to 20% BSA no more than 60 gm/week up to 8 weeks | Non-immunocom-promised patients ≥ 12 years or older for the topical short-term and non-continuous treatment of mild-moderate atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable | nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count elevation, urticaria, folliculitis, tonsillitis, rhinorrhea | • Opzelura is a new formulation of ruxolitinib in a topical cream indicated for mild to moderate atopic dermatitis<br>• Opzelura offers clinically significant improvements in patients with chronic atopic dermatitis<br>• By indirect comparison, Opzelura appears to offer non-inferior benefit to moderate-strength topical corticosteroids<br>• As a JAK-inhibitor, Opzelura risks numerous serious side-effects. However, because of its topical formulation, there is limited systemic absorption.<br>• Opzelura is well-tolerated<br>• Opzelura is another treatment option for mild to moderate atopic dermatitis that has failed earlier-line treatments | • NF<br>• Add to EMMI list |
| serdexmethyl-phenidate/ dexmethyl-phenidate (Azstarys)<br><br>ADHD Agents: Stimulants | • Methylphenidate (MPH) products and generics (Focalin XR, Aptensio XR, Concerta, Jornay PM, Metadate CD/ER, Methylin ER, Ritalin LA/SR, Quillichew ER, Qullivant XR, Cotempla XR-ODT) | • Oral capsules (26.1 mg/5.2 mg, 39.2 mg/7.8 mg, and 52.3 mg/10.4 mg)<br>• 6 to 12 years: start 39.2 mg/7.8 mg QAM, may increase to 52.3 mg/10.4 mg or decrease to 26.1 mg/5.2 mg after one week (max 52.3 mg/10.4 mg once per day)<br>• 13 to 17 years: start 39.2 mg/7.8 mg QAM, increase to 52.3 mg/10.4 mg after one week | Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older | Most common (> 5% and 2x the rate of placebo): decreased appetite, insomnia, nausea vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased | • Azstarys is the 13th marketed long-acting methylphenidate (MPH) product approved for the treatment for ADHD<br>• Contains the combination of a prodrug serdexmethylphenidate and dexmethylphenidate; classified as a C-II like other stimulants with similar side effects and warnings<br>• Approval was granted via the 505(b)(2) pathway using pharmacokinetic bridging between Azstarys and dexmethylphenidate for patients 13 to 17 years of age<br>• One 3-week study conducted in patients aged 6 to 12 years showed a statistically significant a mean reduction from baseline in the SKAMP-Combined score, averaged across the test day, compared to placebo<br>• Based on limited studies, duration of action is unclear<br>• Provides no compelling clinical advantage over existing formulary agents | • UF<br>• Do not add to EMMI list |

## Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the November 2021 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 2021 | **Newly Approved Drugs per 32 CFR 199.21(g)(5)**<br>**Designated NF:**<br>*No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:*<br>• mirabegron granules for oral suspension (Myrbetriq Granules)<br><br>*No reason to exempt from NF-2-Mail requirement, similar agents are already on list, pending availability at mail, and pending final cost:*<br>• ruxolitinib 1.5% cream (Opzelura)<br><br>**Line Extensions**<br>**Designated UF**<br>*Similar/parent agent already on list (all new strengths or dosage forms):*<br>• dupilumab pen (Dupixent)<br>• levothyroxine sodium (Tirosint-Sol) | **SCIG**<br>*Clinical considerations:*<br>• Gammaked, Gamunex, Gammagard<br>• Cuvitru, Cutaquig, Hyqvia, Hizentra, Xembify<br><br>**Continuous Glucose Monitoring (CGM) Systems UF**<br>*Do not add to EMMPI Program due to no advantage to the government to add:*<br>• Dexcom G6<br>• Abbott FreeStyle Libre 2<br><br>**Newly Approved Drugs per 32 CFR 199.21(g)(5)**<br>**Designated UF:**<br>*Acute use or limited duration and drugs in class not currently represented on EMMPI List:*<br>• naloxone nasal spray (Kloxxado)<br><br>*Not yet clear if feasible to provide through mail:*<br>• belumosudil (Rezurock)<br>• mobocertinib (Exkivity)<br>• belzutifan (Welireg)<br><br>*C-II stimulant exception/existing exclusion applies (operational issues):*<br>• serdexmethylphenidate/dexmethylphenidate (Azstarys)<br><br>**Designated NF:**<br>*Acute use or limited duration and drugs in class not currently represented on EMMPI List/comparable pricing at mail order vs MTFs or retail:*<br>• ibrexafungerp (Brexafemme)<br><br>*Antipsychotics exception/existing exclusion applies:*<br>• olanzapine/samidorphan (Lybalvi)<br><br>*Exception due to comparable pricing at mail order vs MTFs or retail:*<br>• finerenone (Kerendia) |

## Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the November 2021 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) |
|---|---|---|
| | | *Not yet clear if feasible to provide through mail order and similar pricing at mail order vs MTFs or retail:*<br>• odevixibat (Bylvay) |

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

| Date | DoD PEC Drug Class | Type of Action | BCF/ECF Medications<br><br>MTFs must have BCF meds on formulary | UF Medications<br><br>MTFs may have on formulary | Nonformulary Medications<br><br>MTFs may not have on formulary | Decision Date / Implement Date | PA and QL Issues | Comments |
|---|---|---|---|---|---|---|---|---|
| Nov 2021 | **Continuous Glucose Monitoring Systems** | UF Class Review<br><br>Class not previously reviewed | **Tier 4/Not Covered Medications**<br><br>**MTFs <u>must not</u> have on formulary**<br>**Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies**<br><br>▪ None | | | Pending signing of the minutes /60 days<br><br>The effective date is April 20, 2022 | ▪ All new and current users are subject to PA criteria.<br>▪ Quantity limits apply. | ▪ See Appendices C and D for PA and QL criteria. |
| | | | ▪ None Note a CGM was not added to the BCF | ▪ Dexcom G6<br>▪ Abbott FreeStyle Libre 2 | ▪ None | | | |
| Nov 2021 | **Subcutaneous Immuno-globulins (SCIG)** | UF Class Review<br><br>Class not previously reviewed | **Tier 4/Not Covered Medications**<br><br>**MTFs <u>must not</u> have on formulary**<br>**Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies**<br><br>▪ None | | | Pending signing of the minutes / 90 days<br><br>The effective date is May 18, 2022 | ▪ Manual PA criteria applies to all new users of Gammagard, Gammaked, Xembify, Hizentra, Cuvitru and Hyqvia | ▪ Step therapy now applies – a trial of Cutaquig or Gamunex-C is required in all new users of a SCIG<br>▪ Tier 1 copay applies for Cutaquig at the Mail Order and Retail POS<br>▪ See Appendix C for full PA criteria. |
| | | | ▪ None. Note that a SCIG was not selected for the BCF. | **UF step-preferred**<br>▪ Cutaquig<br>▪ Gamunex-C<br><br>**UF non-step-preferred**<br>▪ Gammagard Liquid<br>▪ Gammaked<br>▪ Cuvitru<br>▪ Hizentra<br>▪ Hyqvia<br>▪ Xembify | ▪ None | | | |

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

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

| P&T Committee Meeting Date | Drug Class | Tier 4/Not Covered Product | Formulary Alternatives | Implementation |
|---|---|---|---|---|
| Nov 2021 | Antianxiety Agents: Benzodiazepines | • lorazepam ER capsule (Loreev XR) | • lorazepam IR tablets<br>• alprazolam IR and XR tablets | • June 15, 2022 (120 days) |
| Nov 2021 | Migraine Agents | • dihydroergotamine mesylate nasal spray (Trudhesa) | • DHE nasal spray<br>• sumatriptan nasal and oral<br>• rizatriptan<br>• zolmitriptan<br>• eletriptan | • June 15, 2022 (120 days) |
| Aug 2021 | Antilipidemic-1s | • rosuvastatin/ ezetimibe (Roszet) | • rosuvastatin with ezetimibe<br>• atorvastatin with ezetimibe<br>• simvastatin/ezetimibe (Vytorin)<br>• evolocumab (Repatha)<br>• alirocumab (Praluent) | • June 15, 2022 (120 days) |
| May 2021 | Anticonvulsants-Antimania Agents | • levetiracetam (Elepsia XR) | • levetiracetam ER<br>• lamotrigine XR<br>• topiramate ER | • June 15, 2022 (120 days) |
| Feb 2021 | Corticosteroids-Immune Modulators: High Potency | • clobetasol propionate 0.05% lotion metered dose pump (Impeklo) | • betamethasone/propylene glycol 0.05% lotion<br>• betamethasone dipropionate 0.05% gel<br>• clobetasol propionate/emollient 0.05 % (emulsion) foam<br>• clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo<br>• fluocinonide 0.05% solution and gel | • June 15, 2022 (120 days) |
| Feb 2021 | Psoriasis Agents | • calcipotriene/ betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora) | • vitamin D analog (calcipotriene 0.005% cream, ointment or solution) with a high potency topical corticosteroid (clobetasol propionate 0.05% ointment, cream, solution and gel<br>• fluocinonide 0.05% cream, gel, and solution<br>• calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary] | • June 15, 2022 (120 days) |

## 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 2020 | Attention-Deficit/ Hyperactivity Disorder (ADHD) Agents: Stimulants | • methylphenidate ER sprinkle capsules (Adhansia XR) | • methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties<br>• methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties<br>• methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics)<br>• methylphenidate long-acting (Ritalin LA, generics)<br>• methylphenidate controlled delivery (CD) (Metadate CD, generics)<br>• dexmethylphenidate ER (Focalin XR, generics)<br>• mixed amphetamine salts ER (Adderall XR, generics) | • Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020 |
| Nov 2020 | GI-1 Agents | • budesonide ER 9 mg capsules (Ortikos) | • budesonide ER tablets (Entocort EC, generics)<br>• other corticosteroids | • June 2 2021 |
| Nov 2020 | Corticosteroids | • dexamethasone 20 mg tables (Hemady) | • dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs | • June 2 2021 |
| Nov 2020 | Pulmonary I Agents Inhaled Corticosteroids (ICS) | • fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) | • fluticasone (Flovent Diskus)<br>• fluticasone (Flovent HFA)<br>• fluticasone furoate (Arnuity Ellipta) [non formulary]<br>• beclomethasone (QVAR) [non formulary]<br>• budesonide (Pulmicort Flexhaler) [non formulary]<br>• ciclesonide (Alvesco) [non formulary]<br>• flunisolide (Aerospan) [non formulary]<br>• mometasone (Asmanex Twisthaler [non formulary] | • June 2 2021 |
| Nov 2020 | Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA) | • fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) | • fluticasone/salmeterol (Advair Diskus)<br>• fluticasone/salmeterol (Advair HFA)<br>• fluticasone/vilanterol (Breo Ellipta) [non formulary]<br>• mometasone/formoterol (Dulera) [non formulary]<br>• budesonide/formoterol (Symbicort) [non formulary]<br>• fluticasone/salmeterol (AirDuo Respiclick) [non formulary] | • June 2 2021 |

## 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 2020 | Calcium Channel Blockers | • levamlodipine (Conjupri) | • amlodipine<br>• felodipine<br>• nifedipine<br>• diltiazem<br>• verapamil | • June 2 2021 |
| Nov 2020 | GI-2 Agents | • metoclopramide nasal spray (Gimoti) | • metoclopramide oral tablet (Reglan generics)<br>• metoclopramide oral solution (Reglan, generics)<br>• metoclopramide orally disintegrating tablet (Reglan ODT) | • June 2 2021 |
| Aug 2020 | Topical Psoriasis Agents | • calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) | *Scalp Psoriasis:*<br>• calcipotriene 0.005% solution<br>• clobetasol 0.05% solution, shampoo<br>• fluocinonide 0.05% solution<br>• calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary]<br>*Psoriasis involving areas other than the scalp:*<br>• calcipotriene 0.005% ointment, cream, solution<br>• clobetasol 0.05% ointment, cream<br>• fluocinonide 0.05% cream, ointment | • February 24, 2021 |
| Aug 2020 | High-Potency Topical Corticosteroids | • halcinonide 0.1% topical solution (Halog) | • betamethasone propylene glycol 0.05% cream<br>• clobetasol propionate 0.05% cream and ointment<br>• clobetasol propionate/emollient 0.05% cream<br>• desoximetasone 0.25% cream and ointment<br>• fluocinonide 0.05% cream and ointment<br>• fluocinonide/emollient base 0.05% cream<br>• halobetasol propionate 0.05% ointment | • February 24, 2021 |
| Aug 2020 | Acne Agents: Topical Acne and Rosacea | • tazarotene 0.045% lotion (Arazlo) | • adapalene 0.1% lotion, gel, cream<br>• adapalene 0.3% gel<br>• clindamycin phosphate 1% gel, cream, lotion, and solution<br>• clindamycin/ benzoyl peroxide 1.2% - 5% gel<br>• tazarotene 0.1% cream<br>• tretinoin 0.025%, 0.05%, and 0.1% cream<br>• tretinoin 0.01% and 0.025% gel | • February 24, 2021 |

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

*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 |
|---|---|---|---|
| A1c | Hemoglobin A1c | MCL | Mantle cell lymphoma |
| ADHD | Attention Deficit Hyperactivity Disorder | MDI | Multiple daily injections |
| ADR | adverse drug reaction | MHS | Military Health System |
| AE | Adverse event | MN | Medical Necessity |
| ALS | Amyotrophic lateral sclerosis | MS | Multiple Sclerosis |
| ASCO | American Society of Clinical Oncology | MTF | Military Treatment Facility |
| BCF | Basic Core Formulary | MZL | Marginal zone lymphoma |
| BIA | Budget impact analysis | NCCN | National Comprehensive Cancer Network |
| CFR | Code of Federal Regulations | NDAA | National Defense Authorization Act |
| CGM | Continuous Glucose Monitoring system | NDC | National Drug Codes |
| CIU | Chronic idiopathic urticaria | NDO | Neurogenic detrusor overactivity |
| CLL | Chronic lymphocytic leukemia | NICE | National Institute for Health and Care Excellence |
| CMA | Cost minimization analysis | NSCLC | Non-small cell lung cancer |
| CPG | Clinical Practice Guidelines | OAB | Overactive bladder |
| CV | Cardiovascular | ODT | Orally Disintegrating Tablet |
| DHA | Defense Health Agency | OTC | Over-the-counter |
| DHA | docosahexaenoic acid | PA | Prior authorization |
| DLBCL | diffuse large B-Cell lymphoma | PAH | Pulmonary artery hypertension |
| DME | durable medical equipment | PCSK-9 | Proprotein convertase subtilisin-kexin type 9 inhibitor |
| DoD | Department of Defense | PDM | personal diabetes manager |
| ECF | Extended Core Formulary | PEG | polyethylene glycol |
| DR | Delayed release | PNH | paroxysmal nocturnal hemoglobinuria |
| EIP | external insulin pump | POD | Pharmacy Operations Division |
| EMMPI | The Expanded MTF/Mail Pharmacy Initiative | POS | Point of service |
| ER | Extended release | PRN | As needed |
| FDA | U.S. Food and Drug Administration | QL | Quantity limits |
| FDC | Fixed drug combination | RCC | Renal cell carcinoma |

## Appendix I—Table of Abbreviations

| | | | |
|---|---|---|---|
| Fe | iron | RRMS | Relapsing remitting multiple sclerosis |
| GCB | germinal center B-Cell | SC | Subcutaneous |
| GLP-1 RA | Glucagon-like peptide-1 receptor antagonists | SGLT-2 | Sodium glucose cotransporter-2 inhibitor |
| Hgb | hemoglobin | SL | Sublingual |
| iCGM | Integrated Continuous Glucose Monitoring system | SLL | Small lymphocytic lymphoma |
| ICS | Inhaled corticosteroid | SMBG | Self-monitoring blood glucose |
| L | liter | T1DM | Type 1 diabetes mellitus |
| LDL | Low density lipoprotein | T2DM | Type 2 diabetes mellitus |
| LABA | Long acting beta agonists | TIB | Targeted Immunomodulatory Biologics |
| LAMA | Long acting muscarinic antagonist | UC | Ulcerative colitis |
| LHRH | Luteinizing hormone releasing hormone | WM | Waldenström macroglobulinemia |