

**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 solely 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)
 - odeixibat (Bylvay) – Miscellaneous metabolic agent for progressive familial intrahepatic cholestasis (PFIC)
 - olanzapine/samidorphane (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/American 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, aminosaliclates (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.

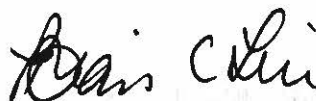
concurs with the recommendations, with the following modifications:

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 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
<ul style="list-style-type: none"> finerenone (Kerendia) <p>Cardiovascular Agents: Miscellaneous</p>	<ul style="list-style-type: none"> Use of formulary agents is contraindicated Patient has experienced significant adverse effects from formulary agents Formulary agents resulted in therapeutic failure <p>Formulary alternatives: empagliflozin</p>
<ul style="list-style-type: none"> ibrexafungerp (Brexafemme) <p>Antifungals</p>	<ul style="list-style-type: none"> Use of formulary agents is contraindicated Patient has experienced significant adverse effects from formulary agents Formulary agents resulted in therapeutic failure <p>Formulary alternatives: oral generic fluconazole, OTC clotrimazole vaginal cream, OTC miconazole vaginal cream</p>
<ul style="list-style-type: none"> mirabegron extended release granules for oral suspension (Myrbetriq Granules) <p>Overactive Bladder Agents</p>	<ul style="list-style-type: none"> Patient has experienced or is likely to experience significant adverse effects from formulary agents Formulary agents resulted in therapeutic failure <p>Formulary alternatives: oxybutynin</p>
<ul style="list-style-type: none"> odevixibat (Bylvay) <p>Metabolic Agents-Miscellaneous</p>	<ul style="list-style-type: none"> All five formulary agents (ursodiol, cholestyramine, rifampin, naltrexone, and at least 1 antihistamine) have resulted in therapeutic failure <p>Formulary alternatives: ursodiol, cholestyramine, diphenhydramine, hydroxyzine, rifampin, naltrexone</p>
<ul style="list-style-type: none"> olanzapine/samidorphan (Lybalvi) <p>Antipsychotic Agents: Atypical</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from two formulary agents <p>Formulary alternatives: olanzapine/fluoxetine, olanzapine, aripiprazole, ziprasidone</p>
<ul style="list-style-type: none"> ruxolitinib 1.5% cream (Opzelura) <p>Corticosteroids-Immune modulators: Atopic dermatitis</p>	<ul style="list-style-type: none"> Use of formulary agents are contraindicated Patient has experienced or is likely to experience significant adverse effects from formulary agents Formulary agents resulted in therapeutic failure <p>Formulary alternatives: topical corticosteroids (various); tacrolimus (generic); pimecrolimus (Elidel)</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<p data-bbox="207 212 480 237">Drug Class Review PAs</p> <ul style="list-style-type: none"> <li data-bbox="217 926 391 951">• Dexcom G6 <li data-bbox="217 957 444 982">• FreeStyle Libre 2 <p data-bbox="248 1024 483 1115">Continuous Glucose Monitoring (CGM) Systems</p>	<p data-bbox="526 254 1459 306">Manual PA criteria apply to all new and current users of Dexcom G6 or Abbott FreeStyle Libre 2.</p> <p data-bbox="526 338 1414 417">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.</p> <p data-bbox="526 449 1425 501">Note: other CGM systems are not part of the TRICARE pharmacy benefit but may be covered through the TRICARE DME process.</p> <p data-bbox="526 533 1192 558"><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> <li data-bbox="557 569 1406 621">• The patient has a diagnosis of Type 1 diabetes mellitus OR Type 2 diabetes mellitus <li data-bbox="557 632 1013 657">• One of the following situations applies: <ul style="list-style-type: none"> <li data-bbox="618 667 1256 693">• Patient is using basal and prandial insulin injections; OR <li data-bbox="618 703 1414 756">• Patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR <li data-bbox="618 766 1474 819">• Patient has Type 2 diabetes mellitus and is receiving insulin therapy and has a history of severe hypoglycemia episodes requiring medical intervention <li data-bbox="557 829 1446 882">• Dexcom G6 or FreeStyle Libre 2 is prescribed by an endocrinologist or diabetes specialist <li data-bbox="557 892 1468 917">• Documentation from the patient record must be submitted with all of the following: <ul style="list-style-type: none"> <li data-bbox="618 928 769 953">• Diagnosis <li data-bbox="618 963 1110 989">• Medication history, including use of insulin <li data-bbox="618 999 1458 1024">• Completion of a comprehensive diabetes education program for the patient <li data-bbox="618 1035 1089 1060">• Patient agrees to wear CGM as directed <li data-bbox="618 1071 1365 1123">• Patient agrees to share device readings with managing healthcare professional for overall diabetes management <li data-bbox="557 1134 1081 1159">• Patient meets the following age requirements <ul style="list-style-type: none"> <li data-bbox="618 1169 1154 1194">• Dexcom G6: Patient is 2 years of age or older <li data-bbox="618 1205 1208 1230">• FreeStyle Libre 2: Patient is 4 years of age or older <li data-bbox="557 1241 1422 1293">• Provider and patient will assess the usage of self-monitoring of blood glucose (SMBG) test strips, with the goal of minimizing/discontinuing use <p data-bbox="526 1335 964 1388">Initial prior authorization expires in 1 year PA renewal will be required annually</p> <p data-bbox="526 1419 1468 1472"><u>Renewal criteria:</u> Coverage will be approved on a yearly basis if all of the following apply (Note that initial TRICARE PA approval is required for renewal)</p> <ul style="list-style-type: none"> <li data-bbox="557 1503 1468 1556">• Confirmation that the patient has seen an endocrinologist or diabetes specialist at least once within the past year <li data-bbox="557 1566 1149 1591">• Confirmation that the patient has utilized CGM daily <li data-bbox="557 1602 1422 1654">• 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 <li data-bbox="557 1665 1455 1690">• Patients with T2DM continue to require daily basal and prandial insulin injections <li data-bbox="557 1701 1479 1753">• 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
<ul style="list-style-type: none"> • Gammagard Liquid • Gammaked • Xembify • Hizentra • Cuvitru • Hyqvia <p>Subcutaneous Immunoglobulins (SCIG)</p>	<p>Manual PA that apply to all new users of Gammagard Liquid, Gammaked, Xembify, Hizentra, Cuvitru, and Hyqvia.</p> <p><u>Manual PA criteria</u>—Coverage is approved if all of the following criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that Cutaquig and Gamunex-C do not require a PA. • Patient is 2 years of age or older • One of the following situations applies: <ul style="list-style-type: none"> • Patient has primary immunodeficiency disease (any) • Patient has a chronic inflammatory demyelinating polyneuropathy (any) • Patient has another diagnosis not listed above for which chronic immunoglobulin replacement therapy is a guideline-recommended therapeutic option Name of Guideline: _____ Guideline Recommendation Strength: _____ • 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) • 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) • 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) • Patient agrees to be monitored at indicated intervals to establish therapeutic immunoglobulin levels <p>Other Non-FDA-approved uses are NOT approved Prior authorization does not expire.</p>
Newly Approved Drugs PAs	
<ul style="list-style-type: none"> • belumosudil (Rezurock) <p>Immunosuppressives</p>	<p>Manual PA criteria apply to all new users of Rezurock</p> <p>Manual PA criteria: Rezurock is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 12 years of age and older • Rezurock is prescribed by or in consultation with a hematologist/oncologist • Patient has chronic graft-versus-host disease (cGVHD) and has failed treatment with steroids alone and at least two prior lines of systemic therapy • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • 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. • 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: _____. <p>Non-FDA-approved uses are not approved except as noted above. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • belzutifan (Welireg) <p>Oncological Agents</p>	<p>Manual PA criteria apply to all new users of Welireg</p> <p>Manual PA criteria: Welireg is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Welireg is prescribed by or in consultation with an oncologist • 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 • Patient does not have metastatic disease • Female patients of childbearing age are not pregnant, confirmed by (-) HCG • Female patients will not breast feed during treatment and for at least 3 weeks after the cessation of treatment • 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 • Male patients have been informed of the risk of infertility • 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 <p>Non-FDA-approved uses are not approved, other than noted above Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • finerenone (Kerendia) <p>Cardiovascular Agents: Miscellaneous</p>	<p>Manual PA criteria apply to all new and current users of Kerendia.</p> <p>Manual PA criteria: Kerendia is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Kerendia is prescribed by or in consultation with a nephrologist • The patient has a diagnosis of type 2 diabetes mellitus (T2DM) • The patient has documented diabetic kidney disease with albuminuria, defined as one of the following <ul style="list-style-type: none"> • An estimated glomerular filtration rate (eGFR) of 25-75 with albuminuria >300mg/g OR • eGFR 25-60 with albuminuria > 30mg/g plus diabetic retinopathy • Patient has been taking max-dose ACE inhibitor or ARB for at least 4 weeks • Patient tried DoDs preferred sodium-glucose-co-transporter 2 (SGLT-2) inhibitor empagliflozin (Jardiance) • The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease • Patient does not have uncontrolled hypertension (>170/110 mmHg) at initiation of Kerendia therapy • Patient does not have renal artery stenosis • Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc) • Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception <p>Non-FDA approved uses are not approved including patients renal transplants Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • mirabegron extended release granules for oral suspension (Myrbetriq Granules) <p>Overactive bladder agents</p>	<p>Manual PA criteria apply to all new users of Myrbetriq Granules</p> <p>Note that the previous automation for Myrbetriq granules and tablets has been removed</p> <p>Manual PA criteria: Myrbetriq Granules are approved if all criteria are met:</p> <ul style="list-style-type: none"> • Myrbetriq granules for oral suspension are prescribed by or in consultation with a urologist or nephrologist • The prescription is written for neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele, and not for overactive bladder • Provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization • Patient has tried and failed or has a contraindication to oxybutynin • Patient requires Myrbetriq granules for oral suspension for one of the following reasons: <ul style="list-style-type: none"> • The patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, etc) and not convenience. OR • The patient weighs less than 35 kg • 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 • Provider acknowledges that Myrbetriq granules for suspension and the Myrbetriq tablets will not be combined to achieve a specific dose • 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 <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • mobocertinib (Exkivity) <p>Oncological Agents: Lung Cancer</p>	<p>Manual PA criteria apply to all new users of Exkivity</p> <p>Manual PA criteria: Exkivity is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Exkivity is prescribed by or in consultation with a hematologist/oncologist • 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 • The patient will be monitored for QTc prolongation, interstitial lung disease, pneumonitis, decreased cardiac function, and diarrhea • If the patient develops diarrhea, he/she will be prescribed an anti-diarrheal agent • Female patients of childbearing age are not pregnant, confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • 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 • 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: _____. <p>Non-FDA-approved uses are not approved except as noted above. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • odeixibat (Bylvay) <p>Metabolic agents-miscellaneous</p>	<p>Manual PA criteria apply to all new and current users of Bylvay.</p> <p><u>Manual PA criteria:</u> Bylvay is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 3 months of age or older and weighs 5 kg or greater • Patient has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus • The prescription is written by a pediatric gastroenterologist, or pediatric hepatology transplant specialist • Patient has been evaluated for possible orthotopic liver transplant (OLT) • Patient has previously tried and failed all of the following: <ul style="list-style-type: none"> • ursodiol • cholestyramine • rifampin • naltrexone • At least one antihistamine (e.g. Atarax, Benadryl, etc.) <p>Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), progressive familial intrahepatic cholestasis (PFIC2), Alagille syndrome, Biliary atresia are not approved.</p> <p>Prior authorization expires after 6 months. Bylvay will be approved for an additional 6 months if the following criteria are met:</p> <p><u>Renewal criteria</u> (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • Patient must demonstrate significant improvement in pruritus symptoms.
<ul style="list-style-type: none"> • olanzapine/ samidorphan (Lybalvi) <p>Antipsychotic Agents: Atypical</p>	<p>Manual PA criteria apply to all new users of Lybalvi.</p> <p><u>Manual PA criteria:</u> Lybalvi is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has a documented diagnosis of schizophrenia or bipolar 1 disorder • Patient has tried for at least 6 months and had an adverse event to at least 2 antipsychotic agents • 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 <ul style="list-style-type: none"> • Drug: Date _____ Duration of therapy _____ Adverse Reaction _____ Therapeutic Failure _____ • Drug: Date _____ Duration of therapy _____ Adverse Reaction _____ Therapeutic Failure _____ <p>Non-FDA-approved uses are not approved including major depressive disorder, fibromyalgia, or other mood disorders.</p> <p>Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • ruxolitinib 1.5% cream (Opzelura) <p>Corticosteroids- Immune modulators: Atopic dermatitis</p>	<p>Manual PA criteria apply to all new and current users of Opzelura.</p> <p>Manual PA criteria: Opzelura is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 12 years of age and older • Opzelura is prescribed by a dermatologist, allergist, or immunologist • The patient has mild to moderate uncontrolled atopic dermatitis • The patient has a contraindication to, intolerance to, or has failed treatment with one medication in each of the following categories: <ul style="list-style-type: none"> • Topical Corticosteroids: <ul style="list-style-type: none"> – 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) – For patients 12 to 17 years of age: any topical corticosteroid <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • 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 <p>Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely.</p> <p>Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • 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 • The patient’s disease severity has improved and stabilized to warrant continued therapy
<ul style="list-style-type: none"> • serdexmethylphenidate/ dexamethylphenidate (Azstarys) <p>ADHD Agents: Stimulants</p>	<p>Manual PA criteria apply to all new users of Azstarys</p> <p><u>Manual PA Criteria:</u> Azstarys is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 6 years of age or older • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been documented in the medical record • 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 • 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 • 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) • Patient has tried, for at least two months, an immediate release formulation methylphenidate product in conjunction with generic Concerta or another long-acting methylphenidate • Please explain why the patient needs Azstarys: <i>(fill-in blank question)</i> <p>Non-FDA-approved uses are NOT approved Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
New PAs	
<ul style="list-style-type: none"> clemastine 0.5 mg/mL syrup <p>Antihistamine-1: First Generation and Combinations</p>	<p>Manual PA criteria applies to new and current users of clemastine syrup.</p> <p>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).</p> <p><u>Manual PA Criteria:</u> clemastine syrup is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider is aware and acknowledges that clemastine tablets and other antihistamines are available to DoD beneficiaries without the need of prior authorization The provider must explain why the patient requires clemastine syrup and cannot take one of the cost effective formulary alternatives. (fill-in blank) <p>Non-FDA approved uses are NOT approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> diclofenac potassium 25 mg tablet (Lofena) <p>Pain Agents: NSAID</p>	<p>Manual PA criteria applies to new and current users of diclofenac potassium 25 mg tablet.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> diclofenac 25 mg tablet is approved if all criteria are met:</p> <ul style="list-style-type: none"> 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 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> meclizine 50 mg tablet (Antivert) <p>Anti-Emetic/Anti-Vertigo Agents</p>	<p>Manual PA criteria applies to new and current users of meclizine 50 mg tablet (Antivert).</p> <p>Note: meclizine 25 mg tablets are available without a PA; providers are encouraged to consider changing the prescription to meclizine 25 mg tablets.</p> <p><u>Manual PA Criteria:</u> meclizine 50 mg tablet (Antivert) is approved if all criteria are met:</p> <ul style="list-style-type: none"> 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 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • niacin 500 mg tablet <p>Antilipidemics-1</p>	<p>Manual PA criteria applies to new and current users of Niacin 500 mg tablet.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Niacin 500 mg tablet is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that other formulations of niacin, including Niaspan and Niacor, are available to DoD beneficiaries without the need of prior authorization • 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 • 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) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • prenatal MVI (Neonatal Complete) <p>Vitamins: Prenatal</p>	<p>Manual PA criteria applies to new and current users of prenatal MVI (Neonatal Complete).</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, or Neonatal Complete is approved if all criteria are met:</p> <ul style="list-style-type: none"> • 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 • The provider must explain why the patient requires Neonatal Complete and cannot take one of the cost effective formulary alternatives. (fill-in blank) <p>Non-FDA approved uses are NOT approved. Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> sertraline 150 mg and 200 mg capsules <p>Antidepressant and Non-Opioid Pain Syndrome Agents: SSRIs</p>	<p>Manual PA criteria applies to new and current users of sertraline 150 mg and 200 mg capsules.</p> <p>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.</p> <p><u>Manual PA Criteria:</u> Sertraline 150 mg or 200 mg capsules are approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider acknowledges that other strengths of sertraline and other formulary SSRIs are available to DoD beneficiaries without the need of prior authorization The provider must explain why the patient cannot take a combination of lower sertraline strengths to achieve the desired dose: (fill-in blank) <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> tizanidine capsules (Zanaflex) <p>Skeletal Muscle Relaxants and Combinations</p>	<p>Manual PA criteria applies to new users of tizanidine capsules (Zanaflex).</p> <p>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.</p> <p><u>Manual PA Criteria:</u> tizanidine capsules (Zanaflex) is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider is aware and acknowledges that tizanidine tablets and other formulary muscle relaxants are available to DoD beneficiaries without the need of prior authorization 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) <p>Non-FDA approved uses are NOT approved. Prior Authorization does not expire.</p>
<p>Updated PAs</p>	

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> evolocumab (Repatha) <p>Antilipidemics 1’ Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors</p>	<p>Changes from November 2021 meeting are in BOLD and strikethrough Manual PA criteria apply to all new users of evolocumab (Repatha).</p> <p><u>Manual PA criteria</u>—Evolocumab is approved if:</p> <ul style="list-style-type: none"> A cardiologist, lipidologist, or endocrinologist initially prescribes the drug. The patient is at least 18 years of age for HeFH and clinical ASCVD. For HeFH HoFH, patients as young as 10 years13 years of age can receive the drug. 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. The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >70 mg/dL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below: <ul style="list-style-type: none"> The patient must have tried both atorvastatin 40-80 mg and rosuvastatin 20-40 mg, OR The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR 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 The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. 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: <ul style="list-style-type: none"> Intolerance <ul style="list-style-type: none"> The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR 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. Contraindication to statin <ul style="list-style-type: none"> The contraindication must be defined. Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. Repatha is not approved for patients who are pregnant or lactating. The dosage must be documented on the PA Form as either: <ul style="list-style-type: none"> 140 mg every 2 weeks, or 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. PA expires in one year. 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: <ul style="list-style-type: none"> The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND The patient has documented adherence
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Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • zanubrutinib (Brukinsa) <p>Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors</p>	<p>Updates from the November 2021 Meeting are in bold. Manual PA criteria apply to all new users of zanubrutinib (Brukinsa).</p> <p><u>Manual PA Criteria:</u> Brukinsa is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) • Patient has Waldenström’s macroglobulinemia (WM), a rare non-Hodgkin lymphoma • Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment • 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: _____. <p>Other non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> • ivosidenib (Tibsovo) <p>Oncological Agents: Acute Myelogenous Leukemia</p>	<p>Updates from the November 2021 Meeting are in bold. Manual PA criteria apply to all new users of ivosidenib (Tibsovo).</p> <p><u>Manual PA Criteria:</u> Tibsovo is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has a diagnosis of: <ul style="list-style-type: none"> ▪ Relapsed/refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by a FDA-approved test OR ▪ 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 ▪ Patient has previously treated, locally advanced, or metastatic cholangiocarcinoma with an IDH1 mutation as detected by a FDA-approved test OR ▪ The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • The patient will be monitored for differentiation syndrome • The patient will be monitored for Guillain-Barre syndrome • Prescribed by or in consultation with a hematologist/oncologist <p>Other Non-FDA-approved uses are not approved. Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> mepolizumab (Nucala) <p>Respiratory Interleukins</p>	<p>Updates from the November 2021 Meeting are in bold. Manual PA is required for all new users of mepolizumab (Nucala).</p> <p><u>Manual PA Criteria:</u> Nucala coverage will be approved for initial therapy for 12 months if all criteria are met:</p> <p><i>For eosinophilic asthma:</i></p> <ul style="list-style-type: none"> The patient has a diagnosis of severe persistent eosinophilic asthma The drug is prescribed by an allergist, immunologist, or pulmonologist The patient must have an eosinophilic phenotype asthma as defined as either <ul style="list-style-type: none"> Eosinophils \geq 150 cells/mcL within past month while on oral corticosteroids OR Eosinophils \geq 300 cells/mcL The patient’s asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: <ul style="list-style-type: none"> Hospitalization for asthma in past year OR Two courses of oral corticosteroids in past year OR Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: <ul style="list-style-type: none"> Long-acting beta agonist (LABA e.g., Serevent, Striverdi), Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) <p><i>For eosinophilic granulomatosis with polyangiitis (EGPA):</i></p> <ul style="list-style-type: none"> The patient has a diagnosis of EGPA The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist The patient is 18 years of age or older A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the EGPA indication <p><i>For Hypereosinophilic Syndrome (HES):</i></p> <ul style="list-style-type: none"> The patient has a diagnosis of HES The patient has had eosinophil levels > 1,000 cells/mcL in the past year The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist or hematologist The patient is 12 years of age or older A quantity limit override for the 300 mg dose to allow three of the 100 mg syringes is approved for the HES indication <p><i>For chronic rhinosinusitis with nasal polyps (CRSwNP):</i></p> <ul style="list-style-type: none"> The patient has a diagnosis of CRSwNP Nucala is being prescribed as add-on maintenance therapy due to patient having inadequate response to nasal corticosteroid <p>AND</p> <ul style="list-style-type: none"> For all indications, the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], dupilumab [Dupixent] or omalizumab [Xolair]) <p>Non-FDA-approved uses are not approved Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely</p>
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Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
	<p>Renewal Criteria; (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> • 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 • EGPA, HES: The patient’s disease severity has improved and stabilized to warrant continued therapy • 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
<ul style="list-style-type: none"> • sodium oxybate/calcium/magnesium/potassium oral solution (Xywav) <p>Sleep Disorders: Wakefulness Promoting Agents</p>	<p>Updates from the November 2021 Meeting are in bold. Manual PA criteria apply to all new users of sodium oxybate/calcium/magnesium/potassium oral solution (Xywav).</p> <p><u>Manual PA Criteria:</u> Coverage of Xywav is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy <ul style="list-style-type: none"> ▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xywav is prescribed for idiopathic hypersomnia OR • Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy & <ul style="list-style-type: none"> ▪ The patient has history of failure, contraindication, or intolerance of both of the following: modafinil or armodafinil AND stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND ▪ Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) OR • Patient is a child 7 years of age or older AND • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic AND • Xywav is prescribed by a neurologist, psychiatrist, or sleep medicine specialist AND • Xywav is prescribed for the treatment of excessive daytime sleepiness and cataplexy in a patient with narcolepsy. <ul style="list-style-type: none"> ▪ Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing OR • Xywav is prescribed for excessive daytime sleepiness in a patient with narcolepsy AND <ul style="list-style-type: none"> ▪ The patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) AND • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, the effects of substances or medications, or other sleep disorders) <p>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</p> <p>Prior Authorization expires after 1 year. Renewal PA criteria; Renewal not allowed. A new prescription will require a new PA to be submitted</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • adalimumab (Humira) <p>Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors</p>	<p>Updates from the November 2021 meeting are in bold.</p> <p>Manual PA criteria applies to all new users of adalimumab (Humira).</p> <p><u>Manual PA Criteria:</u> Humira is approved if all criteria are met:</p> <p>Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication:</p> <ul style="list-style-type: none"> • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy • Moderate to severely active Crohn's disease (CD) • Moderate to severely active ulcerative colitis (UC) • Moderate to severe hidradenitis suppurativa (HS) • Non-infectious intermediate, posterior, and panuveitis • Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation • Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids <p>OR</p> <p>Coverage approved for pediatric patients 12-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Moderate to severe hidradenitis suppurativa (HS) <p>OR</p> <p>Coverage approved for pediatric patients 6-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Moderate to severely active Crohn's disease (CD) <p>OR</p> <p>Coverage approved for pediatric patients 5-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Moderately to severely active ulcerative colitis (UC) <p>OR</p> <p>Coverage approved for pediatric patients 4-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate <p>OR</p> <p>Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication:</p> <ul style="list-style-type: none"> • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) • Non-infectious intermediate, posterior, and panuveitis <p>Below criteria applies to AS indication only:</p> <ul style="list-style-type: none"> • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months <p>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:</p> <ul style="list-style-type: none"> • Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) <p>Below criteria applies to all patients (regardless of age):</p> <ul style="list-style-type: none"> • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) <p>Coverage for non-FDA-approved uses not listed above. Please provide a diagnosis and rationale for treatment. Supportive evidence will be considered.</p> <p>Prior authorization does not expire.</p>
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Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
	<p>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).</p>
<ul style="list-style-type: none"> • baricitinib (Olumiant) <p>Targeted Immunomodulatory Biologics (TIBs): Miscellaneous</p>	<p>Updates from the November 2021 meeting are in bold.</p> <p>Note that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis.</p> <p>Step therapy and manual PA criteria apply to all new users of baricitinib (Olumiant).</p> <p><u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</p> <p>AND</p> <p><u>Manual PA Criteria:</u> If automated criteria are not met, coverage for Olumiant is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent <p>OR</p> <ul style="list-style-type: none"> • The patient has a contraindication to Humira • Patient is 18 years of age or older • Patient has a diagnosis of: <ul style="list-style-type: none"> ○ Moderate to severe active rheumatoid arthritis (RA) • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.) • The patient will not be receiving other biologic DMARDs or potent immunosuppressant's (for example, azathioprine and cyclosporine) concomitantly • Patient has no history of thromboembolic disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient hemoglobin (Hgb) must be > 9 g/dL • Patient absolute neutrophil count (ANC) < 1,000/mm³ • Patient absolute lymphocyte count (ALC) < 500/ mm³ • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents except for Otezla <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • upadacitinib (Rinvoq) <p>Targeted Immunomodulatory Biologics (TIBs): Miscellaneous</p>	<p><u>Updates from the November 2021 meeting are in bold.</u></p> <p>Note that Humira is the Department of Defense's preferred targeted biologic agent for rheumatoid arthritis.</p> <p>Step therapy and manual PA criteria apply to all new users of upadacitinib (Rinvoq).</p> <p><u>Manual PA Criteria:</u> Rinvoq is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has diagnosis of active rheumatoid arthritis • Patient has had an inadequate response or an intolerance to methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient has had an inadequate response to Xeljanz or Olumiant OR • Patient has experienced an adverse reaction to Xeljanz or Olumiant that is not expected to occur with the requested agent OR • Patient has a contraindication to Xeljanz or Olumiant that does not apply to Rinvoq AND • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine). <p>Non-FDA-approved uses are not approved. PA does not expire.</p>

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • Dexcom G6 • Abbott FreeStyle Libre 2 <p>Continuous Glucose Monitoring (CGM) Systems</p>	<p>Dexcom G6</p> <ul style="list-style-type: none"> ▪ Sensors <ul style="list-style-type: none"> ○ Retail: 3 sensors in 30 days ○ MTF/Mail: 9 sensors in 90 days ▪ Transmitters: Retail/MTF/Mail: 1 transmitter in 90 days ▪ Receivers: Retail/MTF/Mail: 1 receiver in 365 days <p>Abbott FreeStyle Libre 2</p> <ul style="list-style-type: none"> ▪ Sensors <ul style="list-style-type: none"> ○ Retail: 2 sensors in 28 days ○ MTF/Mail: 6 sensors in 84 days ▪ Readers: Retail/MTF/Mail: 1 reader in 365 days
<ul style="list-style-type: none"> • belumosudil (Rezurock) <p>Immunosuppressive</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • mobocertinib (Exkivity) <p>Oncological Agents: Lung Cancer</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • belzutifan (Welireg) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • odevixibat (Bylvay) <p>Metabolic Agents- Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • naloxone nasal 8 mg (Kloxxado) <p>Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 2 cartons (2 nasal spray devices per carton) per fill
<ul style="list-style-type: none"> • mirabegron extended release granules for oral suspension (Myrbetriq Granules) <p>Overactive bladder agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 2 bottles per fill
<ul style="list-style-type: none"> • ruxolitinib 1.5% cream (Opzelura) <p>Corticosteroids-Immune modulators: Atopic dermatitis</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • ibrexafungerp (Brexafemme) <p>Antifungals</p>	<ul style="list-style-type: none"> ▪ 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) Immuno-suppressive	<ul style="list-style-type: none"> • abatacept (Orencia) • etanercept (Enbrel) • ibrutinib (Imbruvica) 	<ul style="list-style-type: none"> • 200 mg oral tabs • Take 1 tab once daily with food 	Chronic graft-versus-host disease	<ul style="list-style-type: none"> • Infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension 	<ul style="list-style-type: none"> • Rezurock is a first-in-class ROCK2 inhibitor indicated for chronic Graft vs Host Disease • Based on pivotal trial structure, efficacy only established after the failure of steroids and 2 systemic therapies • Clinically meaningful durability (time before death or new treatment initiation) • High rate of adverse events – especially infections – and discontinuations • Rezurock is another treatment option for cGVHD 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
belzutifan (Welireg) Oncological Agents	<ul style="list-style-type: none"> • pazopanib (Votrient) 	<ul style="list-style-type: none"> • 40 mg oral tabs • 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	<ul style="list-style-type: none"> • Common ADRS: decreased hemoglobin, fatigue, increased creatinine, nausea, increased glucose • Warnings: severe anemia, severe hypoxia, may cause fetal harm 	<ul style="list-style-type: none"> • VHL disease causes cancer in kidneys, pancreas, and CNS • Welireg is the 1st hypoxia-inducible factor 2 alpha (HIF-2α) inhibitor approved for VHL • Welireg reduces transcription and expression of HIF-2 α target genes associated with cellular proliferation, angiogenesis and tumor growth • 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) • NCCN kidney cancer guidelines recommend Welireg as a preferred regimen for VHL disease as a category 2A recommendation • 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” 	<ul style="list-style-type: none"> • UF • 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) Migraine Agents	<ul style="list-style-type: none"> DHE nasal spray generic Migranal ergotamine/caffeine 	<ul style="list-style-type: none"> Dosing: One spray (0.725 mg) into each nostril (Total dose is 1.45 mg) 	Acute treatment of migraine with/without aura in adults	<ul style="list-style-type: none"> Same warning, C/I, precautions, drug interactions as Migranal 	<ul style="list-style-type: none"> Trudhesa is another DHE nasal spray No new studies conducted; efficacy based on bioavailability to DHE nasal spray Maintains all of the same warnings, contraindications, drug interactions, and ADRs as generic DHA nasal spray Trudhesa provides little to no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> Tier 4/Not covered
finerenone (Kerendia) Cardiovascular Agents: Miscellaneous	<ul style="list-style-type: none"> empagliflozin 	<ul style="list-style-type: none"> Oral Tablets: 10 mg, 20mg eGFR 25-59: 10 mg eGFR > 60: 20 mg 	Reduce the risk of sustained eGFR decline in adult patients with chronic kidney disease associated with type 2 diabetes (T2DM)	<ul style="list-style-type: none"> Common ADRs: hyperkalemia, hypotension, and hyponatremia Warnings: Hyperkalemia - Patients with decreased kidney function and higher baseline potassium levels are at increased risk Monitor serum potassium levels and adjust dose as needed 	<ul style="list-style-type: none"> 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 Kerendia was evaluated in two studies (Fidelio-DKD and Figaro-DKD) compared to placebo Reduction of GFR was statistically significant for finerenone vs placebo however clinical significance is unclear Currently, there are no head-to-head studies of Kerendia with other agents such as MRAs or SGLT-2 inhibitors Most common ADRs include hyperkalemia, hypotension, hyponatremia Kerendia offers another option in the treatment of CKD in T2D patients however place in therapy is currently unclear 	<ul style="list-style-type: none"> NF Do not add to EMMI list
ibrexafungerp (Brexafemme) Antifungals	<ul style="list-style-type: none"> fluconazole tablets OTC clotrimazole cream OTC miconazole cream 	<ul style="list-style-type: none"> Packaging: 4 x 150 mg oral tablets Two 150 mg tablets taken every 12 hours x 1 day (4 doses total) with or without food 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: <ul style="list-style-type: none"> diarrhea (16.7%) nausea (11.7%) abdominal pain (11.4%) dizziness (3.3%) vomiting (2%) 	<ul style="list-style-type: none"> First triterpenoid antifungal drug for VVC tx Statistically significant results in reaching key efficacy endpoints; well-tolerated compared to placebo In a non-pivotal phase IIb trial, Brexafemme and fluconazole appeared equally efficacious Guidelines strongly recommend topical antifungals and oral fluconazole for the treatment of VVC; Brexafemme not yet addressed Disadvantages compared to fluconazole: greater pill burden; not available as a single dose 	<ul style="list-style-type: none"> NF 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
					<ul style="list-style-type: none"> • Further research is needed to determine if there are any comparative efficacy or safety advantages over azole antifungals • 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) Antianxiety Agents: Benzodiazepines	<ul style="list-style-type: none"> • lorazepam tablets • alprazolam IR • alprazolam ER 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Same as generic lorazepam 	<ul style="list-style-type: none"> • Loreev XR is a new extended-release formulation of lorazepam • Lorazepam (Ativan) originally approved in 1977 • No new studies • Advantage of Ativan is its short-acting duration • Provides no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> • Tier 4/Not covered
mirabegron extended release granules for oral suspension (Myrbetriq Granules) Overactive Bladder Agents	<ul style="list-style-type: none"> • oxybutynin syrup • Vesicare LS • Toviaz 	<ul style="list-style-type: none"> • Granules for ER oral suspension • For patients < 35 kg: doses of 24 - 64 mg/day • For patients ≥ 35 kg: doses up to 80 mg/day • Renal and hepatic dose adjustments • Tablets and granules not substitutable 	For treatment of neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 3 years old	<ul style="list-style-type: none"> • Most commonly reported adverse reactions (≥ 3%): UTI, headache, nasopharyngitis, constipation, 	<ul style="list-style-type: none"> • New formulation of mirabegron for use in NDO patients ≥ 3 years old • 3rd pharmacy-benefit drug approved for NDO, 1st β-3 adrenergic agonist for NDO • Convenient once daily dosing compared to up to three times a day dosing with oxybutynin syrup • Guidelines do not yet address the role of Myrbetriq Granules; they strongly encourage the use of antimuscarinic medications for NDO • 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 • Short shelf-life after reconstitution (28 days) is a disadvantage compared to other available agents • Myrbetriq granules are another option for the treatment of NDO in pediatric patients; it’s place in therapy is still to be determined 	<ul style="list-style-type: none"> • NF • 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) Oncological Agents: Lung Cancer	<ul style="list-style-type: none"> • amivantinib (Rybrevant) – medical benefit agent 	<ul style="list-style-type: none"> • 40 mg caps • Dosing: 4 caps once daily with or without food 	NSCLC with EGFR exon 20 mutation	<ul style="list-style-type: none"> • Most common (>20%) ADRs: diarrhea, rash, nausea, stomatitis, vomiting, decreased appetite, paronychia, fatigue, dry skin, and musculoskeletal pain • Most common (≥2%) Grade 3/4 lab abnormalities: decreased lymphocytes, potassium, and magnesium; increased amylase, lipase, and creatinine; anemia 	<ul style="list-style-type: none"> • Exkivity is FDA-approved to treat adults with EGFR Exon20 insertion mutated Non-Small Cell Lung Cancer (NSCLC) • 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. • 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 • Exkivity is poorly tolerated with ~40% of population requiring dose-reduction or discontinuation. • Exkivity is an important addition to the treatment of EGFR Exon 20 insertion-mutated NSCLC able to be sequenced with its comparator 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
naloxone nasal 8 mg (Kloxxado) Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists	<ul style="list-style-type: none"> • naloxone nasal 4 mg/0.1 mL (Narcan) • naloxone autoinjector (Evzio) - discontinued 	<ul style="list-style-type: none"> • Nasal Spray: 8 mg of naloxone hydrochloride in 0.1mL • 2 vials per package • 1 spray (8mg) intranasally into 1 nostril • May repeat every 2-3 minutes prn until EMS arrival 	Emergency treatment of known or suspected opioid overdose	<ul style="list-style-type: none"> • Abdominal pain, asthenia, dizziness, headache, nasal irritation, precipitation of severe opioid withdrawal, risk of recurrent respiratory and CNS depression 	<ul style="list-style-type: none"> • Kloxxado is a new formulation of naloxone nasal spray for acute opioid overdose • First 8 mg ready to use nasal spray (vs standard Narcan 4 mg) • Both Narcan and Kloxxado have same indication • No new clinical studies or administration studies to demonstrate efficacy, tolerability, or superiority to Narcan • Two small pharmacokinetic studies available with bioavailability of Kloxxado vs IM and IV naloxone • Kloxxado provides another nasally administered naloxone that is more concentrated for treatment of opioid overdose 	<ul style="list-style-type: none"> • UF • 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) Metabolic Agents- Miscellaneous	<ul style="list-style-type: none"> • ursodiol • cholestyramine • naltrexone • rifampin • phenobarbital • antihistamines 	<ul style="list-style-type: none"> • Oral Pellets: 200 mcg, 600 mcg • Oral Capsules: 400 mcg, 1200 mcg • 40 mcg/kg once daily in the morning with a meal. • Can be increased in 40 mcg/kg increments up to 120 mcg/kg once daily after 3 months of minimal improvement. • Do not exceed 6 mg/day 	Pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)	<ul style="list-style-type: none"> • Liver enzyme elevation • Diarrhea • Fat-soluble vitamin deficiency 	<ul style="list-style-type: none"> • 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 • May not be effective in PFIC Type 2 patients with ABCB11 variants that result in non-functional or absent BSEP-3 protein • Guidelines recommend initial treatment with ursodeoxycholic acid, followed by cholestyramine as second line alternative • Evaluated in one small (n=62), unpublished study compared to placebo (long term efficacy and safety study ongoing) • Bylvay achieved little to no scratching in a significantly greater proportion of patients compared to placebo (30-35% vs 13%) • Only 1/3 of Bylvay treated patients achieved primary endpoint • Greater difference seen using 40 mcg/kg/day dosing • Higher dosing did not achieve greater effectiveness • Most common AEs (incidence ≥ 2%) include liver enzyme elevation, diarrhea, vomiting, abdominal pain, fat soluble vitamin deficiencies • 14.2% (n=6) of Bylvay-treated patients dropped out due to lack of efficacy compared to 25% (n=5) with placebo • Bylvay has only been studied and approved to treat pruritus related to PFIC, cannot validate efficacy of treating underlying disease process • Bylvay provides an additional treatment option for pruritus secondary to PFIC, however place in therapy is unclear 	<ul style="list-style-type: none"> • NF • 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) Antipsychotic Agents: Atypical	<ul style="list-style-type: none"> • olanzapine • olanzapine/ fluoxetine • aripiprazole • ziprasidone 	<ul style="list-style-type: none"> • olanzapine/ samidorphan 5mg/10mg, 10mg/10mg, 15mg/10mg, or 20mg/10mg • Once daily tablet with or without food 	<ul style="list-style-type: none"> • Schizophrenia in adults • Bipolar I in adults; Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate; Maintenance monotherapy treatment 	<p>Schizophrenia: weight gain, somnolence, dry mouth, headache</p> <p>Bipolar I disorder, manic, or mixed episodes: asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor</p>	<ul style="list-style-type: none"> • Lybalvi is another formulation of olanzapine combined with an opioid antagonist (samidorphan) • The addition of samidorphan is designed to mitigate weight gain associated with olanzapine • 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. • 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. • Differences with Lybalvi vs. olanzapine on related metabolic parameters have not been adequately studied • No new bipolar studies were conducted • All of the same warnings and contraindications of olanzapine exist, with the addition of potential opioid withdrawal or overdose when using opioid analgesics. • 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. • Lybalvi provides no compelling advantage over existing formulary agents. 	<ul style="list-style-type: none"> • NF • 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) Corticosteroids-Immune Modulators: Atopic Dermatitis	<ul style="list-style-type: none"> • tacrolimus (Protopic) 0.1% ointment • pimecrolimus (Elidel) 1% cream • crisaborole (Eucrisa) 2% ointment 	<ul style="list-style-type: none"> • 1.5% Cream in 60 gm tube • Dosing: AAA twice daily up to 20% BSA no more than 60 gm/week up to 8 weeks 	Non-immunocompromised 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	<ul style="list-style-type: none"> • Opzelura is a new formulation of ruxolitinib in a topical cream indicated for mild to moderate atopic dermatitis • Opzelura offers clinically significant improvements in patients with chronic atopic dermatitis • By indirect comparison, Opzelura appears to offer non-inferior benefit to moderate-strength topical corticosteroids • As a JAK-inhibitor, Opzelura risks numerous serious side-effects. However, because of its topical formulation, there is limited systemic absorption. • Opzelura is well-tolerated • Opzelura is another treatment option for mild to moderate atopic dermatitis that has failed earlier-line treatments 	<ul style="list-style-type: none"> • NF • Add to EMMI list
serdexmethylphenidate/dexmethylphenidate (Azstarys) ADHD Agents: Stimulants	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Oral capsules (26.1 mg/5.2 mg, 39.2 mg/7.8 mg, and 52.3 mg/10.4 mg) • 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) • 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	<ul style="list-style-type: none"> • Azstarys is the 13th marketed long-acting methylphenidate (MPH) product approved for the treatment for ADHD • Contains the combination of a prodrug serdexmethylphenidate and dexmethylphenidate; classified as a C-II like other stimulants with similar side effects and warnings • Approval was granted via the 505(b)(2) pathway using pharmacokinetic bridging between Azstarys and dexmethylphenidate for patients 13 to 17 years of age • 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 • Based on limited studies, duration of action is unclear • Provides no compelling clinical advantage over existing formulary agents 	<ul style="list-style-type: none"> • UF • 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	<p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated NF:</p> <p><i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:</i></p> <ul style="list-style-type: none"> mirabegron granules for oral suspension (Myrbetriq Granules) <p><i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, pending availability at mail, and pending final cost:</i></p> <ul style="list-style-type: none"> ruxolitinib 1.5% cream (Opzelura) <p>Line Extensions Designated UF</p> <p><i>Similar/parent agent already on list (all new strengths or dosage forms):</i></p> <ul style="list-style-type: none"> dupilumab pen (Dupixent) levothyroxine sodium (Tirosint-Sol) 	<p>SCIG</p> <p><i>Clinical considerations:</i></p> <ul style="list-style-type: none"> Gammaked, Gamunex, Gammagard Cuvitru, Cutaquig, Hyqvia, Hizentra, Xembify <p>Continuous Glucose Monitoring (CGM) Systems UF</p> <p><i>Do not add to EMMPI Program due to no advantage to the government to add:</i></p> <ul style="list-style-type: none"> Dexcom G6 Abbott FreeStyle Libre 2 <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF:</p> <p><i>Acute use or limited duration and drugs in class not currently represented on EMMPI List:</i></p> <ul style="list-style-type: none"> naloxone nasal spray (Kloxxado) <p><i>Not yet clear if feasible to provide through mail:</i></p> <ul style="list-style-type: none"> belumosudil (Rezurock) mobocertinib (Exkivity) belzutifan (Welireg) <p><i>C-II stimulant exception/existing exclusion applies (operational issues):</i></p> <ul style="list-style-type: none"> serdexmethylphenidate/dexmethylphenidate (Azstarys) <p>Designated NF:</p> <p><i>Acute use or limited duration and drugs in class not currently represented on EMMPI List/comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> ibrexafungerp (Brexafemme) <p><i>Antipsychotics exception/existing exclusion applies:</i></p> <ul style="list-style-type: none"> olanzapine/samidorphan (Lybalvi) <p><i>Exception due to comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> 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)
		<p><i>Not yet clear if feasible to provide through mail order and similar pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • odevixibat (Bylvay)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Nov 2021	Continuous Glucose Monitoring Systems	UF Class Review Class not previously reviewed	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <p align="center">▪ None</p>			<p>Pending signing of the minutes /60 days</p> <p>The effective date is April 20, 2022</p>	<ul style="list-style-type: none"> ▪ All new and current users are subject to PA criteria. ▪ Quantity limits apply. 	<ul style="list-style-type: none"> ▪ See Appendices C and D for PA and QL criteria.
Nov 2021	Subcutaneous Immunoglobulins (SCIG)	UF Class Review Class not previously reviewed	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <p align="center">▪ None</p>			<p>Pending signing of the minutes / 90 days</p> <p>The effective date is May 18, 2022</p>	<ul style="list-style-type: none"> ▪ Manual PA criteria applies to all new users of Gammagard, Gammaked, Xembify, Hizentra, Cuvitru and Hyqvia 	<ul style="list-style-type: none"> ▪ Step therapy now applies – a trial of Cutaquig or Gamunex-C is required in all new users of a SCIG ▪ Tier 1 copay applies for Cutaquig at the Mail Order and Retail POS ▪ See Appendix C for full PA criteria.

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

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

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2021	Antianxiety Agents: Benzodiazepines	<ul style="list-style-type: none"> lorazepam ER capsule (Loreev XR) 	<ul style="list-style-type: none"> lorazepam IR tablets alprazolam IR and XR tablets 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Nov 2021	Migraine Agents	<ul style="list-style-type: none"> dihydroergotamine mesylate nasal spray (Trudhesa) 	<ul style="list-style-type: none"> DHE nasal spray sumatriptan nasal and oral rizatriptan zolmitriptan eletriptan 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Aug 2021	Antilipidemic-1s	<ul style="list-style-type: none"> rosuvastatin/ezetimibe (Roszet) 	<ul style="list-style-type: none"> rosuvastatin with ezetimibe atorvastatin with ezetimibe simvastatin/ezetimibe (Vytorin) evolocumab (Repatha) alirocumab (Praluent) 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
May 2021	Anticonvulsants-Antimania Agents	<ul style="list-style-type: none"> levetiracetam (Elepsia XR) 	<ul style="list-style-type: none"> levetiracetam ER lamotrigine XR topiramate ER 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Corticosteroids-Immune Modulators: High Potency	<ul style="list-style-type: none"> clobetasol propionate 0.05% lotion metered dose pump (Impeklo) 	<ul style="list-style-type: none"> betamethasone/propylene glycol 0.05% lotion betamethasone dipropionate 0.05% gel clobetasol propionate/emollient 0.05% (emulsion) foam clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo fluocinonide 0.05% solution and gel 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene/betamethasone dipropionate 0.005%/0.064% topical cream (Wynzora) 	<ul style="list-style-type: none"> 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) fluocinonide 0.05% cream, gel, and solution calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary] 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) methylphenidate long-acting (Ritalin LA, generics) methylphenidate controlled delivery (CD) (Metadate CD, generics) dexmethylphenidate ER (Focalin XR, generics) mixed amphetamine salts ER (Adderall XR, generics) 	<ul style="list-style-type: none"> Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	<ul style="list-style-type: none"> budesonide ER 9 mg capsules (Ortikos) 	<ul style="list-style-type: none"> budesonide ER tablets (Entocort EC, generics) other corticosteroids 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Corticosteroids	<ul style="list-style-type: none"> dexamethasone 20 mg tables (Hemady) 	<ul style="list-style-type: none"> dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	<ul style="list-style-type: none"> fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) 	<ul style="list-style-type: none"> fluticasone (Flovent Diskus) fluticasone (Flovent HFA) fluticasone furoate (Arnuity Ellipta) [non formulary] beclomethasone (QVAR) [non formulary] budesonide (Pulmicort Flexhaler) [non formulary] ciclesonide (Alvesco) [non formulary] flunisolide (Aerospan) [non formulary] mometasone (Asmanex Twisthaler) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	<ul style="list-style-type: none"> fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) 	<ul style="list-style-type: none"> fluticasone/salmeterol (Advair Diskus) fluticasone/salmeterol (Advair HFA) fluticasone/vilanterol (Breo Ellipta) [non formulary] mometasone/formoterol (Dulera) [non formulary] budesonide/formoterol (Symbicort) [non formulary] fluticasone/salmeterol (AirDuo Resplick) [non formulary] 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> levamlodipine (Conjupri) 	<ul style="list-style-type: none"> amlodipine felodipine nifedipine diltiazem verapamil 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	GI-2 Agents	<ul style="list-style-type: none"> metoclopramide nasal spray (Gimoti) 	<ul style="list-style-type: none"> metoclopramide oral tablet (Reglan generics) metoclopramide oral solution (Reglan, generics) metoclopramide orally disintegrating tablet (Reglan ODT) 	<ul style="list-style-type: none"> June 2 2021
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% solution clobetasol 0.05% solution, shampoo fluocinonide 0.05% solution calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% ointment, cream, solution clobetasol 0.05% ointment, cream fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> betamethasone propylene glycol 0.05% cream clobetasol propionate 0.05% cream and ointment clobetasol propionate/emollient 0.05% cream desoximetasone 0.25% cream and ointment fluocinonide 0.05% cream and ointment fluocinonide/emollient base 0.05% cream halobetasol propionate 0.05% ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> adapalene 0.1% lotion, gel, cream adapalene 0.3% gel clindamycin phosphate 1% gel, cream, lotion, and solution clindamycin/ benzoyl peroxide 1.2% - 5% gel tazarotene 0.1% cream tretinoin 0.025%, 0.05%, and 0.1% cream tretinoin 0.01% and 0.025% gel 	<ul style="list-style-type: none"> 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

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

August 2021

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on August 4 and 5, 2021. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

- 1. Status of February and May 2021 Minutes**—Both the February 2021 and May 2021 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) February 2021 Meeting—Utilization Management: Updated PAs for new FDA-approved indications or age ranges:** Due to the delay in the February 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 June, 2021. PAs where recommended updates to criteria that are not due to the above reasons are awaiting the BAP meeting and Director’s signature.

- b) February 2021 Meeting—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. Due to the BAP delay, the empagliflozin PA was updated on June 4, 2021 to allow use for patients with heart failure and reduced ejection fraction or chronic kidney disease who do not have diabetes. Updates to the remaining SGLT-2 inhibitors await the BAP meeting and signing by the Director.

- c) November 2020 Meeting—Attention Deficit Hyperactivity Drugs (ADHD): lisdexamfetamine (Vyvanse) and Mandatory Mail requirements:** Vyvanse was added to the Expanded MTF/Mail Pharmacy Initiative (EMMPI) program at the November 2020 P&T Committee meeting, with an implementation date of March 3, 2021. Due to operational issues the EMMPI requirement for Vyvanse was removed on May 14, 2021. There are currently no schedule II ADHD drugs included on the EMMPI program.

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. Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the three agents in the BTK inhibitor subclass, comprised of ibrutinib (Imbruvica), acalabrutinib (Calquence), and zanubrutinib (Brukinsa). The Committee comprehensively reviewed the evidence including what was reviewed when Imbruvica (tablet formulation), Calquence, and Brukinsa were presented as innovators in May 2018, February 2018, and February 2020, respectively.

The BTK inhibitors are indicated for use in chronic lymphocytic leukemia (CLL) and a variety of non-Hodgkin lymphoma subtypes including small lymphocytic lymphoma (SLL) and mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), non-germinal center B-Cell diffuse large B-Cell lymphoma (non-GCB-DLBCL), and Waldenström macroglobulinemia (WM).

The comprehensive evidence review included information from individual clinical trial data; guidelines from the National Cancer Comprehensive Network (NCCN), American Society of Clinical Oncology (ASCO), and European Society for Medical Oncology (ESMO); meta-analyses; FDA labeling; current Military Health System (MHS) patterns of use; and MHS provider comments.

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

- Ibrutinib (Imbruvica) has the greatest number of FDA-approved indications, guideline-recommended uses, and the most voluminous and validated evidence base. In the Military Health System, it is the most utilized and the de facto preferred agent by oncologists.
- Where data is available, by indirect comparison, via network meta-analysis, and in head-to-head trials, all three agents appear to be equally clinically effective.
- While their safety profiles largely overlap, each agent has unique features. Specialists will tailor their choice of agent based on patient comorbidities.
- Acalabrutinib (Calquence) and zanubrutinib (Brukinsa) have favorable safety profiles relative to ibrutinib (Imbruvica) among certain clinically significant adverse events. Some providers prefer acalabrutinib over ibrutinib, either for specific patient comorbidities or indications.
- Zanubrutinib (Brukinsa) is the newest of the three agents, and has an immature evidence base and generally lower rankings where guidelines recommend use, when compared to the other two drugs.
- The ibrutinib capsule formulation allows for more flexible dosage titration, either for increasing the dose or reducing the dose due to adverse events, compared to the ibrutinib tablets.
- Once a patient's disease becomes refractory to one BTK inhibitor, it tends to be refractory to all BTK inhibitors.

Relative Cost-Effectiveness Analysis and Conclusion—Cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that acalabrutinib (Calquence), ibrutinib (Imbruvica), and zanubrutinib (Brukinsa) were all cost effective, when compared to each other. For Imbruvica, the capsule formulations are more cost effective than the tablet formulations.
- 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 acalabrutinib (Calquence), ibrutinib (Imbruvica), and zanubrutinib (Brukinsa) as UF demonstrated the greatest cost avoidance for the MHS.

1. COMMITTEE ACTION: UF RECOMMENDATION—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - acalabrutinib (Calquence)
 - ibrutinib (Imbruvica)

- zanubrutinib (Brukinsa)
 - NF – None
 - Tier 4/Not Covered – None
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—Existing PA criteria currently apply to all three drugs. For the ibrutinib tablets, further justification is required on the PA to state why the capsules cannot be used, due to more flexible dosage titration with the capsules. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) minor updates to the ibrutinib PA criteria to reflect the clinical and cost differences of the capsules and tablets, and recommended maintaining the current PA criteria for acalabrutinib and zanubrutinib. See Appendix C for the full criteria.

Note that Brukinsa received new FDA indications following the August 2021 P&T Committee meeting, and prior to the BAP meeting and P&T Committee minutes' signing. The new indications are noted in Appendix C in bold.

3. **COMMITTEE ACTION: QUANTITY LIMITS**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs. See Appendix D for the full QLs.
4. **EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS**—Due to the complex dose adjustments and monitoring for the class, the P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current status - acalabrutinib, ibrutinib and zanubrutinib are not included on the EMMPI program.
5. **COMMITTEE ACTION: UF, PA, QL EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Based on the P&T Committee's recommendation, the effective date is March 2, 2022.

B. Laxatives-Cathartics-Stool Softeners: Bowel Preparations Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the bowel preparations indicated for colon cleansing in preparation for colonoscopy. Drugs in the class include generic preparations comprised of polyethylene glycol (PEG) 3350 with and without additional electrolytes. Six branded products are marketed, Osmoprep, Plenvu, Clenpiq, Suprep, Sutab, and Moviprep. The class has not been previously reviewed for

formulary status, although Clenpiq, Plenvu and Sutab were evaluated as newly approved drugs at the February 2018, November 2018, and February 2021, respectively.

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

- Several different dosage formulations are available, including powders for reconstitution, oral solutions, and tablets. The bowel preparations vary in the amount of liquid that is required for consumption, ranging from 2 to 4 liters.
 - Full-volume (standard volume) preparations require consumption of 4 liters (L) of total volume and include Colyte, GoLYTELY, NuLYTELY, and TriLyte, and their generics.
 - Low-volume preparations range from 2 to 3.5 liters of total volume consumed and include Osmoprep (2 L), Plenvu (2 L), Clenpiq (2.2 L), Suprep (3 L), Sutab (3 L), and Moviprep (3 L). Although the tablet formulations (Osmoprep and Sutab) do not require mixing of solutions, significant additional water consumption is still required.
- There do not appear to be clinically relevant differences in efficacy, based on indirect evidence. Compared with standard-volume preparations, low volume products demonstrate superior bowel prep completion rate, improved adenoma detection rates, improved patient satisfaction for the prep and procedure, and increased likelihood that the patient will undergo future colonoscopy.
- Professional treatment guidelines recommend split-dose regimens over single dose traditional regimens (which are administered the day before the colonoscopy), due to improved cleansing. However, no one specific agent is recommended over another.
- Tolerability issues, including poor palatability and the requirement for large volumes of liquid may result in an inadequate bowel prep. Safety concerns vary by product and include gastrointestinal obstruction/perforation, gastric retention, and electrolyte disturbances, potentially exacerbating heart failure or renal dysfunction. PEG products are preferred in patients with heart failure, renal dysfunction or liver disease.
- Specific clinical considerations for the products are as follows:
 - **PEG 3350 with electrolytes powder for solution (Colyte, GoLYTELY, TriLyte, NULYTELY)** advantages include availability in generic formulations; approval for children as young as 6 months of age (TriLyte and NuLYTELY); additional indications for bowel cleansing prior to barium enema X-ray examinations (Colyte and GoLYTELY); and availability in sulfate-free formulations (TriLYTE

and NULYTELY). Disadvantages include the large volumes required (4 L), poor taste, and tolerability issues.

- **PEG 3350 with electrolytes powder for solution (MoviPrep)** is a low volume preparation (3 L) that has high MHS utilization, is well tolerated in elderly patients, and was frequently mentioned by providers as requiring inclusion on the formulary. MoviPrep should be used with caution in patients with phenylketonuria.
 - **PEG 3350 with electrolytes powder for solution (Plenvu)** is a low volume (2 L) preparation that is similar to MoviPrep.
 - **Sodium picosulfate, magnesium oxide, anhydrous citric acid oral solution (Clenpiq)** is a low volume formulation (2.2 L) indicated for patients 9 years of age and older that is already constituted and well-tolerated. Electrolyte disturbances can occur.
 - **Sodium sulfate, potassium sulfate, magnesium sulfate, concentrated oral solution (Suprep)** is a low volume (3 L) product indicated for patients 12 years of age and older. Safety concerns include a higher risk of nausea, vomiting and abdominal distension compared to other products. Overall Suprep offers no compelling clinical advantages relative to the other bowel prep agents.
 - **Sodium sulfate, potassium chloride, magnesium sulfate tablets (Sutab):** Although Sutab provides the convenience of a tablet, it requires consumption of 24 tablets and 3 L of extra volume. Overall Sutab offers no compelling clinical advantages relative to the other bowel prep agents.
 - **Sodium phosphate tablets (Osmoprep)** requires 32 tabs and 2 L of extra volume and has existing low utilization in the MHS. Significant safety concerns include the boxed warning for acute phosphate nephropathy. Overall Osmoprep offers no compelling clinical advantages relative to the other bowel prep agents.
 - **Sodium picosulfate, magnesium oxide, anhydrous citric acid power packets (Prepopik)** is an older formulation that was voluntarily discontinued from the market.
- In order to meet the needs of MHS beneficiaries, at least one product approved in young children, and at least one low volume product is required.

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

- CMA results showed that the generic standard volume PEG formulations (Colyte, GoLYTELY, NULYTELY, TriLYTE) were the most cost effective bowel preparations, followed by the branded products (ranked from most cost effective to least cost effective) Moviprep, Plenvu, Clenpiq, Suprep, Sutab and Osmoprep.
- 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 the generic PEG formulations, Moviprep, Plenvu, and Clenpiq as UF, and designating Suprep, Sutab, Osmoprep and Prepopik as NF, demonstrated significant cost avoidance for the MHS.

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

- UF
 - PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics)
 - PEG 3350, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (NuLYTELY, TriLyte, generics)
 - PEG 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for oral solution (Moviprep)
 - PEG 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for solution (Plenvu)
 - sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution (Clenpiq) (*moves from NF to UF*)
- NF
 - sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution (Suprep) (*moves from UF to NF*)
 - sodium sulfate, potassium chloride and magnesium sulfate tablets (Sutab)
 - sodium phosphate tablets (Osmoprep) (*moves from UF to NF*)
 - sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets (Prepopik) (*moves from UF to NF*)
- Tier 4/Not Covered: None

2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (16 for, 1 opposed, 1 abstained, 0 absent) adding PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride

and potassium chloride powder for oral solution (generic GoLYTELY) to the BCF, based on cost effectiveness and existing high utilization in the MHS.

3. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Suprep, Sutab, Osmoprep and Prepopik. See Appendix B for the full criteria.
4. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) AND NF TO MAIL REQUIREMENTS**—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) exempting the non-formulary bowel preparations (Sutab, Suprep, Osmoprep, Prepopik) from the EMMPI program and nonformulary to mail requirement due to the acute use exception.
5. **COMMITTEE ACTION: UF, BCF, MN, EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) 1) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Note that letters won't be sent to patients who have received Suprep, Sutab, Osmoprep or Prepopik, due to the acute use of these drugs, and since the majority of prescriptions are for one-time use. Based on the P&T Committee's recommendation, the effective date is March 2, 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 for group 1: (16 for, 0 opposed, 1 abstained, 1 absent); group 2: (14 for, 1 opposed, 1 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 August 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: 16 for, 0 opposed, 1 abstained, 1 absent; group 2: 14 for, 0 opposed, 2 abstained, 2 absent; and for Accrufer 12 for, 4 opposed, 1 abstained, 1 absent) the following:

- UF:

- dasiglucagon injection (Zegalogue) – Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents for severe hypoglycemia
- infiratinib (Truseltiq) – Oncological agent for cholangiocarcinoma
- omalizumab syringe (Xolair) – Respiratory Interleukin for asthma, nasal polyps, and chronic idiopathic urticaria (CIU)
- pegcetacoplan injection (Empaveli) – Hematological agent for paroxysmal nocturnal hemoglobinuria (PNH)
- relugolix/estradiol/norethindrone (Myfembree) – Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
- riluzole oral film (Exservan) – Miscellaneous neurological agent for amyotrophic lateral sclerosis (ALS)
- semaglutide injection (Wegovy) – Weight loss agent and a GLP-1 receptor antagonist for the treatment of obesity
- sotorasib (Lumakras) – Oncological agent for non-small cell lung cancer (NSCLC)
- NF:
 - drospirenone/estetrol (Nextstellis) – Contraceptive Agents: Monophasics with 20 mcg estrogen
 - ferric maltol (Accrufer) – Electrolyte-Mineral-Trace Element Replacement for iron deficiency
 - viloxazine extended release (Qelbree) – Non-Stimulant for Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17 years of age
- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
 - rosuvastatin/ezetimibe (Roszet) – Antilipidemic 1
 - Roszet was recommended as Tier 4 as it has little to no additional clinical effectiveness relative to the statins that are combined with ezetimibe, and the needs of TRICARE beneficiaries are met by available alternative agents. Formulary alternatives include rosuvastatin taken with ezetimibe separately, atorvastatin with ezetimibe, simvastatin/ezetimibe (Vytorin), and the PCSK-9 inhibitors.

B. COMMITTEE ACTION: MN CRITERIA—The P&T Committee recommended MN criteria for the following: 16 for, 0 opposed, 1 abstained, 1 absent for

Qelbree; 14 for, 0 opposed, 2 abstained, 2 absent for Nextstellis, and 12 for, 4 opposed, 1 abstained, 1 absent for Accrufer. See Appendix B for the full criteria.

C. COMMITTEE ACTION: PA CRITERIA—The P&T Committee recommended (group 1 16 for, 0 opposed, 1 abstained, 1 absent; group 2 14 for, 0 opposed, 2 abstained, 2 absent, and for Accrufer (12 for, 4 opposed, 1 abstained, 1 absent) the following (see Appendix C for the full criteria):

- Weight loss drugs: Applying manual PA criteria to new users of Wegovy, consistent with the requirements for Saxenda and the other weight loss drugs. A trial of all the other weight loss drugs except Saxenda will be required before Wegovy.
- Oncologic drugs: Applying manual PA criteria to new users of Lumakras and Truseltiq, consistent with PA requirements in general for oncology drugs.
- Respiratory Interleukins: Applying manual PA criteria to new users of the Xolair syringe, consistent with the requirements for the other respiratory biologics intended for patient self-administration.
- LHRH Agonists-Antagonists: Applying manual PA criteria to new users of Myfembree, similar to the requirements for Oriahnn.
- ALS Drugs: Applying manual PA criteria to new users of Exservan oral film, consistent with the requirements for riluzole oral suspension (Tiglutik).
- Applying manual PA criteria to new users of Accrufer, Empaveli, Nextstellis, and Qelbree.

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

PERIOD—The P&T Committee recommended group 1 (16 for, 0 opposed, 1 abstained, 1 absent); group 2 (14 for, 0 opposed, 2 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/Not Covered 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

- a) **Miscellaneous Insulin Devices—Omnipod and Omnipod DASH: PA and QLs:**
The Omnipod and Omnipod DASH cartridge pods are wearable, tubeless insulin management systems that are controlled using a personal diabetes manager (PDM). These FDA-approved medical devices must be filled with insulin by the patient, and supply up to 3 days (72 hours) of insulin. Omnipod systems are meant for those who require multi-day injections of insulin (defined as at least three times daily). The smartphone-like PDM allows for remote management of basal and bolus insulin dosing.

The Omnipod and Omnipod DASH are covered under the TRICARE pharmacy benefit, but the starter kit is packaged with the actual device and is not a pharmacy benefit. Prior authorization was recommended to reflect current TRICARE Policy Manual coverage requirements for external infusion pumps (EIPs).

In addition to PA, QLs were also recommended for Omnipod and Omnipod DASH, along with new QLs for similar external infusion pump, V-Go. (See Appendix D)

COMMITTEE ACTION: NEW MANUAL PA CRITERIA FOR OMNIPOD AND OMNIPOD DASH CARTRIDGES; NEW QLs for OMNIPOD, OMNIPOD DASH, and V-Go AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for new and current users of Omnipod and Omnipod DASH cartridge pods to ensure appropriate use in the expected patient population, as well as to ensure continued monitoring of blood glucose levels and proper patient education on the device. (See Appendix C for full criteria).

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) the new PA criteria will become effective the first Wednesday 90 days after the signing of the minutes. DHA will send letters to beneficiaries affected by the new PA requirements for these products, as new and current users will be subject to the PA. (May 18, 2022)

QLs were also recommended for Omnipod, Omnipod DASH, and V-Go, to ensure appropriate use. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the QLs for Omnipod, Omnipod DASHm and V-Go become effective the first Wednesday 2 weeks after signing of the minutes (prior to implementation of the PA). (See Appendix D)

- b) **Laxatives-Cathartics-Stool Softeners – Lactulose Packet (Kristalose, generics)**—Lactulose formulated in packets (Kristalose brand and generic) are not

cost effective relative to other formulary lactulose products or other laxatives (i.e., glycerin, lactitol, polyethylene glycol 3350, sorbitol), which are all available in low-cost formulations. PA was recommended to require a trial of other cost effective lactulose solutions or laxatives prior to Kristalose packets.

COMMITTEE ACTION: NEW PA CRITERIA FOR KRISTALOSE, BRAND AND GENERICS AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for lactulose packets (Kristalose, generics) in new users, due to the significant cost differences compared with numerous available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2022). See Appendix C for the full criteria.

- c) **Vitamins: Prenatal – Prenatal Multivitamins (Neonatal-DHA, Neonatal FE)**—Neonatal-DHA and Neonatal FE are prenatal dietary supplements manufactured by a single company and require a prescription prior to dispensing. The primary ingredients of Neonatal-DHA and Neonatal FE are similar to that found in Azesco, Zalvit, and Trinaz, which require manual PA. Several 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. Manual PA criteria were recommended for all new and current users of Neonatal-DHA and Neonatal FE, to require a trial of cost-effective formulary prenatal vitamins first.

COMMITTEE ACTION: NEW PA CRITERIA FOR NEONATAL-DHA AND NEONATAL FE AND IMPLEMENTATION PLAN—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for Neonatal-DHA and Neonatal FE (regardless of the woman's age) in new users, due to the significant cost differences compared with numerous available alternative agents. The new PA will become effective the first Wednesday 90 days after the signing of the minutes. See Appendix C for the full criteria.

2. Updated PA Criteria and Step Therapy

Updates to the manual PA criteria and step therapy were recommended for the following products, due to availability of cost-effective alternative treatments, results from clinical trial data, clinical practice guideline updates, or provider recommendation. The updated PAs and step therapy outlined below will apply to new users. See Appendix C for full criteria.

- a) **Multiple Sclerosis Agents – ozanimod (Zeposia)**—Zeposia is a sphingosine-1 phosphate receptor modulator originally approved for treating relapsing forms of multiple sclerosis. It recently gained approval for ulcerative colitis

(UC), another type of immune-mediated inflammatory disorder. At the time of review the trial supporting Zeposia for UC was not published. Other treatments, including non-biologics (e.g., azathioprine, sulfasalazine) and the targeted immunomodulatory biologic (TIBs) adalimumab (Humira) are well-established therapies for UC, and are more cost effective than Zeposia. The Zeposia PA was updated to allow for treatment of UC after a trial of non-biologic systemic therapy and trial of Humira.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updating the current PA criteria for Zeposia to require more clinically established and cost effective treatments first. See Appendix C for the full PA criteria.

- b) Migraine Agents —rimegepant (Nurtec ODT): PA and QLs; and ubrogepant (Ubrelvy) and lasmiditan (Reyvow) – PA update:** These three oral drugs were originally approved for acute treatment of migraine headache, and were reviewed at the May 2020 P&T Committee meeting. PA criteria currently apply. Rimegepant orally disintegrating tablets (Nurtec ODT) is now FDA-approved for preventive treatment of episodic migraine in adults. Other migraine preventive medications (e.g., antiepileptics, beta blockers, antidepressants, and the injectable calcitonin gene-related peptide [CGRP] antagonists) are available that have shown greater reductions in monthly migraine days than Nurtec ODT, based on indirect comparison, and are more cost-effective.

The PA criteria for Nurtec ODT was updated to require a trial of other preventive medications (oral agents, and injectable CGRPs) first. QLs were also updated for Nurtec ODT, as the new preventive indication allows for every other day dosing. The PAs for Nurtec ODT, Ubrelvy, and Reyvow were also updated to include renewal criteria, to assess for efficacy.

COMMITTEE ACTION: NURTEC ODT, UBRELVY, AND REYVOW, UPDATED MANUAL PA CRITERIA AND NURTEC ODT QL—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updating the current PA criteria for Nurtec ODT, Ubrelvy, and Reyvow and to also update the QLs on Nurtec ODT. See Appendix C for the full PA criteria and Appendix D for QLs.

3. Updated PA Criteria for New FDA-Approved Indications or Expanded Age Ranges

Updates to the PA criteria for several drugs were recommended due to new FDA-approved indications and expanded age ranges. The updated PA criteria summarized below will apply to new users. See Appendix C for full criteria.

- **Oncological Agents–avapritinib (Ayvakit)**—Includes the new indication for adult patients with advanced systemic mastocytosis (comprises patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia)
- **Targeted Immunomodulatory Biologic secukinumab (Cosentyx)**—Manual PA criteria now allow use in pediatric patients 6 years of age and older, as well as in adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- **Overactive Bladder Agents**
 - **mirabegron tablets and granules (Myrbetriq)**—The manual PA criteria were updated to allow for the new indication for treatment of neurogenic detrusor overactivity (NDO) in patients 3 years of age and older (for the granules) (*note that the granules were reviewed as an innovator at the November 2021 meeting*) and weighing 35 kg or more (for the tablets).
 - **fesoterodine (Toviaz)**—Manual PA criteria were updated to allow for the new indication for treatment of neurogenic detrusor overactivity (NDO) in patients 6 years of age and older and weighing more than 25 kg.
- **Hepatitis C Agents: Direct Acting Agents– sofosbuvir/velpatasvir (Epclusa) and authorized generic; glecaprevir/pibrentasvir (Mavyret)**—The manual PA criteria now allow use in pediatric patients 3 years of age and older as well as adults for treatment of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6.
- **ADHD Agents: Stimulants – amphetamine sulfate ODT (Evekeo ODT)**—The manual PA criteria now allow use in pediatric patients between the ages of 3 to 17 years for treatment of ADHD.
- **Gastrointestinal-2 Agents – obeticholic acid (Ocaliva)** —The manual PA criteria was revised and updated for safety information to narrow the indication for the patient population with primary biliary cholangitis (PBC), based on information from the manufacturer.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—

The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) updates to the manual PA criteria for Ayvakit, Cosentyx, Myrbetriq, Toviaz, Epclusa and authorized generic, Mavyret, Evekeo ODT, and Ocaliva. See Appendix C for the full PA criteria.

B. Quantity Limits

1. **General QLs:** QLs were reviewed for the newly approved drugs where there are existing QLs for the class, (including hypoglycemia agents, electrolyte-mineral-trace element replacements, oncological agents, and respiratory interleukins), and a previously reviewed targeted immunomodulatory biologic (Stelara 90 mg syringe).

COMMITTEE ACTION: QLs—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Zegalogue, Lumakras, Truseltiq, Xolair syringe, Accrufer, and Stelara 90 mg strength only. See Appendix D for the QLs.

2. **Antiinfectives: Anti-Helminthics: ivermectin (Stromectol):** A review of MHS prescription data noted a large increase in the quantity of ivermectin dispensed at the Mail Order and Retail pharmacies, likely related to off-label use for COVID-19 infection. The recently updated 2021 updated National Institutes of Health (NIH) COVID-19 treatment guidelines state there is insufficient evidence to recommend either for or against the use of ivermectin for treatment of COVID-19. A quantity limit of 60 tablets per prescription fill at all 3 points of service (POS) were recommended to minimize potential off-label ivermectin use. The QLs will not impact the treatment regimens for FDA-approved uses (e.g., intestinal strongyloidiasis, scabies). The QLs noted here will not impact any DoD-conducted investigational trials. (See Appendix D)

COMMITTEE ACTION: QLs—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for ivermectin. See Appendix D for the QLs.

C. Updated PAs and QLs Implementation Periods

COMMITTEE ACTION: PA AND QLs IMPLEMENTATION

PERIOD—The P&T Committee recommended the following implementation periods:

- (16 for, 0 opposed, 1 abstained, 1 absent)
 - Updates to the current PA criteria in new users for Zeposia will become effective the first Wednesday 30 days after the signing of the minutes (Month day, 2021).
 - Updates to the current PA criteria in new users for Nurtec ODT, Ubrelvy, and Reyvow will become effective the first Wednesday 60 days after the signing of the minutes. (*Note that implementation occurred on October 5, 2021.*)
 - Updates to the current PA criteria in new users for the oncology drug Ayvakit; the TIB Cosentyx; the Overactive Bladder Agents Myrbetriq and Toviaz; the hepatitis C drugs Epclusa and authorized generic and Mavyret; the ADHD stimulant Evekeo ODT; the GI-2 agent Ocaliva will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2021)
- (17 for, 0 opposed, 0 abstained, 1 absent) the QLs listed in Appendix D will become effective the first Wednesday **2 weeks** after the signing of the minutes in all POS. Note that the QLs for Nurtec

ODT will be implemented before the PA is updated. (March 2, 2022).

VII. 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. COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMPI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (March 2, 2022).

- **Oncological Agents: Multiple Myeloma**—designating **selinexor (Xpovio) 40 mg twice weekly dosing, 40 mg, 60 mg, 80 mg, and 100 mg once weekly dosing** as UF, with the same manual PA criteria requirements, QL, and specialty status as Xpovio 20 mg.
- **TIBs:**
 - Designating **adalimumab (Humira CF) 80 mg/0.8 mL pen carton and starter package for pediatric UC** as UF, step-preferred, same manual PA criteria, QL, specialty status, and EMMPI List status similar to various other strengths and dosage forms of Humira CF.
 - Designating **risankizumab-rzaa (Skyrizi) 150 mg/mL pen injector and single syringe** as NF, non-step-preferred, same MN criteria, manual PA criteria, QL, specialty status, and EMMPI List status similar to Skyrizi 75 mg single-use prefilled syringe.
 - Designating **secukinumab (Cosentyx) 75 mg/0.5 mL syringe** as UF (step therapy required), same manual PA criteria, QL, specialty status, and EMMPI List status similar to Cosentyx 150 mg and 300 mg syringes and pens.
- **Pancreatic Enzyme Replacement Therapy (PERT)**—designating **lipase/protease/amylase (Pancreaze) 37k-97.3k capsule** as NF, same MN criteria, manual PA criteria, and EMMPI List status similar to various other strengths of Pancreaze.

- **Neurological Agents Miscellaneous: Movement Disorders**—designating **valbenazine (Ingrezza) 60 mg capsule** as UF, same manual PA criteria, and QL similar to Ingrezza 40 mg and 80 mg.
- **Anticonvulsants-Antimania Agents**—designating **cenobamate (Xcopri) 250 mg tablet** as UF and specialty status similar to other strengths of Xcopri.
- **Oncological Agents**—designating **avapritinib (Ayvakit) 25 mg and 50 mg tablets** as UF, same manual PA criteria, QL, and specialty status similar to Ayvakit 100 mg, 200 mg, and 300 mg.
- **Cystic Fibrosis Agents**—designating **elexacaftor/tezacaftor/ivacaftor (Trikafta) 50-25-37.5/75 mg tablet** as UF, same manual PA criteria, QL, and specialty status similar to Trikafta 100-50-75 mg/150 mg.
- **Calcium Channel Blocking Agents**—designating **nimodipine (Nymalize) 60 mg/10 mL oral syringe** as UF similar to Nymalize 30 mg/5 mL oral syringe.

**VIII. PULMONARY 3 AGENTS: COMBINATIONS SUBCLASS—
BUDESONIDE/GLYCOPYRROLATE/FORMOTEROL (BREZTRI INHALER)
COPAYMENT CHANGE AND EMMPI PROGRAM INCLUSION**

Background—The fixed-dose triple combination inhalers containing an inhaled corticosteroid, long-acting muscarinic antagonist, and long-acting beta agonist (ICS/LAMA/LABA) were reviewed for formulary status at the February 2021 Committee meeting. Both budesonide/glycopyrrolate/formoterol (Breztri) and fluticasone/umeclidinium/vilanterol (Trelegy) were recommended to remain on the UF. Following the meeting, more favorable pricing for Breztri became available, making it the most cost effective triple combination inhaler. (Note that Committee recommendations from February 2021 had not yet been implemented at the time of the August 2021 P&T Committee meeting, due to the BAP zero-based review.) As a result the Tier 1 copay was recommended for Breztri. In addition it was recommended to include Breztri on the EMMPI Program, as the Mail Order and MTF points of service are more cost effective than at retail network pharmacies. (*Note that this is an update from the February 2021 P&T Committee meeting minutes.*)

Applying the Tier 1 copay at both Retail and Mail will also encourage use of the most cost-effective triple fixed-dose combination inhaler. Additionally, lowering the copay for this agent is consistent with 32 CFR 199.21(e)(3) from the Final Rule published June 3, 2020, in that the P&T 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.”

COMMITTEE ACTION: BREZTRI COPAYMENT CHANGE, EMMPI PROGRAM ADDITION, AND IMPLEMENTATION—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent)

changing the copay for Breztri inhaler from Tier 2 (brand) to the Tier 1 (generic) copay at the purchased care points of service (Retail and Mail), and adding Breztri to the EMMPI program. Implementation will two weeks after signing of the minutes. *(Note addition to EMMPI is a change from the February 2021 P&T Committee meeting minutes.)*

IX. BRAND OVER GENERIC AUTHORIZATION FOR AMBRISENTAN (LETAIRIS) AND POST-IMPLEMENTATION REVIEW FOR PULMONARY ARTERIAL HYPERTENSION (PAH) DRUGS

Background—The PAH drugs including the endothelin receptor antagonist subclass were most recently reviewed for formulary placement in May 2019. The Committee originally recommended brand over generic authorization and Tier 1 status for branded ambrisentan (Letairis). However, multiple cost effective generic formulations were subsequently available prior to the implementation date of October 2019, so this requirement was removed at the August 2019 meeting.

At this meeting, the Committee reviewed overall trends in utilization and expenditures since implementation of the formulary recommendations in October 2019. The post-implementation review did reveal that supply of cost effective generic ambrisentan was unreliable. As a result, branded Letairis is currently more cost-effective than generic ambrisentan products. Due to these supply and cost issues, the Committee recommended implementing the brand over generic requirements for ambrisentan, requiring use of the branded Letairis formulation prior to a generic formulation, and applying the Tier 1 copay to the brand.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT FOR AMBRISENTAN (LETAIRIS), PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) requiring brand Letairis over generic ambrisentan in all new and current users, based on cost effectiveness. The prescriber will provide patient-specific justification as to why branded Letairis cannot be used. The Tier 1 (generic) copayment will apply to brand Letairis. The effective date will two weeks after signing of the minutes in all POS. The “brand over generic” requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. See Appendix C for the full PA criteria for generic ambrisentan.

The authority for the Tier 1 copayment is codified in 32 CFR 199.21(j)(3):
[W]hen a blanket purchase agreement, incentive price agreement, Government contract, or other circumstances results in a brand pharmaceutical agent being the most cost effective agent for purchase by the Government, the P&T Committee may also designate that the drug be cost-shared at the generic rate.

X. 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 August 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 August 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: 16 for, 0 opposed, 1 abstained, 1 absent; group 2: 14 for, 0 opposed, 2 abstained, 2 absent; and for Accrufer 12 for, 4 opposed, 1 abstained, 1 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.

XI. PHARMACY AND THERAPEUTICS COMMITTEE ADMINISTRATIVE FUNCTIONS

Management of the TRICARE pharmacy benefit requires a wide variety of actions, with various levels of involvement of the DoD P&T Committee, the Beneficiary Advisory Panel (BAP), and the Director, DHA. In May 2005 when the UF Rule was implemented, the P&T Committee developed a comprehensive list of the functions associated with formulary management and categorized each into one of three decision pathways, depending on the level of involvement required. Periodic updates have been made (May 2017 and May 2019 meeting minutes.)

The Committee reviewed an update to allow implementation of PAs and QLs for shortages/pandemic/other emergencies, after consultation with the P&T Committee Chair and others as needed (e.g., Deputy Assistant Director – Health Affairs). Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QLs implemented in these situations will be removed when the situation has resolved. (See Appendix I.)

XII. ITEMS FOR INFORMATION

A. Biosimilar and Specialty Generics: The Committee was briefed on the definition of and FDA approval pathway for biosimilars, and the current market place spend and utilization for biosimilars and specialty medications and biologics.

XIII. ADJOURNMENT

The meeting adjourned at 1500 hours on August 6, 2021. The next meeting will be in November 2021.

Appendix A—Attendance: August 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 August 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—DoD P&T Committee and the Updated Table of Processes and Recommendation/Approval Authorities

Appendix J—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 Feb 2022

Date

Appendix A—Attendance: August 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	Interim Chief, Formulary Management Branch (Recorder)
MAJ Sebastian Welsh, MC	Army, Physician at Large
COL Jeffrey Neigh, MSC for COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, COL (Ret.) MC, USA for MAJ Wendra Galfand	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj 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
Lt Col Justin Lusk, BSC, for Col Corey Munro, BSC	Air Force, Pharmacy Officer
Maj Christin Destefano, MSC	Air Force, Oncologist
Lara Au, PharmD, BCOP	Oncology Pharmacist
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR William Agbo	DLA Troop Support
Bernadette Heron PharmD (Aug 4 th) Francine Goodman, PharmD (Aug 5 th)	Department of Veterans Affairs

Appendix A—Attendance: August 2021 P&T Committee Meeting

Guests	
CPT Hope Shen, MSC	DLA Troop Support
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Hilary Lewis	DHA Contracting Officer
Ms. Madison Northern	DHA Contracting
Mr. Hudson Tompkins	DHA Contracting
Ms. Grace Steier	DHA Contracting
Mr. Monroe Porter	DHA Contracting
Others Present	
MAJ Adam Davies, MSC	Chief, P&T Section, DHA Formulary Management Branch
Dr. Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Dr. Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
Dr. Amy Lugo, PharmD, BCPS	DHA Formulary Management Branch
LCDR Todd Hansen, MC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
Dr. Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Dr. Julia Trang, PharmD	DHA Formulary Management Branch
LCDR Giao Phung, MSC	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
Samantha Valliant	University of North Carolina at Chapel Hill PharmD student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
Class Review MN Criteria	
<ul style="list-style-type: none"> • sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution (Suprep) • sodium sulfate, potassium chloride and magnesium sulfate tablets (Sutab) • sodium phosphate tablets (Osmoprep) • sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets (Prepopik) <p>Laxatives-Cathartics-Stool Softeners: Bowel Preparations</p>	<ul style="list-style-type: none"> • No alternative formulary agent: the patient is unable to comply with the mixing requirements for the formulary alternatives. <p>Formulary alternatives: CoLyte, Galvilyte-A, Galvilyte-C, GalviLyte-G, NuLyteLy, GoLyteLy, TriLyte, MoviPrep, Clenpiq, Plenvu</p>
Newly Approved Drugs MN Criteria	
<ul style="list-style-type: none"> • drospirenone /estetrol (Nextstellis) <p>Contraceptive Agents: Monophasics with 20 mcg estrogen</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from formulary agents <p>Formulary alternatives: ethinyl estradiol/drospirenone (Yaz, Yasmin), ethinyl estradiol/levonorgestrel (Sronyx, generics), or any other formulary contraceptive agents</p>
<ul style="list-style-type: none"> • ferric maltol (Accrufer) <p>Electrolyte-Mineral-Trace Element Replacement</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from two other oral iron products (must be different salts) <p>Formulary alternatives: ferrous sulfate, ferrous gluconate, ferrous fumarate, and polysaccharide Fe complex</p>
<ul style="list-style-type: none"> • viloxazine (Qelbree) <p>ADHD Agents: Non-Stimulants</p>	<ul style="list-style-type: none"> • Use of formulary ADHD non-stimulant agents are contraindicated • Formulary ADHD non-stimulant agents resulted in or are likely to result in therapeutic failure <p>Formulary ADHD non-stimulant alternatives: atomoxetine (Strattera, generic), clonidine ER (Kapvay, generic), guanfacine ER (Intuniv, generic)</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
<ul style="list-style-type: none"> • ibrutinib (Imbruvica) <p>Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors</p>	<p>Updates from the August 2021 meeting are in bold</p> <p>Manual PA is required for new users of Imbruvica capsules and tablets.</p> <p><u>Manual PA Criteria:</u> Imbruvica is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for DoD • If the Rx is for Imbruvica tablets, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below. • • If the Rx is for the Imbruvica capsules, please continue with the PA criteria below. • If the Rx is for Imbruvica tablets, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below. • Patient is 18 years of age or older • Drug is prescribed by or in consultation with a hematologist/oncologist • Will be used in one of the following contexts: <ul style="list-style-type: none"> • Pretreatment to limit the number of cycles of RhyperCVAD/rituximab maintenance therapy for Mantle Cell Lymphoma • Second line (or subsequent therapy) for Mantle Cell Lymphoma • Second line (or subsequent therapy) for Marginal Zone Lymphoma • Second line (or subsequent therapy) for non-germinal center B cell-like Diffuse Large B Cell Lymphoma if unable to receive chemotherapy • Frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation <ul style="list-style-type: none"> • Patient fits one of the following categories: <ul style="list-style-type: none"> • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patients < 65 years old • Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation • Waldenström macroglobulinemia • Chronic Graft versus Host Disease • Monitor for bleeding, infection, hypertension, cardiac arrhythmias, cytopenias, and Tumor Lysis Syndrome • If the patient is female, she is not pregnant or planning to become pregnant • Breastfeeding female patients will be advised that the potential harm to the infant is unknown • All patients (males and females) of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. <p>Other non-FDA-approved uses are not approved, except as noted above PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • acalabrutinib (Calquence) <p>Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors</p>	<p>(Note – no changes to the PA criteria made at the August 2021 meeting)</p> <p>Manual PA is required for all new users of Calquence</p> <p><u>Manual PA Criteria:</u> Calquence is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Age 18 years of age or older • Must be prescribed by or in consultation with a hematologist/oncologist • Patient meets one of the following categories: <ul style="list-style-type: none"> • Patient must have pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 that had a short response duration to prior therapy (< median progression-free survival). • Patient will use acalabrutinib as frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation <ul style="list-style-type: none"> • Patient fits one of following categories: <ul style="list-style-type: none"> • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patients < 65 years old • Patient will use acalabrutinib as frontline or relapsed refractory therapy for CLL/SLL with del(17p)/TP53 mutation • If the patient has CLL, the patient's disease has no evidence of a BTK C481S mutation nor prior ibrutinib-refractory disease • Patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec • Monitor for bleeding, infection, cardiac arrhythmias, and cytopenias • If the patient is female and of childbearing potential, advise the patient of the risk of significant fetal harm • Female patients will not breastfeed during treatment and for at least 2 weeks following cessation of treatment • 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: _____. <p>Other non-FDA-approved uses are not approved, except as noted above PA does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • zanubrutinib (Brukinsa) <p>Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors</p>	<p>(Note – Changes made after the August 2021 meeting, and are in bold)</p> <p>Manual PA criteria apply to all new users of Brukinsa.</p> <p><u>Manual PA Criteria:</u> Brukinsa is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years if age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL). or • Patient has Waldenström’s macroglobulinemia (WM) or, a rare non-Hodgkin lymphoma • Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen • • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment • 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: _____. <p>Other non-FDA-approved uses are not approved. PA does not expire.</p>
Newly Approved Drug PAs	
<ul style="list-style-type: none"> • drospirenone /estetrol (Nextstellis) <p>Contraceptive Agents: Monophasics with 20 mcg estrogen</p>	<p>Manual PA criteria apply to all new users of Nextstellis.</p> <p><u>Manual PA criteria:</u> Nextstellis is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that ethinyl estradiol/drospirenone (Yaz, Yasmin) and numerous other contraceptives are available for TRICARE patients and do not require a PA. Providers are encouraged to consider changing the prescription to Yaz, Yasmin, or another formulary contraceptive • Patient has tried an ethinyl estradiol containing oral contraceptive and has had significant adverse effects attributed to the ethinyl estradiol component • Provider acknowledges that Nextstellis may be less effective in females with a body mass index (BMI) ≥ 30 kg/m² per the FDA label <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • ferric maltol (Accrufer) <p>Electrolyte-Mineral-Trace Element Replacement</p>	<p>Manual PA criteria apply to all new users of Accrufer.</p> <p><u>Manual PA criteria:</u> Accrufer is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has a documented diagnosis of iron deficiency • Patient is 18 years of age or older • Patient has tried and failed two oral iron products (must be different salts e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) for at least six weeks in duration for each product, unless contraindicated or clinically significant adverse effects are experienced. <ul style="list-style-type: none"> ○ The provider must provide the date of when the patient previously tried each medication, or the contraindication or clinically significant adverse effect that the patient experienced: ○ Oral iron product: _____ Date: _____ Contraindication or clinically significant adverse effect: _____ ○ Oral iron product: _____ Date: _____ Contraindication or clinically significant adverse effect: _____ • Provider acknowledges there is insufficient data on drug interactions at this time. <p>Non-FDA-approved uses are not approved. Prior authorization expires in 6 months.</p> <p><u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional 6 months for continuation of therapy if:</p> <ul style="list-style-type: none"> • Patient is still iron deficient • Documentation of clinically significant improvement in patient's iron deficiency required.
<ul style="list-style-type: none"> • infigratinib (Truseltiq) <p>Oncological Agents</p>	<p>Manual PA criteria apply to all new users of Truseltiq.</p> <p><u>Manual PA criteria:</u> Truseltiq is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. • The patient will be monitored for retinal pigment epithelial detachment, hyperphosphatemia, and soft-tissue mineralization • The drug is prescribed by or in consultation with a hematologist/oncologist • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 month after cessation of therapy • 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: _____. <p>Other non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • pegcetacoplan injection (Empaveli) <p>Hematological Agents</p>	<p>Manual PA criteria apply to all new users of Empaveli.</p> <p><u>Manual PA criteria:</u> Empaveli is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • Patient has been counseled on the appropriate administration of the drug via infusion pump • Patient has been vaccinated against certain encapsulated bacteria (e.g., <i>Streptococcus pneumoniae</i>, <i>Neisseria meningitidis</i> types A, C, W, Y, and B, and <i>Haemophilus influenzae</i> type B) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • riluzole oral film (Exservan) <p>Neurological Agents Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Exservan.</p> <p><u>Manual PA criteria:</u> Exservan is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is diagnosed with amyotrophic lateral sclerosis (ALS) • Patient has dysphagia/swallowing dysfunction <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • relugolix/estradiol/norethindrone (Myfembree) <p>Luteinizing Hormone-Releasing Hormone Agonists-Antagonists</p>	<p>Manual PA criteria apply to all new users of Myfembree. Note that the PA criteria are similar to Oriahnn, with differences bolded below.</p> <p><u>Manual PA criteria:</u> Myfembree is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD) • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or a history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 • Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs or if the patient has a sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions • Patient does not have uncontrolled hypertension • Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly • Patient does not have osteoporosis • Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes • Patient does not have a history of breast cancer or other hormonally-sensitive malignancies • Patient does not have known liver impairment or disease • Provider agrees to counsel patients on the signs and symptoms of liver injury • Patient does not have undiagnosed abnormal uterine bleeding • Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors • Patient is not using Myfembree with oral P-gp inhibitors (e.g., erythromycin) or combined P-gp and strong CYP3A inducers (e.g., rifampin) <p>Non-FDA-approved uses are not approved including contraception or pain associated with endometriosis.</p> <p>Prior authorization expires after 24 months (lifetime expiration). Cumulative treatment with Oriahnn and Myfembree will not exceed 24 months during the patient's lifetime.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • semaglutide injection (Wegovy) <p>Weight Loss Agents</p>	<p>Manual PA criteria apply to all new users of Wegovy.</p> <p><u>Manual PA criteria:</u> Wegovy is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has a BMI \geq to 30, or a BMI \geq to 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried and failed or has a contraindication to all of the following agents (generic phentermine, Qsymia, Xenical, and Contrave). (Note: provider must include the date of use and duration of therapy or contraindication to the drug) <ul style="list-style-type: none"> ○ Phentermine: Date _____ Duration of therapy _____ ○ Qsymia: Date _____ Duration of therapy _____ ○ Xenical: Date _____ Duration of therapy _____ ○ Contrave: Date _____ Duration of therapy _____ • If the patient is diabetic, they must have tried and failed metformin and the DoD's preferred GLP1RAs (Trulicity and Bydureon BCise) • If the patient is an active duty service member, the individual is enrolled in a Service-specific Health/Wellness Program AND will adhere to Service policy, AND will remain engaged throughout course of therapy • Patient is not pregnant • Concomitant use of Wegovy with other GLP1RA drugs is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or does not have a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Non-FDA approved uses are NOT approved including diabetes mellitus and for those less than 18 years of age. • Initial prior authorization expires after 4 months and then annually. <p>Non-FDA-approved uses are not approved, including for diabetes mellitus and for patients younger than 18 years of age.</p> <p>Initial prior authorization expires after 4 months, and then annually</p> <p><u>Renewal PA Criteria:</u> Wegovy will be approved for an additional 12 months if the following are met:</p> <ul style="list-style-type: none"> • The patient is currently engaged in behavioral modification and remains on a reduced calorie diet • Wegovy will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant • Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • sotorasib (Lumakras) <p>Oncological Agents: Lung Cancer</p>	<p>Manual PA criteria apply to all new users of Lumakras.</p> <p><u>Manual PA criteria:</u> Lumakras is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test • The patient will be monitored for interstitial lung disease and hepatotoxicity • The drug is prescribed by or in consultation with a hematologist/oncologist • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • 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: _____. <p>Other non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • viloxazine (Qelbree) <p>ADHD Agents: Non-Stimulants</p>	<p>Manual PA criteria apply to all new users of Qelbree.</p> <p><u>Manual PA criteria:</u> Qelbree is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 6 to 17 years of age • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed, had an inadequate response, OR contraindication to amphetamine salts XR (Adderall XR, generic) or other long acting amphetamine or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to methylphenidate OROS and other (Concerta, generic) or other long acting methylphenidate or derivative drug • Patient has tried and failed, had an inadequate response, OR contraindication to at least one non-stimulant ADHD medication (generic formulations of Strattera, Kapvay, or Intuniv) <p>Non-FDA-approved uses are not approved (to include depression and anxiety). Prior authorization does not expire.</p>

<ul style="list-style-type: none"> • omalizumab syringe (Xolair) <p>Respiratory Interleukins</p>	<p>Manual PA criteria apply to all new users of Xolair syringe.</p> <p><u>Manual PA criteria:</u> Xolair is approved for initial therapy for 12 months if <u>all</u> criteria are met:</p> <p>For all indications:</p> <ul style="list-style-type: none"> • Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc. • Patient has received at least 3 doses of Xolair under the guidance of a healthcare provider without experiencing any hypersensitivity reactions • Provider agrees to ensure that the patient or caregiver is able to recognize symptoms of anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue. Provider agrees to counsel the patient that anaphylaxis has occurred up to 2 hours post administration and appropriate monitoring will occur. • Provider agrees to ensure that the patient or caregiver is able to treat anaphylaxis appropriately and consider co-prescribing epinephrine. • Provider agrees to ensure that the patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe with proper technique according to the prescribed dosing regimen • For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or dupilumab [Dupixent]) <p>For Asthma:</p> <ul style="list-style-type: none"> • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist, pulmonologist, or asthma specialist • The patient has moderate to severe asthma with baseline IgE levels that are greater than 30 IU/ml • The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: <ul style="list-style-type: none"> ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi) ▪ Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse) ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zflo) <p>For chronic rhinosinusitis with nasal polyposis:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: <ul style="list-style-type: none"> ▪ Presence of nasal polyposis is confirmed by imaging or direct visualization AND ▪ At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Xolair will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments <ul style="list-style-type: none"> ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND ▪ The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery
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Drug / Drug Class	Prior Authorization Criteria
	<p>For chronic idiopathic urticaria (CIU):</p> <ul style="list-style-type: none"> The patient is 12 years of age or older The drug is prescribed by an allergist, immunologist, or dermatologist Xolair is not indicated for any other form of urticaria Patient has symptoms lasting for greater than 6 weeks Patient remains symptomatic despite trial of at least 4 weeks with recommended urticarial dosing of a second generation H1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine) <p>Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely.</p> <p><u>Renewal Criteria:</u> (initial TRICARE PA approval is required for renewal) AND</p> <ul style="list-style-type: none"> Asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations or improvements in forced expiratory volume in one second (FEV1) Chronic rhinosinusitis with nasal polyposis: There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score Chronic Idiopathic Urticaria: The patient has had a positive response to therapy and improvement in clinical symptoms to warrant maintenance of therapy
New PAs	
<ul style="list-style-type: none"> Omnipod and Omnipod DASH <p>Insulins: Miscellaneous Insulin Device</p>	<p>Manual PA applies to new and current users of Omnipod/Omnipod DASH</p> <p><u>Manual PA criteria</u>—Omnipod/Omnipod DASH is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> The patient has diabetes mellitus AND requires insulin therapy The patient is on an insulin regimen of 3 or more injections per day and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy The patient performs 4 or more blood glucose tests per day or is using a Continuous Glucose Monitoring (CGM) system The patient has completed a comprehensive diabetes education program The patient has demonstrated willingness and ability to play an active role in diabetes self-management <p>Initial prior authorization expires after 1 year.</p> <p><u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Omnipod or Omnipod DASH is approved for 1 year for continuation of therapy if all criteria are met:</p> <ul style="list-style-type: none"> Patient has been successful with therapy Patient does not require changing the Omnipod DASH unit more frequently than every 72 hours (e.g., changing the unit every 48 hours is not allowed)

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • ambrisentan (generics) <p>Pulmonary Arterial Hypertension Agents (PAH) – Endothelin Receptor Antagonist (ERA) Subclass</p>	<p>Manual PA criteria applies to new and current users of generic ambrisentan.</p> <p><u>Manual PA criteria</u>—Ambrisentan generics are approved if all criteria are met:</p> <ul style="list-style-type: none"> • The brand Letairis formulation is preferred product over generic Letairis (ambrisentan) and is covered at the lowest copayment, which is the generic formulary copayment for non-Active Duty patients, and at no cost share for Active Duty patients. (Although Letairis is a branded product, it will be covered at the generic formulary copayment or cost share.) • Please provide a patient-specific justification as to why the brand Letairis product cannot be used in this patient: _____(fill in the blank) • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has documented diagnosis of WHO group 1 <ul style="list-style-type: none"> – Patient has had a right heart catheterization (documentation required) – Results of the right heart catheterization confirm the diagnosis of WHO group 1 • Patient and provider are enrolled in the Letairis REMS program • Patient is not pregnant • Women of childbearing potential must use adequate contraception • Patient has no history of LFT elevations on previous ERA therapy accompanied by signs or symptoms of liver toxicity or increases in bilirubin >2x ULN • Patient does not have moderate or severe liver impairment (e.g., Child-Pugh Class B or C) <p>Non-FDA approved uses are not approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> • lactulose packet (Kristalose, generics) <p>Laxatives-Cathartics-Stool Softeners</p>	<p>Manual PA criteria applies to new users of lactulose packet (Kristalose, generics).</p> <p>Note: lactulose solution and other laxatives are available without a PA; providers are encouraged to consider changing the prescription to one of the drugs listed: lactulose solution or other laxatives (i.e., glycerin, lactitol, polyethylene glycol 3350, sorbitol)</p> <p><u>Manual PA criteria</u>—Kristalose and generic packets are approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that lactulose solution and other laxatives are available to DoD beneficiaries without the need of prior authorization • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives: (fill-in blank) <p>Non-FDA approved uses are not approved. Prior Authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • prenatal MVI (Neonatal-DHA, Neonatal FE) <p>Vitamins: Prenatal</p>	<p>Manual PA criteria applies to new users of prenatal MVI (Neonatal-DHA, Neonatal FE).</p> <p>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, and Neonatal FE 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</p> <p><u>Manual PA criteria</u>—Azesco, Zalvit, Trinaz, Neonatal-DHA, or Neonatal FE is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider is aware and 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, and Neonatal FE 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 • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives (fill-in the blank) <p>Non-FDA approved uses are not approved. Prior Authorization does not expire.</p>
Updated PAs	

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • ozanimod (Zeposia) <p>Multiple Sclerosis Agents</p>	<p>Updates from the August 2021 Meeting are in bold.</p> <p>Manual PA criteria apply to all new users of Zeposia.</p> <p><u>Manual PA criteria:</u> Zeposia is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • All recommended Zeposia monitoring has been completed and patient will be monitored throughout treatment as recommended in the label. Monitoring includes CBC, LFT, varicella zoster virus (VZV) antibody serology, ECG, and macular edema screening as indicated. • Patients of childbearing potential agree to use effective contraception during treatment and for 3 months after stopping therapy • Do not use in patients with significant cardiac history, including: <ul style="list-style-type: none"> ○ Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization ○ Those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker <p><u>For relapsing Multiple Sclerosis</u></p> <ul style="list-style-type: none"> • Zeposia is prescribed by a neurologist • Patient has a documented diagnosis of relapsing forms of MS • No concurrent use of other MS disease-modifying therapy • Patient has not failed a course of another S1p receptor modulator (e.g., Gilenya, Mazyzent) <p><u>For Ulcerative Colitis</u></p> <p>Coverage for Zeposia is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of moderate to severe active Ulcerative Colitis • The patient is 18 years of age or older • Humira is the Department of Defense's preferred targeted immunomodulatory biologic agent for ulcerative colitis. • The patient must have tried Humira AND: <ul style="list-style-type: none"> ○ Had an inadequate response to Humira OR ○ Experienced an adverse reaction to Humira that is not expected to occur with Zeposia OR ○ Has a contraindication to Humira • The patient is not receiving oral immunomodulatory or biologic therapies concomitantly • 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.) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

<ul style="list-style-type: none"> • rimegepant (Nurtec ODT) <p>Migraine Agents</p>	<p><u>Updates from the August 2021 Meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of rimegepant (Nurtec ODT).</p> <p><u>Manual PA criteria:</u> Nurtec ODT is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrovelvy or another gepant) is not allowed • Not approved for patients who have clinically significant or unstable cardiovascular disease <p><u>For Acute Treatment</u></p> <ul style="list-style-type: none"> • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications <ul style="list-style-type: none"> ○ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) <p><u>For Prevention of Episodic Migraine</u></p> <ul style="list-style-type: none"> • The patient has episodic migraine as defined by one of the following: <ul style="list-style-type: none"> ○ Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR ○ Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: <ul style="list-style-type: none"> ○ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate ○ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol ○ Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents <ul style="list-style-type: none"> ○ erenumab-aooe (Aimovig) ○ fremanezumab-vfrm (Ajovy) ○ galcanezumab-gnlm (Emgality) <p>Non-FDA-approved uses are NOT approved. PA expires after 6 months</p> <p>Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if one of the following apply (Note that initial TRICARE PA approval is required for renewal):</p> <p>Acute Treatment</p> <ul style="list-style-type: none"> • Patient has a documented positive clinical response to therapy <p>Preventive Treatment</p> <ul style="list-style-type: none"> • The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR • The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: <ul style="list-style-type: none"> ○ Migraine Disability Assessment (MIDAS) <ul style="list-style-type: none"> • Reduction of ≥ 5 points when baseline score is 11–20
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Drug / Drug Class	Prior Authorization Criteria
	<ul style="list-style-type: none"> • Reduction of $\geq 30\%$ when baseline score is > 20 <ul style="list-style-type: none"> ○ Headache Impact Test (HIT-6) • Reduction of ≥ 5 points <ul style="list-style-type: none"> ○ Migraine Physical Functional Impact Diary (MPFID) • Reduction of ≥ 5 points
<ul style="list-style-type: none"> • ubrogepant (Ubrelvy) <p>Migraine Agents</p>	<p>Updates from the August 2021 Meeting are in bold.</p> <p>Manual PA criteria apply to all new users of ubrogepant (Ubrelvy).</p> <p><u>Manual PA criteria:</u> Ubrelvy is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or another gepant) is not allowed • Not approved for patients who have clinically significant or unstable cardiovascular disease • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications <ul style="list-style-type: none"> ○ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • Patient has had a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT <p>Non-FDA-approved uses are not approved. PA expires after 6 months</p> <p>Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met (Note that initial TRICARE PA approval is required for renewal):</p> <p>Acute Treatment</p> <ul style="list-style-type: none"> • Patient has a documented positive clinical response to therapy

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • lasmiditan (Reyvow) <p>Migraine Agents</p>	<p>Updates from the August 2021 Meeting are in bold.</p> <p>Manual PA criteria apply to all new users of lasmiditan (Reyvow).</p> <p><u>Manual PA criteria:</u> Reyvow is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Reyvow is not approved for patients who have history of hemorrhagic stroke • Reyvow is not approved for patients with a history of epilepsy or any other condition with increased risk of seizure • Not approved for patients who have clinically significant or unstable cardiovascular disease • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications <ul style="list-style-type: none"> ○ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) • The patient has a contraindication to, intolerability to, or has failed a 2-month trial of Nurtec ODT • If Reyvow is used with a triptan, provider acknowledges Reyvow and the triptan should not be used within 24 hours of each other • Reyvow will be used with caution in patients with low heart rate and/or those using beta blockers, such as propranolol <p>Non-FDA-approved uses are not approved.</p> <p>PA expires after 6 months</p> <p>Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met (Note that initial TRICARE PA approval is required for renewal):</p> <p>Acute Treatment</p> <ul style="list-style-type: none"> • Patient has a documented positive clinical response to therapy

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • avapritinib (Ayvakit) <p>Oncological Agents</p>	<p>Updates from the August 2021 Meeting are in bold.</p> <p>Manual PA criteria apply to all new users of avapritinib (Ayvakit).</p> <p><u>Manual PA criteria:</u> Ayvakit is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Must be prescribed by or in consultation with a hematologist/oncologist • Patient has: <ul style="list-style-type: none"> ○ Pathologically confirmed unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation with or without the D842V mutation OR ○ Advanced systemic mastocytosis (includes patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia) OR • Provider agrees to monitor for intracranial bleeding and other central nervous system (CNS) adverse effects • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy <p>Other Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • secukinumab (Cosentyx) <p>Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor Inhibitors</p>	<p><u>Updates from the August 2021 meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of Cosentyx.</p> <p><u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days.</p> <p>AND</p> <p><u>Manual PA Criteria:</u> If automated criteria are not met, Cosentyx is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Humira is the Department of Defense’s preferred targeted biologic agent. The patient must have tried Humira AND: <ul style="list-style-type: none"> • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR • The patient has a contraindication to Humira • Patient is 18 years of age or older AND has diagnosis/indication of one of the following: <ul style="list-style-type: none"> • Active psoriatic arthritis (PsA) • Active ankylosing spondylitis (AS) • Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation AND patient has evidence of elevated CRP and/or MRI evidence of sacroiliitis and ASDAS ≥ 2.1 <p>OR</p> <ul style="list-style-type: none"> • Patient is 6 years of age or older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy • 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.)? <ul style="list-style-type: none"> • Does not apply to ankylosing spondylitis (AS) indication ONLY • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months <ul style="list-style-type: none"> • Applies to ankylosing spondylitis (AS) ONLY • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • mirabegron tablets (Myrbetriq) <p>Overactive Bladder Agents</p>	<p>Updates from the August 2021 meeting are in bold. Note that the previous automation has been removed. Manual PA criteria apply to all new users of mirabegron (Myrbetriq).</p> <p><u>Manual PA criteria:</u> Myrbetriq is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient has a confirmed diagnosis of: <ul style="list-style-type: none"> ○ Neurogenic detrusor overactivity (NDO) ○ Use granules unless patient weighs at least 35 kg, then use tablets unless documented swallowing difficulties ○ Provider acknowledges and knows that granules are not bioequivalent and cannot be substituted on a mg to mg basis to tablets and will not combine dosage forms to achieve a specific dose for pediatric patients ○ Patient does not have a CrCl less than 15 mL/min OR severe hepatic impairment (Child-Pugh Class C) ○ If the CrCl is between 15-29 mL/min OR patient has moderate hepatic impairment (Child-Pugh Class B) AND the patient weighs less than 35 kg, the dosage does not exceed 32 mg once a day for granules ○ If the CrCl is between 15-29 mL/min OR patient has moderate hepatic impairment (Child-Pugh Class B) AND the patient weighs at least 35 kg, the dosage does not exceed 48 mg once a day for tablets <p>OR</p> <ul style="list-style-type: none"> ○ Overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency AND ○ The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training ○ The patient has: <ul style="list-style-type: none"> • Had a 12-week trial with 2 formulary step-preferred products (oxybutynin IR, oxybutynin ER, tolterodine ER) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such central nervous system effects due to comorbid conditions or other medications ○ Patient has tried and failed or has a contraindication to vibegron (Gemtesa) ○ The patient does not have: <ul style="list-style-type: none"> • A CrCl < 15 mL/min The patient's CrCl >15 mL/min OR • If the CrCl is between 15-29 mL/min, the dosage does not exceed 25 mg once a day <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • fesoterodine (Toviaz) <p>Overactive Bladder Agents</p>	<p><u>Updates from the August 2021 meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of fesoterodine (Toviaz).</p> <p><u>Manual PA criteria:</u> Detrol, Enablex, Gelnique, Oxytrol, Santura/Sanctura XR, Toviaz, or Vesicare is approved if all criteria are met:</p> <ul style="list-style-type: none"> • *Note OTC Oxytrol for Women is the name of the over-the-counter (OTC) version of Oxytrol. This OTC medication is not covered under the TRICARE pharmacy benefit. Please enter your initials in the text box to acknowledge that OTC Oxytrol for Women is not covered under the TRICARE pharmacy benefit. • *Toviaz only* Patient has confirmed and documented diagnosis of: <ul style="list-style-type: none"> ○ Neurogenic detrusor overactivity (NDO) ○ Patient is 6 years of age or older ○ Patient weighs more than 25 kg ○ Patient does not have a CrCl less than 30 mL/min OR severe hepatic impairment (Child-Pugh Class C) <p>OR</p> <ul style="list-style-type: none"> • *All other medications listed to include Toviaz* The patient has a confirmed diagnosis of: <ul style="list-style-type: none"> ○ Overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency ○ Patient has had a trial tolterodine extended-release (Detrol LA), oxybutynin IR or ER, or trospium immediate-release (Sanctura immediate-release) and experienced an inadequate response OR experienced intolerable adverse effects OR have a contraindication to all of these medications which is not expected to occur with the requested medication <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • sofosbuvir/velpatasvir (Epclusa) • glecaprevir/pibrentasvir (Mavyret) <p>Hepatitis C Agents: Direct Acting Agents</p>	<p><u>Updates from the August 2021 Meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of sofosbuvir/velpatasvir (Epclusa) and glecaprevir/pibrentasvir (Mavyret).</p> <p><u>Manual PA criteria:</u> Epclusa, Harvoni, Mavyret, Sovaldi, Zepatier, or Viekira Pak is approved if all criteria are met:</p> <ul style="list-style-type: none"> • *Note: The branded agents on the top of this form are the preferred agents for TRICARE. If the authorized generics of either Epclusa or Harvoni are required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. • *Epclusa, Harvoni, Mavyret, and Sovaldi* <ul style="list-style-type: none"> ○ Patient is 3 years of age or older • Zepatier and Viekira Pak <ul style="list-style-type: none"> ○ Patient is 18 years of age or older • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of chronic hepatitis C virus (HCV) infection • Patient has HCV genotype is 1a, 1b or other genotype 1, 2, 3, 4, 5, or 6 (check box) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • sofosbuvir/velpatasvir (Authorized generic Epclusa) <p>Hepatitis C Agents: Direct Acting Agents</p>	<p><u>Updates from the August 2021 Meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria apply to all new users of sofosbuvir/velpatasvir (Authorized generic Epclusa).</p> <p><u>Manual PA criteria:</u> Authorized generic Epclusa is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • *Note: The Brand Epclusa is preferred over the authorized generic product. Please provide a patient-specific justification as to why the brand Epclusa product cannot be used in this patient. (fill-in the blank) • Patient is 6 3 years of age or older • Patient weighs greater than or equal to 17 kg • Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician • Patient has laboratory evidence of chronic hepatitis C virus (HCV) infection • Patient has HCV genotype is 1a, 1b or other genotype 1, 2, 3, 4, 5, or 6 (check box) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • amphetamine sulfate ODT (Evekeo ODT) <p>ADHD Agents: Stimulants</p>	<p><u>Updates from the August 2021 Meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria apply to all new users of amphetamine sulfate ODT (Evekeo ODT).</p> <p><u>Manual PA criteria:</u> Evekeo ODT is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is six three to 17 years of age • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record • Must have tried, for at least two months, and failed OR has difficulty swallowing mixed amphetamine salts IR (Adderall, generic) • Must have tried, for at least two months, and failed OR has a contraindication to methylphenidate IR tablets or solution <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • obeticholic acid (Ocaliva) <p>Gastrointestinal-2 Agents</p>	<p>Updates from the August 2021 Meeting are in bold.</p> <p>Manual PA criteria apply to all new users of obeticholic acid (Ocaliva).</p> <p><u>Manual PA criteria:</u> Ocaliva is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Patient has diagnosis of primary biliary cholangitis (PBC) • Patient does not have decompensated cirrhosis, or have they had a prior decompensation event, or do they have compensated cirrhosis with evidence of portal hypertension (for example, ascites, gastroesophageal varices, or persistent thrombocytopenia)? • Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician • Diagnosis of PBC has been confirmed by at least TWO of the following: <ul style="list-style-type: none"> ○ Alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values ○ Positive anti-mitochondrial antibodies (AMAs) ○ Histologic evidence of PBC from a liver biopsy • Patient has received ursodiol therapy (for example, ursodiol generics, Urso 250, Urso Forte, Actigall) for one year or greater and has had an inadequate response OR • Patient is unable to tolerate ursodiol therapy <p>Non-FDA-approved uses are not approved. PA expires after 1 year Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if all of the following criteria are met (Note that initial TRICARE PA approval is required for renewal): Acute Treatment</p> <ul style="list-style-type: none"> • Patient has responded to Ocaliva as determined by the prescribing physician (for example, improved biochemical markers of PBC [alkaline phosphatase (ALP), bilirubin, gamma-glutamyl transpeptidase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT) levels])

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • ibrutinib (Imbruvica) <p>Leukemia and Lymphoma Agents: BTK Inhibitors</p>	<p>Note: no change to current status</p> <ul style="list-style-type: none"> ▪ MTF/Mail: maximum of 56 tablets for a 56 day supply ▪ Retail: maximum of 28 tablets for a 28 day supply ▪ MTF/Mail: maximum of 180 capsules for a 45 day supply ▪ Retail: maximum of 120 capsules for a 30 day supply
<ul style="list-style-type: none"> • acalabrutinib (Calquence) • zanubrutinib (Brukinsa) <p>Leukemia and Lymphoma Agents: BTK Inhibitors</p>	<p>Note: no change to current status</p> <ul style="list-style-type: none"> ▪ MTF/Mail: 60 day supply ▪ Retail: 30 day supply
<ul style="list-style-type: none"> • dasiglucagon injection (Zegalogue) <p>Antidotes-Overdose Agents: Hypoglycemia Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 2 syringes/pens per fill (one two-pack or two individual packs)
<ul style="list-style-type: none"> • ferric maltol (Accrufer) <p>Electrolyte-Mineral-Trace Element Replacement</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 60 capsules/30 days and 30 day supply
<ul style="list-style-type: none"> • infigratinib (Truseltiq) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 28 day supply
<ul style="list-style-type: none"> • omalizumab syringe (Xolair) <p>Respiratory Interleukins</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • sotorasib (Lumakras) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • semaglutide (Wegovy) <p>Weight Loss Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • ivermectin (Stromectol) <p>Antiinfectives: Anti-Helminthics</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 60 tablets per fill
<ul style="list-style-type: none"> • Omnipod, Omnipod DASH • V-Go <p>Insulins: Miscellaneous Insulin Device</p>	<ul style="list-style-type: none"> ▪ Retail: Omnipod/Omnipod DASH: 10 pods/30 days V-Go: 1 system/30 days ▪ Mail/MTF: Omnipod/Omnipod DASH: 30 pods/90 days V-Go: 3 systems/90 days
<ul style="list-style-type: none"> • rimegepant (Nurtec ODT) <p>Migraine Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 16 ODTs/30 days ▪ MTF/Mail: 48 ODTs/90 days <p>QLs increased for new QOD dosing for preventive treatment of migraine were implemented in October 2021</p>
<ul style="list-style-type: none"> • ustekinumab (Stelara) 90 mg only <p>Targeted Immunomodulatory Biologics: Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail: 1 syringe per fill ▪ MTF/Mail: 3 syringes per fill <p>Note: previous QL at MTF/Mail was 2 syringes per fill</p>

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
<p>dasiglucagon injection (Zegalogue)</p> <p>Binders-Chelators-Antidotes-Overdose Agents: Hypoglycemia Agents for severe hypoglycemia</p>	<ul style="list-style-type: none"> glucagon nasal (Baqsimi) glucagon autoinjector and pre-filled syringe (Gvoke) 	<ul style="list-style-type: none"> Autoinjector PFS 	<p>Severe hypoglycemia in 6 year olds and older</p>	<ul style="list-style-type: none"> Injection site reaction Diarrhea 	<ul style="list-style-type: none"> New glucagon formulation available as a prefilled syringe and auto-injector for rescue of hypoglycemia Evaluated in three placebo-controlled clinical trials; established superiority in terms of efficacy Common adverse effects are limited to nausea and vomiting, as well as injection site edema, headache and diarrhea Faster time to plasma recovery compared to Gvoke (13.8 vs 10 mins), but shorter stability at room temperature vs Gvoke (12 vs 24 mos) Zegalogue offers a significant advantage over the glucagon kit but offers no compelling clinical advantage over newer glucagon formulations and a disadvantage in shelf life 	<ul style="list-style-type: none"> UF Do not add to EMMI list
<p>drosperinone/estretol (Nextstellis)</p> <p>Contraceptive Agents</p>	<ul style="list-style-type: none"> ethinyl estradiol/ drospirenone (Yaz) other combined oral contraceptives 	<ul style="list-style-type: none"> Take one tablet by mouth at the same time every day in the order directed on the blister pack Each pack consists of 28 tablets with 24 pink active tablets each containing drospirenone 3 mg and estretol 14.2 mg and 4 white inert tablets 	<p>Contraception</p>	<p>Common ADRs (≥2%):</p> <ul style="list-style-type: none"> bleeding irregularities mood disturbance headache breast symptoms acne dysmenorrhea weight increase libido decrease 	<ul style="list-style-type: none"> First contraceptive agent to contain the estrogen, estretol Overall Pearl Index (efficacy measure) met FDA guidance recommendations Limitations of use: May be less effective in females with a BMI ≥ 30 kg/m2 Indirectly compared to other combined oral contraceptives, Nextstellis has similar safety, discontinuation rates due to adverse events, and unscheduled bleeding profile Post-marketing trials are required to assess venous thromboembolism risk Further research is needed to confirm if there are any comparative efficacy or safety advantages with estretol vs. ethinyl estradiol Nextstellis is another oral contraceptive option in the crowded contraceptive class No compelling clinical advantages over existing formulary options at this time 	<ul style="list-style-type: none"> NF Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
ferric maltol (Accrufer) Electrolyte-Mineral-Trace Element Replacement	<ul style="list-style-type: none"> ferrous sulfate ferrous gluconate ferrous fumarate polysaccharide Fe complex 	<ul style="list-style-type: none"> One 30 mg capsule taken twice daily on an empty stomach Treatment duration is variable, but typically is for at least 12 weeks 	Iron deficiency	Most common ADRs (≥ 1%): <ul style="list-style-type: none"> flatulence diarrhea constipation feces discolored abdominal pain nausea vomiting abdominal discomfort abdominal distension 	<ul style="list-style-type: none"> Ferric maltol is another option to treat iron deficiency in a crowded therapeutic space with many oral and IV iron formulations available Effective at raising hemoglobin (Hgb) in inflammatory bowel disease, but only modestly effective in chronic kidney disease Claims of better tolerability than other oral irons not substantiated due to lack of direct head-to-head trials Lack of sufficient drug-drug interaction data is a clinical disadvantage Offers little to no compelling clinical advantage over other available treatment options 	<ul style="list-style-type: none"> NF Do not add to EMMI list
infigratinib (Truselq) Oncological Agent	<ul style="list-style-type: none"> pemigatinib (Pemazyre) 	<ul style="list-style-type: none"> 25 and 100 mg oral capsules 125 mg once daily x 21 days followed by 7 days off in a 28-day cycle Swallow whole Reduce dose for mild-moderate renal impairment and mild-moderate hepatic impairment 	Adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test	<ul style="list-style-type: none"> Common ADRs (≥20%): nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodyesthesia syndrome, arthralgia, dysgeusia, constipation, abd pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, vision blurred and vomiting Common lab abnormalities (≥20%): ↑ creatinine, phosphate, alk phos, ALT, AST, lipase, calcium, urate, triglycerides, bilirubin, and ↓ phosphate, Hgb, lymphocytes, 	<ul style="list-style-type: none"> Accelerated approval with immature data in a low quality study without an active comparator; limited data currently available to review Few clinically-effective treatment options for unresectable advanced refractory cholangiocarcinoma with 0% 5-year survival for inoperable disease Median duration of response higher than 50% overall survival for disease state Drug is poorly tolerated Infigratinib is the second treatment option for cholangiocarcinoma with a FGFR2 fusion 	<ul style="list-style-type: none"> UF Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
				sodium, platelets, leukocytes, albumin, and potassium		
omalizumab syringe (Xolair) Respiratory Interleukin	<ul style="list-style-type: none"> benralizumab inj (Fasenra) dupilumab inj (Dupixent) mepolizumab inj (Nucala) 	<ul style="list-style-type: none"> prefilled syringe 	<ul style="list-style-type: none"> Moderate to severe allergic asthma, ≥ 6 years Nasal Polyps, inadequate nasal corticosteroid response, ≥ 18 years Chronic Idiopathic Urticaria (CIU), inadequate response to H1 antihistamines, ≥ 12 years 	<ul style="list-style-type: none"> BBW - Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair ≥3% - headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness 	<ul style="list-style-type: none"> Omalizumab (Xolair) was the first biologic approved for moderate to severe asthma, but required physician office administration. The new prefilled syringe makes it the 4th respiratory biologic approved for patient self-administration Guidelines for asthma recommend Xolair for patients with elevated IgE Guidelines for nasal polyps do not provide strong recommendations for using Xolair, although newer studies show a statistical improvement in symptom scores compared to placebo; MHS providers feel Dupixent is a better option Xolair is in the treatment algorithm for chronic idiopathic urticaria Xolair, by targeting IgE, provides another option in treating moderate to severe asthma and nasal polyps. It is the only respiratory biologic approved for CIU. 	<ul style="list-style-type: none"> UF Do not add to EMMI list
pegcetacoplan injection (Empaveli) Hematological agent	<u>Medical benefit drugs</u> <ul style="list-style-type: none"> eculizumab (Soliris) ravulizumab-cwvz (Ultomiris) 	<ul style="list-style-type: none"> 1,080 mg/20 mL single-dose vials Injected SQ via a pump twice each week Dose: 1,080 mg infused over 20-40 min 	<ul style="list-style-type: none"> Paroxysmal nocturnal hemoglobinuria 	<ul style="list-style-type: none"> Common ADRs (incidence ≥10%): inj site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, viral infection, and fatigue 	<ul style="list-style-type: none"> Empaveli is a new targeted complement inhibitor approved for the rare disease of paroxysmal nocturnal hemoglobinuria (PNH) Use of Empaveli increased Hgb and decreased the need for blood transfusions Empaveli was superior to eculizumab for the change from baseline in hemoglobin level at Week 16 (P<0.0001) Non-inferiority was demonstrated in the endpoints of transfusion avoidance and change from baseline in ARC Contraindicated in patients not vaccinated against certain encapsulated bacteria Empaveli provides another treatment option to treat rare PNH 	<ul style="list-style-type: none"> UF Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
relugolix/ estradiol/ norethindrone (Myfembree) LHRH Agonist-Antagonists	<ul style="list-style-type: none"> Elagolix 40mg, estradiol 1mg, norethindrone 0.5mg (OriaHnn) tablets 	<ul style="list-style-type: none"> Relugolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg tablets One capsule once daily for up to 24 months. Start no later than 7 days after menses has started. 	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	<ul style="list-style-type: none"> Most common adverse events include hot flush, hyperhidrosis, or night sweats (10.6%), abnormal uterine bleeding (6.3%), alopecia (3.5%), and decreased libido (3.1%) 	<ul style="list-style-type: none"> Myfembree is the 2nd oral GnRH antagonist approved for the treatment of heavy menstrual bleeding associated with uterine fibroids (OriaHnn was the 1st) Evaluated in two phase III studies; effective at decreasing heavy menstrual bleeding in more women than placebo Treatment is limited to 24 months due to bone mineral density loss Contraindicated in patients with a high risk of arterial, venous thrombotic, or thromboembolic disorders, pregnancy, osteoporosis, current or history of breast cancer or other hormonally-sensitive malignancies, known liver impairment or disease, undiagnosed abnormal uterine bleeding, or known hypersensitivity to ingredients of Myfembree. In an indirect comparison, Myfembree appears to have similar efficacy and tolerability to OriaHnn. OriaHnn is dosed twice daily while Myfembree is dosed once daily. Myfembree provides another option for the treatment of heavy menstrual bleeding associated with uterine fibroids for longer than three months. 	<ul style="list-style-type: none"> UF Do not add to EMMI list
riluzole oral film (Exservan) Miscellaneous Neurological Agent	<ul style="list-style-type: none"> riluzole 50 mg tablets riluzole (Tiglutik) 50mg/10ml oral solution 	<ul style="list-style-type: none"> 50mg oral film 50 mg BID taken at least 1 hour before or 2 hours after meals Placed on top of the tongue and allowed to dissolve 	ALS	<ul style="list-style-type: none"> Most common ADRs ($\geq 5\%$ and greater than placebo): oral hypoesthesia, asthenia, nausea, decreased lung function, hypertension, and abdominal pain 	<ul style="list-style-type: none"> Riluzole oral film is the first oral film for the treatment of ALS and the second option for patients with swallowing difficulties. No new clinical trials were conducted on riluzole oral film; pharmacokinetics demonstrated equivalence with oral tablets. Riluzole oral film provides little to no advantages over riluzole solution and is a second option other than crushing tablets for patients with dysphagia/swallowing difficulties. 	<ul style="list-style-type: none"> UF Do not add to EMMI list

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

<p>rosuvastatin calcium/ezetimibe (Roszet) Antilipidemic-1</p>	<ul style="list-style-type: none"> rosuvastatin with ezetimibe atorvastatin with ezetimibe bempedoic acid/ezetimibe (Nexlizet) evolocumab (Repatha) 	<p>Oral tablets</p> <ul style="list-style-type: none"> Strengths 5 mg/10 mg 10 mg/10 mg 20mg /10 mg 40 mg/10 mg 	<ul style="list-style-type: none"> Adjunct in patients with primary non-familial hyperlipidemia to reduce LDL-C HoFH to reduce LDL-C 	<p>Similar to rosuvastatin and ezetimibe given separately</p>	<ul style="list-style-type: none"> 2nd fixed dose combination (FDC) of a statin/ezetimibe (Vytorin was 1st) Approved using data from Crestor and Zetia (FDA 505b2 approval pathway) No clinical trials conducted with this product other than LDL comparisons to statin monotherapy; but components well-studied Limited indications, compared with Crestor label LDL cholesterol reductions range from 64% to -72%, similar to giving rosuvastatin and ezetimibe together DoD rosuvastatin available at \$0 copay (Medication Adherence Program) Other than offering a small convenience to patients with swallowing difficulties, Roszet offers no clinically compelling advantages compared to taking the individual components separately 	<ul style="list-style-type: none"> Tier 4/Not covered
<p>semaglutide injection (Wegovy) Weight Loss Agent</p>	<ul style="list-style-type: none"> phentermine phentermine/topiramate (Qsymia) naltrexone/bupropion (Contrave) liraglutide (Saxenda) 	<ul style="list-style-type: none"> Pre-filled, single-dose injection pen that delivers doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg Dose: 2.4 mg subcutaneously once weekly 	<ul style="list-style-type: none"> Adjunct to diet and exercise for chronic weight management in adults with a body mass index (BMI) of: <ul style="list-style-type: none"> ≥ 30 kg/m² or ≥ 27 kg/m² with at least one weight-related comorbid condition (e.g. HTN, T2DM, Dyslipidemia) 	<p><u>Contraindications:</u> Personal or family history of MTC or in patients with MEN 2</p> <p><u>Warnings</u></p> <ul style="list-style-type: none"> Risk of thyroid C-cell tumors Acute pancreatitis (fatal and non-fatal) (0.2% vs 0%) Cholelithiasis and cholecystitis Hypoglycemia HR increases Avoid in patients with a history of suicide attempts or ideation Reduce dose of concomitant insulin or sulfonylureas Acute kidney injury <u>Most common ADRs:</u> nausea, diarrhea, vomiting 	<ul style="list-style-type: none"> Wegovy is another formulation of semaglutide approved for obesity as adjunctive treatment for patients with a BMI > 30kg/m², or > 27kg/m² with a comorbid condition Wegovy is the second GLP-1 agonist approved for obesity, liraglutide (Saxenda) is the other It is dosed once weekly, vs daily for Saxenda Wegovy was evaluated in four studies, and consistently demonstrated statistical significance compared to placebo in weight-related outcomes Most common ADRs include gastrointestinal effects that affect nearly half of patients While Wegovy appears to have a much larger clinical effect than other obesity medications, the rate of adverse reactions remain high and there are no head-to-head comparisons with other agents. Long-term cardiovascular, pancreas, and biliary effects are currently being investigated Wegovy provides another GLP-1 treatment option for obesity however long-term duration of effect remains unclear 	<ul style="list-style-type: none"> UF Do not add to EMMI list

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

<p>sotorasib (Lumakras) Oncological Agent</p>	<p>none</p>	<p>960 mg orally once daily; swallow tablets whole with or without food; available in 120 mg tabs</p>	<p>NSCLC: adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test</p>	<ul style="list-style-type: none"> • Most common ADRs ($\geq 20\%$): diarrhea, musculoskeletal pain, nausea, fatigue, hepatotoxicity, and cough • Common lab abnormalities $\geq 25\%$: decreased lymphocytes, Hgb, calcium and sodium; increased AST, ALT, alk phos and urine protein 	<ul style="list-style-type: none"> • Sotorasib received an accelerated approval with immature data in a low quality study without an active comparator • Doubles progression-free survival relative to standard of care options (by indirect comparison) • Despite sotorasib’s high serious adverse event rate, its discontinuation rate was $< 10\%$ • Sotorasib is the first and only FDA-approved KRAS inhibitor for NSCLC with unparalleled survival rates 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
<p>viloxazine extended-release (Qelbree) ADHD: Non-stimulant</p>	<ul style="list-style-type: none"> • atomoxetine (Strattera) • clonidine ER (Kapvay) • guanfacine ER (Intuniv) 	<ul style="list-style-type: none"> • extended-release oral capsules (100 mg, 150 mg, and 200 mg) • 6 to 11 years of age: start 100 mg once a day, may titrate in increments of 100 mg weekly to max of 400 mg once a day • 12 to 17 years of age: start 200 mg once a day, may titrate by an increment of 200 mg to max does of 400 mg once a day 	<p>Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age</p>	<p>Most common ADRs ($\geq 5\%$ and at least twice the rate of placebo): somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability</p>	<ul style="list-style-type: none"> • Qelbree is the 4th non-stimulant for the treatment of ADHD • Only indicated for patients 6 to 17 years of age • Qelbree is a selective norepinephrine reuptake inhibitor with a similar mechanism of action to atomoxetine (Strattera), although there are no head-to-head trials comparing the agents • Approval was based on three short-term (6 or 8 week) placebo-controlled pivotal trials where Qelbree demonstrated moderate efficacy vs placebo • Non-stimulant agents are not recommended in most pediatrics and adolescents due to efficacy not being as robust • ADHD treatments should always be in combination with non-pharmacologic therapies • Provides an alternative treatment to atomoxetine and other formulary non-stimulant options, however provides no compelling advantage over existing agents 	<ul style="list-style-type: none"> • NF • Do not add to EMMI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the August 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)
August 2021	<p>Pulmonary-3 Agents: Combinations UF <i>Add to the EMMPI Program:</i></p> <ul style="list-style-type: none"> • budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere) <i>(Note this is updated from the February 2021 P&T Committee meeting minutes)</i> <p>Line Extensions Designated UF <i>Similar/parent agent already on list (all new strengths or dosage forms):</i></p> <ul style="list-style-type: none"> • adalimumab pen carton (Humira CF) • adalimumab starter package for UC (Humira CF) • lipase/protease/amylase (Pancreaze) • secukinumab syringe (Cosentyx) <p>Line Extensions Designated NF <i>No reason to exempt from NF-2-Mail requirement, similar/parent agent already on list (new strength and dosage form):</i> risankizumab-rzaa (Skyrizi)</p>	<p>Oncological Agents: Bruton Tyrosine Kinase Inhibitors UF (brand maintenance only) <i>Maintain current status and do not add to EMMPI Program due complex dose-adjustment and some agents not being available at mail:</i></p> <ul style="list-style-type: none"> • acalabrutinib (Calquence) • ibrutinib (Imbruvica) • zanubrutinib (Brukinsa) <p>Laxatives, Cathartics, & Stool Softeners: Bowel Preparations NF <i>Exempt from NF-2 Mail requirement due to acute use exception:</i></p> <ul style="list-style-type: none"> • sodium picosulfate, citric acid, mag oxide (Prepopik) • sodium phosphate tablets (OsmoPrep) • sodium SO4, K+ SO4, Mg SO4 (Suprep) • sodium SO4, KCl, Mg SO4 (Sutab) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Acute use or limited duration and drugs in class not currently represented on EMMPI List:</i></p> <ul style="list-style-type: none"> • dasiglucagon injection (Zegalogue) <p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • infigratinib (Truselq) • omalizumab (Xolair) • pegcetacoplan injection (Empaveli) • riluzole oral film (Exservan) • sotorasib (Lumakras) <p><i>Similar agents not on list and comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • relugolix/estradiol/norethindrone (Myfembree) • semaglutide (Wegovy) <p>Designated NF: <i>Contraceptive exception/existing exclusion applies:</i></p> <ul style="list-style-type: none"> • drospirenone/estetrol (Nextstellis) <p><i>Exception due to a combination of factors:</i></p> <ul style="list-style-type: none"> • viloxazine (Qelbree) <p><i>Not yet clear if feasible to provide through mail order and similar pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • ferric maltol (Accrufer)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2021	Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase inhibitors	UF Class Review	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None 			Pending signing of the minutes: 2 weeks The effective date is March 2, 2022	<ul style="list-style-type: none"> ▪ PAs and QLs for all three drugs 	<ul style="list-style-type: none"> ▪ Imbruvica tabs require a trial of caps first on the PA
			None	<ul style="list-style-type: none"> ▪ acalabrutinib (Calquence) ▪ ibrutinib (Imbruvica) ▪ zanubrutinib (Brukinsa) 	<ul style="list-style-type: none"> ▪ None 			

Appendix G—Table of Implemented Status of UF Recommendations/Decision Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Aug 2021	Laxatives-Cathartics-Stool Softeners: Bowel Preparations	UF Class Review	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None 		<ul style="list-style-type: none"> ▪ sodium sulfate, potassium sulfate, and magnesium sulfate concentrated oral solution (Suprep) ▪ sodium sulfate, potassium chloride and magnesium sulfate tablets (Sutab) ▪ sodium phosphate tablets (Osmoprep) ▪ sodium picosulfate, magnesium oxide, and anhydrous citric acid power packets (Prepopik) 	<p>Pending signing of the minutes: 2 weeks</p> <p>The effective date is March 2, 2022</p>	<ul style="list-style-type: none"> ▪ No PAs or QLs 	<ul style="list-style-type: none"> ▪ Generic GoLYTELY added to the BfCF
			<ul style="list-style-type: none"> ▪ PEG 3350, Standard volume (generic Golytely)) 	<ul style="list-style-type: none"> ▪ PEG 3350, sodium sulfate, sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (Colyte, GoLYTELY, Galvilyte-A, Galvilyte-C, GalviLyte-G, generics) ▪ PEG 3350 sodium bicarbonate, sodium chloride and potassium chloride powder for oral solution (NuLYTELY, TriLyte, generics) ▪ PEG sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for oral solution (Moviprep) ▪ PEG sodium sulfate, sodium chloride, potassium chloride, ascorbic acid, and sodium ascorbate powder for solution (Plenvu) ▪ sodium picosulfate, magnesium oxide, and anhydrous citric acid oral solution (Clenpiq) 				

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives (Last 12 months)*†

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
August 2021	Antilipidemic-1s	<ul style="list-style-type: none"> rosuvastatin/ezetimibe (Roszet) 	<ul style="list-style-type: none"> rosuvastatin with ezetimibe atorvastatin with ezetimibe simvastatin/ezetimibe (Vytorin) evolocumab (Repatha) alirocumab (Praluent) 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
May 2021	Anticonvulsants-Antimania Agents	<ul style="list-style-type: none"> levetiracetam (Elepsia XR) 	<ul style="list-style-type: none"> levetiracetam ER lamotrigine XR topiramate ER 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Corticosteroids-Immune Modulators: High Potency	<ul style="list-style-type: none"> clobetasol propionate 0.05% lotion metered dose pump (Impeklo) 	<ul style="list-style-type: none"> betamethasone/propylene glycol 0.05% lotion betamethasone dipropionate 0.05% gel clobetasol propionate/emollient 0.05 % (emulsion) foam clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo fluocinonide 0.05% solution and gel 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene/betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora) 	<ul style="list-style-type: none"> 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 fluocinonide 0.05% cream, gel, and solution calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary] 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Nov 2020	Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) methylphenidate long-acting (Ritalin LA, generics) methylphenidate controlled delivery (CD) (Metadate CD, generics) dexmethylphenidate ER (Focalin XR, generics) mixed amphetamine salts ER (Adderall XR, generics) 	<ul style="list-style-type: none"> Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	<ul style="list-style-type: none"> budesonide ER 9 mg capsules (Ortikos) 	<ul style="list-style-type: none"> budesonide ER tablets (Entocort EC, generics) other corticosteroids 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Corticosteroids	<ul style="list-style-type: none"> dexamethasone 20 mg tables (Hemady) 	<ul style="list-style-type: none"> dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs 	<ul style="list-style-type: none"> June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	<ul style="list-style-type: none"> fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) 	<ul style="list-style-type: none"> fluticasone (Flovent Diskus) fluticasone (Flovent HFA) fluticasone furoate (Arnuity Ellipta) [non formulary] beclomethasone (QVAR) [non formulary] budesonide (Pulmicort Flexhaler) [non formulary] ciclesonide (Alvesco) [non formulary] flunisolide (Aerospan) [non formulary] mometasone (Asmanex Twisthaler) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	<ul style="list-style-type: none"> fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) 	<ul style="list-style-type: none"> fluticasone/salmeterol (Advair Diskus) fluticasone/salmeterol (Advair HFA) fluticasone/vilanterol (Breo Ellipta) [non formulary] mometasone/formoterol (Dulera) [non formulary] budesonide/formoterol (Symbicort) [non formulary] fluticasone/salmeterol (AirDuo Respiclick) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Calcium Channel Blockers	<ul style="list-style-type: none"> levamlodipine (Conjupri) 	<ul style="list-style-type: none"> amlodipine felodipine nifedipine diltiazem verapamil 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	GI-2 Agents	<ul style="list-style-type: none"> metoclopramide nasal spray (Gimoti) 	<ul style="list-style-type: none"> metoclopramide oral tablet (Reglan generics) metoclopramide oral solution (Reglan, generics) metoclopramide orally disintegrating tablet (Reglan ODT) 	<ul style="list-style-type: none"> June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% solution clobetasol 0.05% solution, shampoo fluocinonide 0.05% solution calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% ointment, cream, solution clobetasol 0.05% ointment, cream fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> betamethasone propylene glycol 0.05% cream clobetasol propionate 0.05% cream and ointment clobetasol propionate/emollient 0.05% cream desoximetasone 0.25% cream and ointment fluocinonide 0.05% cream and ointment fluocinonide/emollient base 0.05% cream halobetasol propionate 0.05% ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> adapalene 0.1% lotion, gel, cream adapalene 0.3% gel clindamycin phosphate 1% gel, cream, lotion, and solution clindamycin/ benzoyl peroxide 1.2% - 5% gel tazarotene 0.1% cream tretinoin 0.025%, 0.05%, and 0.1% cream tretinoin 0.01% and 0.025% gel 	<ul style="list-style-type: none"> February 24, 2021

* 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>. 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. 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.

† For a cumulative list of previous Tier 4 recommendations, refer to the November 2020 DoD P&T Committee minutes, found at health.mil/pandt

**Appendix I—DoD P&T Committee Processes and Recommendations/Approval Authorities
Updated August 6th 2020 (Updates are in Bold)**

Process	Function
<p>Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required)</p> <p>Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; P&T Committee Chair and others as needed</p>	<ul style="list-style-type: none"> ▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTs] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non step preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to prior authorization forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as “innovator” drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting

	<p>minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be “grandfathered” when the permanent criteria become effective, unless directed otherwise.</p> <ul style="list-style-type: none"> ▪ Establishing drug class definitions for maintenance medications as part of the Expanded MTF/Mail Order Pharmacy Initiative. ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the Expanded MTF/Mail Order Pharmacy Initiative from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing “brand over generic” authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon prior authorization. The branded product will adjudicate at the Tier 1 co-pay at the Retail Pharmacy Network and Mail Order Pharmacy. The “brand over generic” authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating “line extension” products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the “parent” drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug, and must be from the same manufacturer. Line extensions may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., Handi-Haler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product.
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	<ul style="list-style-type: none"> ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA “health.mil” website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying manual PA criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QIs implemented in these situations will be removed when the situation has resolved.
<p>Approval by Director, DHA, required based on DoD P&T Committee recommendations and BAP comments</p>	<ul style="list-style-type: none"> ▪ Classification of a medication as non-formulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication as Tier 4 (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and implementation plan (including effective date). ▪ Establishment of prior authorization requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing prior authorization (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of prior authorization requirements for a drug. ▪ Clarification of a medication as non-formulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as non-formulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as non-formulary (Tier 3 co-pay).

<p>Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to BAP for comments)</p>	<ul style="list-style-type: none"> ▪ Establishment of quantity limits for a medication or class of medications; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for non-formulary drugs. ▪ Addition or deletion of medications listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes on the Expanded MFT/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.
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Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
ASCO	American Society of Clinical Oncology	LDL	Low density lipoprotein
ADHD	Attention Deficit Hyperactivity Disorder	LHRH	Leutinizing hormone releasing hormone
ADR	adverse drug reaction	L	liter
AE	Adverse event	LABA	Long acting beta agonists
ALS	Amyotrophic lateral sclerosis	LAMA	Long acting muscarinic antagonist
BCF	Basic Core Formulary	MCL	Mantle cell lymphoma
BIA	Budget impact analysis	MDI	Multiple daily injections
CFR	Code of Federal Regulations	MHS	Military Health System
CIU	Chronic idiopathic urticaria	MN	Medical Necessity
CLL	Chronic lymphocytic leukemia	MS	Multiple Sclerosis
CMA	Cost minimization analysis	MTF	Military Treatment Facility
CV	Cardiovascular	MZL	Marginal zone lymphoma
DHA	Defense Health Agency	NCCN	National Comprehensive Cancer Network
DHA	docosahexaenoic acid	NDA	National Defense Authorization Act
DLBCL	diffuse large B-Cell lymphoma	NDC	National Drug Codes
DoD	Department of Defense	NDO	Neurogenic detrusor overactivity
DR	Delayed release	NSCLC	Non-small cell lung cancer
ECF	Extended Core Formulary	OAB	Overactive bladder
EIP	external insulin pump	ODT	Orally Disintegrating Tablet
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	OTC	Over the counter
ER	Extended release	PA	Prior authorization
FDC	Fixed drug combination	PAH	Pulmonary artery hypertension
FDA	U.S. Food and Drug Administration	PDM	personal diabetes manager
Fe	iron	PEG	polyethylene glycol
GCB	germinal center B-Cell	PNH	paroxysmal nocturnal hemoglobinuria
GLP-1 RA	Glucagon-like peptide-1 receptor antagonists	POD	Pharmacy Operations Division
Hgb	hemoglobin	POS	Point of service
ICS	Inhaled corticosteroid	PRN	As needed

Term	Definition	Term	Definition
QL	Quantity limits	SLL	small lymphocytic lymphoma
RCC	Renal cell carcinoma	TIB	Targeted Immunomodulatory Biologics
RRMS	Relapsing remitting multiple sclerosis	UC	Ulcerative colitis
SC	Subcutaneous	WM	Waldenström macroglobulinemia
SL	Sublingual		

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

May 2021

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on May 5 and 6, 2021. Due to the COVID-19 pandemic, the meeting was held via teleconference.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Review Minutes of Last Meetings

- 1. Status of February 2021 Minutes**—The February 2021 meeting minutes have not been signed yet, due to the zero based review of the TRICARE Beneficiary Advisory Panel by the Secretary of Defense.
- 2. Clarification of Previous Minutes**
 - a) May 2019 Meeting—MHS GENESIS OTC Test List:** Due to a shortage of acetaminophen 325mg tablets, acetaminophen 500mg tablets (GCN 16965) were added to the MHS GENESIS OTC list until the shortage resolves.
- 3. Formulary Status of immunoglobulin gamma subcutaneous injection human-klhw solution (Xembify):** Xembify is a subcutaneous immunoglobulin (SCIG) product that was FDA-approved in 2019 and was designated UF on May 13, 2020.

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. Menopausal Hormone Therapy: Single Agents, Combination Agents, and Vaginal Agents Subclasses

Background—The Menopausal Hormone Therapy (MHT) class has not previously been reviewed for formulary placement, however several products have been designated as Basic Core Formulary (BCF) dating back to 1999 (prior to the implementation of the UF Final Rule in 2005). Estradiol vaginal insert (Imvexxy) and estradiol/micronized progesterone (Bijuva) were reviewed as innovators in 2018 and 2019, respectively, and both were designated nonformulary with Imvexxy also requiring prior authorization (PA) criteria. Three MHT subclasses, Oral Single Agents, Oral Combination Agents, and Vaginal Agents, are the subject of this review.

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

Oral Single Agents Subclass

- The subclass is made up of three drugs, estradiol (Estrace and generics), conjugated equine estrogens (Premarin), and esterified estrogens (Menest).
- Estradiol and esterified estrogens are plant-derived. The conjugated equine estrogens (CEE) found in Premarin products are derived from pregnant mares' urine. While potency and doses differ among the drugs in this subclass, there is little difference in efficacy for treating vasomotor symptoms of menopause (hot flashes). (North American Menopause Society (NAMS) 2017 Position Statement)
- Data from one randomized controlled trial included in the 2016 Cochrane Review does not suggest a safety difference between estradiol and CEE; however, small observational trials suggest cardiovascular and cognitive benefits with estradiol over CEE.
- Estradiol is preferred over CEE in transgender patients due to ease of monitoring.

Oral Combination Agent Subclass

- The oral combination subclass is primarily used to treat vasomotor symptoms of menopause. The class is comprised of estrogen/progestogen combinations and estrogen/testosterone combinations.

- The purpose of adding a progestin to an estrogen for the combination products is to prevent endometrial hyperplasia and cancer in women who have a uterus. Uterine cancer can develop in as little as 6 months with use of unopposed estrogen therapy in women who have not had a hysterectomy.
- There is conflicting data regarding the relative endometrial protection provided with different progestogens (i.e., norethindrone acetate, medroxyprogesterone acetate, progesterone). (American Association of Clinical Endocrinologists and American College of Endocrinology [AACE/ACE] 2017)
- The 2017 AACE/ACE guidelines state that micronized progesterone is considered the safer alternative when progesterone is necessary.
- Compared to medroxyprogesterone acetate, micronized progesterone appears to have better outcomes for cardiovascular effects, blood pressure, venous thromboembolism, stroke, and breast cancer. However, safety risks with medroxyprogesterone acetate are diminished if used for 5 years or less.
- Bijuva is the only combination product that contains estradiol and micronized progesterone.
- Estradiol/drospirenone (Angeliq) has additional contraindications (renal impairment and adrenal insufficiency) and drug interactions (NSAIDs, ACEIs, ARBs) compared to the other oral combination agents. However, it is the only product that contains the progestin drospirenone, which has anti-mineralocorticoid activity, and may cause small reductions in blood pressure.
- Combination products containing methyltestosterone (i.e., Covaryx, generics) may be used in menopausal women with sexual interest/arousal disorder.

Vaginal Agents Subclass

- The subclass is further divided into vaginal creams, inserts, and rings. With the exception of Femring, which is a systemically acting hormone therapy, all other drugs in this subclass are locally acting.
- The Vaginal Agents are almost exclusively used to treat the genitourinary syndrome of menopause (GSM). There are no significant differences in efficacy between the various estrogen creams, inserts, and rings for the treatment of GSM, including urogenital atrophy (Cochrane 2016).
- Overall, there are little to no differences in safety between the various vaginal estrogens when used at typical doses and dosing frequencies.

- Estradiol acetate vaginal ring (Femring) bypasses the GI tract and thus has a less anticipated impact on lipids and blood clotting and is not associated with an increased risk of venous thromboembolism compared to oral products.
- Vaginal rings (Estring, Femring) are convenient as they last for three months, but they can become dislodged and may not initially be used in patients with significant vaginal stenosis.
- Vaginal creams (Premarin, Estrace) allow for dose titration and for application directly to external tissues, but are messier than the other vaginal dosage forms.
- Vaginal inserts (Yuvafem vaginal tablets and Imvexxy vaginal capsules) are less messy than the creams, but cannot be titrated. Imvexxy capsules are available in a lower estradiol strength of 4 mcg in addition to 10 mcg.
- Some patients may prefer the vaginal rings and tablets over the vaginal creams, as they may be easier to administer, are less messy, and some patients consider these formulations more comfortable.

Overall Clinical Conclusions

In order to meet the needs of Military Health System (MHS) beneficiaries, a variety of menopausal hormone therapy products are needed on the formulary. The formulation, dose, and route of administration should be determined individually and reassessed periodically. Inclusion of multiple agents in each subclass on the uniform formulary is beneficial in supporting differences in patient and provider preferences.

Relative Cost-Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that generic formulations in each subclass were the most cost-effective, followed by the branded products, which are ranked from least to most costly, as outlined below:
 - **For the oral single agents**, generic estradiol tablets were the most cost-effective agent followed by conjugated equine estrogens tablets (Premarin), and esterified estrogens (Menest).
 - **For the oral combination agents**, the generics (e.g., generic Femhrt, Activella, Femt) were most cost effective, followed by conjugated equine estrogens/medroxyprogesterone acetate tablet (Prempro), conjugated equine estrogens plus medroxyprogesterone acetate tablets (Premphase), estradiol/progesterone caps (Bijuva), estradiol/norgestimate (Prefest) and estradiol/drospirenone (Angeliq).

- **For the vaginal agents:** Generic estradiol vaginal cream and vaginal tablets were the most cost effective products, followed by estradiol vaginal ring (Estring), estradiol vaginal insert (Imvexxy), conjugated equine estrogens vaginal cream (Premarin cream), and estradiol acetate vaginal ring (Femring).
 - BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating all oral single, oral combination and vaginal agents as UF and none as NF or Tier 4 demonstrated significant cost avoidance for the MHS.
1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Oral Single Agents Subclass

- UF
 - conjugated equine estrogens tablets (Premarin)
 - estradiol tablets (Estrace, generics)
 - esterified estrogens tablets (Menest)
- NF – None
- Tier 4/Not Covered – None

Oral Combination Agents Subclass

- UF
 - conjugated equine estrogens/medroxyprogesterone acetate tablets (Prempro)
 - conjugated equine estrogens plus medroxyprogesterone acetate tablets (Premphase)
 - ethinyl estradiol/norethindrone acetate tablets (Femhrt, and generics Jinteli, Fyavolv)
 - estradiol/norethindrone acetate tablets (Activella, and generics Amabelz, Jinteli, Mimvey, Mimvey Lo)
 - esterified estrogens/methyltestosterone (Covaryx, Covaryx HS, Eemt, Eemt HS, generics)
 - estradiol/drospirenone (Angeliq)
 - estradiol/norgestimate (Prefest)
 - estradiol/progesterone capsules (Bijuva) (*moves from NF to UF*)
- NF – None

- Tier 4/Not Covered – None

Vaginal Agents Subclass

- UF
 - conjugated equine estrogens vaginal cream (Premarin)
 - estradiol vaginal cream (Estrace, generics)
 - estradiol vaginal ring (Estring)
 - estradiol acetate vaginal ring (Femring)
 - estradiol vaginal tablet (Yuvaferm, Vagiferm generics)
 - estradiol vaginal insert (Imvexxy) (*moves from NF to UF*)
- NF – None
- Tier 4/Not Covered – None

2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following for the BCF:

Oral Single Agents Subclass

- Adding estradiol oral tablet (generic)
- Removing conjugated equine estrogens tablet (Premarin)

Oral Combination Agents Subclass

- Removing conjugated equine estrogens/medroxyprogesterone acetate tablet (Prempro)

Vaginal Agents Subclass

- Estradiol vaginal cream (generic) is added to the BCF (*previous BCF recommendation allowed for the MTFs to select the estrogenic vaginal cream of their choice*)

3. **COMMITTEE ACTION: MANUAL PA CRITERIA**—Existing PA criteria currently apply to estradiol vaginal insert (Imvexxy). The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing the PA for Imvexxy. As a result, there are no PA requirements in any of the three MHT subclasses reviewed.

4. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS**—The P&T Committee recommended (18 for, 0

opposed, 0 abstained, 0 absent), removing Premarin, Menest, Prempro, Premphase, Estring, and Prefest from the EMMPI program, as they have comparable pricing across all three points of service. The Committee also recommended maintaining Bijuva, Imvexxy, Femring, Vagifem, Estrace tablet, Activella, Femhrt, and Angeliq on the EMMPI program. Premarin vaginal cream and Estrace vaginal cream remain not subject to the EMMPI program requirements, due to package size and day supply issues.

- 5. COMMITTEE ACTION: UF, BCF, PA REMOVAL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30-days after signing of the minutes in all points of service. Based on the P&T Committee’s recommendation, the effective date is March 30, 2022.

B. Sleep Disorders: Insomnia Agents Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the drugs used to treat insomnia. This class was last reviewed in May 2012. Drugs in the class include numerous formulations of zolpidem (immediate-release, extended-release, oral spray, and sublingual), eszopiclone, zaleplon, and doxepin, melatonin agonists (ramelteon and tasimelteon), and the newer dual orexin receptor antagonists (DORAs) suvorexant (Belsomra) and lemborexant (Dayvigo). The DORAs were previously reviewed as individual new drugs in May 2015 and August 2020, respectively.

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

Guidelines and Therapies

- Non-pharmacological therapies including sleep hygiene, relaxation, and cognitive behavioral therapy for insomnia (CBT-I) are recommended as first-line treatment of chronic insomnia.
- Pharmacologic treatment can be used in addition to non-pharmacologic therapies for patients who continue to have insomnia.
- Guidelines recommend treating insomnia with pharmacologic therapies for the shortest possible treatment course.
- Options for sleep onset insomnia include zolpidem IR (Ambien, generics), zaleplon (Sonata, generics), and the melatonin agonist ramelteon (Rozerem, generics). Agents approved for both sleep onset and sleep maintenance include zolpidem ER (Ambien CR, generics), eszopiclone (Lunesta, generics), and the DORAs suvorexant (Belsomra) and lemborexant (Dayvigo).

Older Agents

- All the older agents improve sleep latency (the time to fall asleep) by approximately 10 to 15 minutes, compared to placebo.
- For the older insomnia drugs, there was no new data to change the conclusions from the May 2012 meeting which stated that there are no clinically relevant differences between the drugs.
- Doxepin tablets (Silenor, generics) improve insomnia due to sleep maintenance problems; no comparative data exists with doxepin and the other drugs in the class. One advantage is that doxepin is not a controlled substance.
- Other than providing an alternative dosage formulation for patients with swallowing difficulties, zolpidem oral spray (Zolpimist), and zolpidem sublingual (Edluar and Intermezzo) do not offer clinically compelling advantages over other insomnia drugs.

DORAs

- Suvorexant (Belsomra) and lemborexant (Dayvigo) competitively inhibit the wakefulness-promoting neuropeptides orexin A and B.
- No direct comparative data are available between Belsomra and Dayvigo, and indirect comparisons are confounded due to the different endpoints used. An indirect comparison showed both DORAs decrease the time to fall asleep by approximately 15 minutes and increase the total time asleep by about 30 minutes.
- Both agents have efficacy and safety data in older adults and in patients with dementia related to Alzheimer's disease who have insomnia. There is currently no evidence to support that one DORA is better than another when treating elderly patients.
- More data is needed to determine comparative effectiveness in patients experiencing middle of the night awakenings.
- Both DORAs have drug-drug interactions that should be considered when treating patients. Lemborexant has a longer half-life (17-19 hours) compared to suvorexant (12 hours). Adverse events with lemborexant and suvorexant are generally similar and dose-related.
- Warnings and precautions for the DORAs include daytime somnolence (patients using higher doses are cautioned against driving the next day); sleep paralysis, hallucinations, and cataplexy-like symptoms; and complex sleep behaviors. The DORAs should be used with caution in patients with compromised respiratory function; and worsening of depression.

Melatonin Agonists

- Ramelteon (Rozerem, generics) is a melatonin agonist that improves sleep onset and is not a controlled substance.
- Tasimelteon (Hetlioz) is another prescription melatonin agonist, and has been designated as NF with PA criteria since February 2015. It was originally indicated for blind patients with non-24 hour sleep-wake disorder.
- The prescription products ramelteon (Rozerem generics) and tasimelteon (Hetlioz) have similar chemical compositions to the dietary supplement melatonin.
- Since the last formulary review, tasimelteon is now indicated for use in Smith-Magenis Syndrome (SMS), a rare condition. A liquid formulation (Hetlioz LQ) specifically approved for children aged 3 to 15 years with SMS was recently marketed. Use of tasimelteon in SMS is based on one unpublished study with poor efficacy results and numerous limitations.
- Other than its unique indications, tasimelteon offers no compelling clinical advantages over other melatonin agonists.

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

- CMA results showed that doxepin tablets (Silenor, generics), eszopiclone (Lunesta, generics), ramelteon (Rozerem, generics), zaleplon (Sonata, generics), and zolpidem IR and ER tablets (Ambien, Ambien CR, and generics) are more cost-effective than lemborexant (Dayvigo) and suvorexant (Belsomra). Intermezzo, Zolpimist, Edluar, Hetlioz and Hetlioz LQ are not cost-effective relative to the other insomnia drugs.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating generic doxepin, eszopiclone, ramelteon, zaleplon, and zolpidem IR/ER as UF, with lemborexant (Dayvigo) and suvorexant (Belsomra) as UF and step-preferred branded products, and branded tasimelteon (Hetlioz, Hetlioz LQ), zolpidem spray (Zolpimist), and zolpidem tablets (Edluar, Intermezzo, and generics) as NF and non-step-preferred demonstrated significant cost avoidance for the MHS.

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

- UF generics

- eszopiclone (Lunesta, generics)
- zaleplon (Sonata, generics)
- zolpidem IR (Ambien, generics)
- zolpidem ER (Ambien CR, generics)
- doxepin 3 mg, 6 mg (Silenor, generics)
- ramelteon (Rozerem, generics) (*moves from NF to UF*)
- UF and step-preferred brands
 - lemborexant (Dayvigo)
 - suvorexant (Belsomra) (*moves from NF to UF*)
 - Note that as part of the formulary recommendation for Belsomra and Dayvigo, a trial of zolpidem ER or eszopiclone is required
- NF and non-step-preferred brands
 - zolpidem oral spray (Zolpimist)
 - zolpidem 5 mg, 10 mg sublingual tabs (Edluar)
 - zolpidem 1.75 mg, 3.5 mg sublingual tabs (Intermezzo)
 - tasimelteon capsules (Hetlioz)
 - tasimelteon oral suspension (Hetlioz LQ)
 - Note that as part of this formulary recommendation for Zolpimist, Edluar, and Intermezzo, a trial of zolpidem IR or zaleplon and Belsomra or Dayvigo are required in new and current users
 - Note that as part of this formulary recommendation for Hetlioz and Hetlioz LQ, a trial of ramelteon and melatonin are required in new users
- Tier 4/Not Covered: None

2. **COMMITTEE ACTION: BCF RECOMMENDATION**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining zolpidem IR on the BCF, and adding zolpidem ER to the BCF.

3. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA has applied to the older insomnia drugs since 2010, the DORA Belsomra since 2015, the DORA Dayvigo since 2020, and to Hetlioz since 2014. The P&T Committee

recommended (16 for, 1 opposed, 0 abstained, 1 absent) updates to the manual PA criteria as outlined below. See Appendix C for the full criteria.

- Ramelteon (Rozerem generics) and doxepin 3 mg, 6 mg (Silenor generics): The existing PA criteria will be removed. Use of these two agents will be monitored for inappropriate use and consideration will be given to reinstating PA criteria if necessary.
 - Edluar, Intermezzo and Zolpimist: The updated PA criteria in new and current users will include a trial of cognitive behavioral therapy for insomnia (CBT-I) as part of the non-pharmacologic therapy options. In addition to a trial of a generic zolpidem IR or zaleplon first, the PA will also require a trial of a DORA (Belsomra or Dayvigo). The current automated setup will be removed and replaced with manual criteria. Renewal criteria will now be required.
 - Dayvigo and Belsomra: The updated PA criteria in new users will include a trial of CBT-I as a non-pharmacologic therapy option and require renewal criteria.
 - Hetlioz and Hetlioz LQ: The updated PA criteria in new users will include a trial of ramelteon in addition to OTC melatonin. Note that melatonin 3 mg and 5 mg were added to the MHS GENESIS OTC test list, in order to standardize dispensing of melatonin at MTFs. See p 21-22 for more detail.
4. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated MN criteria for Edluar, Intermezzo, Zolpimist to allow in cases of swallowing difficulties, and updated MN criteria for Hetlioz, and Hetlioz LQ, requiring a trial of ramelteon and OTC melatonin first. See Appendix B for the full criteria.
5. **COMMITTEE ACTION: QLS**—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) applying a 30 day supply quantity limit (QL) at all points of service for Hetlioz and Hetlioz LQ. See Appendix D.
6. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) AND NF TO MAIL REQUIREMENTS**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) maintaining Dayvigo on the program, and adding Edluar, Intermezzo and Zolpimist to the EMMPI program. Belsomra, Hetlioz, and Hetlioz LQ are not subject to the EMMPI requirements.

7. **COMMITTEE ACTION: UF, BCF, PA, MN, QL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service; 2) DHA send letters to beneficiaries who are affected by the updated PA requirements for Edluar, Intermezzo and Zolpimist. Based on the P&T Committee’s recommendation, the effective date is April 20, 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 (17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 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 (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- UF:
 - cabotegravir (Vocabria) – Integrase strand transfer inhibitor antiretroviral for HIV
 - ponesimod (Ponvory) – Oral miscellaneous multiple sclerosis (MS) agent for relapsing forms of MS
 - tepotinib (Tepmetko) – Oral oncologic agent for non-small cell lung cancer (NSCLC)
 - tivozanib (Fotivda) – Oral oncologic agent for renal cell carcinoma (RCC)
 - umbralisib (Ukoniq) – Oral oncologic agent for marginal zone lymphoma (MZL) and follicular lymphoma (FL)
 - vericiguat (Verquvo) – Miscellaneous cardiovascular agent for reducing risk of cardiovascular death in adults with chronic heart failure
 - vibegron (Gemtesa) – Overactive Bladder (OAB) drug

- NF:
 - ethinyl estradiol (EE) 20 mcg/ levonorgestrel 0.1 mg chewable tablet (Tyblume) – Monophasic combination oral contraceptive with 20 mcg estrogen
 - levothyroxine sodium 100 mcg/5 mL oral solution (Thyquidity) – Thyroid Agent
 - mannitol inhalation powder (Bronchitol) – Miscellaneous Respiratory Agent for Cystic Fibrosis
 - methotrexate injection (Reditrex) – Antirheumatic
 - solifenacin oral suspension (Vesicare LS) – Antimuscarinic Overactive Bladder Agent for pediatric neurogenic detrusor overactivity (NDO)
 - tirbanibulin 1% ointment (Klisyri) – Antineoplastic for actinic keratosis
 - voclosporin (Lupkynis) – Calcineurin inhibitor immunosuppressive for active lupus nephritis (LN)

- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
 - levetiracetam 1,000 mg and 1,500 mg extended-release tablets (Elepsia XR) – Anticonvulsant Agent
 - Elepsia XR was recommended for Tier 4 status as it has little to no additional clinical effectiveness relative to other levetiracetam products and similar agents in the class, and the needs of TRICARE beneficiaries are met by available alternative anticonvulsant agents. Alternatives include levetiracetam 500 mg and 750 mg ER tablets (Keppra generics), lamotrigine XR, and topiramate ER.

B. COMMITTEE ACTION: MN CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Bronchitol, Klisyri, Lupkynis, Reditrex, Thyquidity, Tyblume, and Vesicare LS. See Appendix B for the full criteria.

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

- OAB Drugs: Applying manual criteria to new users of vibegron (Gemtesa), requiring a trial of two formulary generic OAB drugs first. [See the Utilization Management (UM) Section on pages 16 and 38 for updates to the PA for the branded OAB drug mirabegron (Myrbetriq)].

- Antirheumatics: Applying manual criteria to new users of Reditrex, requiring a trial of oral methotrexate first. [See the UM section on pages 16 for updated PAs for the Otrexup and Rasuvo injectable MTX products].
- Oncologic drugs: Applying manual PA criteria to new users of Fotivda, Tepmetko, and Ukoniq.
- Applying manual PA criteria to new users of Bronchitol, Klisyri, Lupkynis, Ponvory, Thyquidity, Tyblume, and Verquvo.
- Applying manual PA criteria to new users of Vesicare LS.

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

PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 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/Not Covered Status:** 1) An effective date 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. BCF CLARIFICATION: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR ANTAGONISTS (GLP1 RAs)

The Diabetes Non-Insulin: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) subclass was last reviewed at the February 2018 DoD P&T Committee meeting. At that time, the recommendation was to maintain exenatide once weekly (Bydureon) and add exenatide once weekly autoinjector (Bydureon BCise) to the BCF. These two products, along with dulaglutide (Trulicity) are the UF and step-preferred products in the subclass.

Early in 2021, the manufacturer of Bydureon informed DoD that Bydureon would be discontinued, but noted that production of the Bydureon BCise formulation would continue.

A. COMMITTEE ACTION: EXENATIDE ONCE WEEKLY

(BYDUREON) ON THE BCF—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing exenatide once weekly (Bydureon) from the BCF upon signing of the minutes. Bydureon will be removed from the manual PA criteria of the non step-preferred GLP1RA drugs. As a result, the exenatide once weekly autoinjector (Bydureon BCise) will be the sole GLP1RA remaining on the BCF.

VII. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria

- a) **Attention Deficit/Hyperactivity Disorder (ADHD) Stimulants – Methylphenidate Extended Release 72 mg tablets (Relexxii, generics)**—Relexxii 72 mg ER tablets use the same technology as found in Concerta, which is available in 18 mg, 27 mg, 36 mg, and 54 mg tablets. FDA approval for Relexxii was based on the data for Concerta. Several cost-effective extended release methylphenidate formulations are available on the UF without PA. Relexxii and its generics are not cost effective relative to other formulary long-acting methylphenidate formulations including generic Concerta and methylphenidate ER/CD/LA, Quillivant XR, and Aptensio XR.

COMMITTEE ACTION: NEW PA CRITERIA FOR RELEXXII 72 mg—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for methylphenidate 72 mg extended release tablets in new and current users, to ensure that more cost-effective methylphenidate ER products are tried first. See Appendix C for the full criteria.

- b) **Targeted Immunomodulatory Biologics (TIBs) – Rilonacept injection (Arcalyst)**—The targeted immunomodulatory biologic rilonacept (Arcalyst) was originally approved in 2008 for the treatment of cryopyrin-associated periodic syndrome (CAPS), and for maintenance of remission of deficiency of interleukin-1 receptor antagonist (DIRA), which are rare conditions. In March 2021, Arcalyst received a new indication for treatment of recurrent pericarditis.

The 2015 European Society of Cardiology treatment guidelines for pericardial disease recommend aspirin or NSAIDs plus colchicine for six months as first-line therapy to improve remission rates and prevent recurrences of pericarditis. Corticosteroids may be added if there is an incomplete response to first-line therapies. MHS provider input supported PA to require a trial of conventional therapies for recurrent pericarditis.

COMMITTEE ACTION: TARGETED IMMUNOMODULATORY BIOLOGICS – RILONACEPT (ARCALYST)—The P&T Committee recommended (16 for, 0 opposed, 1 abstained, 1 absent) manual PA criteria for rilonacept (Arcalyst) in new users, to ensure that guideline recommended therapies for recurrent pericarditis are tried first. See Appendix C for the full criteria.

2. Updated PA Criteria and Step Therapy

Updates to the manual PA criteria and step therapy were recommended due to availability of cost-effective alternative treatments, clinical trial data, clinical practice

guideline updates, or provider recommendation. The updated PAs and step therapy outlined below will apply to new users. See Appendix C for full criteria.

- a) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Irritable Bowel Syndrome Constipation predominant (CIC/IBS-C) — lubiprostone (Amitiza)**—The CIC/IBS-C class was reviewed in November 2018. Amitiza, linaclotide (Linzess), and plecanatide (Trulance) were made uniform formulary, with prucalopride (Motegrity) designated non-formulary and tegaserod (Zelnorm) designated as Tier 4/Not covered. As of November 2018, the drugs in the class all require PA, with a trial of standard laxatives required first. A generic to Amitiza has recently entered the market; however, it is markedly more expensive than Linzess. The manual PA criteria for Amitiza was updated to require a trial of linaclotide (Linzess) prior to use of Amitiza for all new users.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Amitiza.

- b) **Antirheumatics: Injectable methotrexate—Otrexup and Rasuvo**—The injectable methotrexate agents were reviewed in November 2015. Generic methotrexate injectable solution is uniform formulary while both methotrexate autoinjector formulations (Otrexup and Rasuvo) are NF. Oral methotrexate tablets are BCF. The manual PA criteria for Otrexup and Rasuvo were updated to require oral methotrexate in addition to generic injectable methotrexate prior to use of these less cost-effective autoinjector formulations for all new users. The updated PA criteria are similar to the PA criteria recommended for the new drug Reditrex (See p 12).

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Otrexup and Rasuvo.

- c) **OAB Drugs – mirabegron (Myrbetriq)**—Manual PA criteria for Myrbetriq have been in place since 2014. Vibegron (Gemtesa) is a new beta-3 adrenergic receptor agonist also approved for OAB, which was recommended for UF status (see p 12 in the new drug section). Vibegron is a therapeutic alternative to mirabegron, and is more cost effective. New users of Myrbetriq will now be required to try Gemtesa first, in addition to the existing PA requirements. *Note that Myrbetriq tablets received an additional indication for neurogenic detrusor overactivity (NDO) at the August 2021 P&T meeting; refer to the August 2021 meeting for the full updates.*

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Myrbetriq.

- d) **Renin-Angiotensin Antihypertensives: Combinations – sacubitril/valsartan (Entresto)**—Sacubitril/valsartan is an angiotensin receptor-neprilysin inhibitor

(ARNI) approved for treating patients with chronic heart failure (HF). Entresto was reviewed and recommended for UF status with a manual PA in May 2016. Current PA criteria requires the patient to have been stabilized on an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) first, and to have a left ventricular ejection fraction (LVEF) $\leq 35\%$, based on the inclusion criteria of the PARADIGM clinical trial, which was used to gain FDA approval.

The Committee reviewed the February 2021 American College of Cardiology (ACC) Expert Consensus Decision Pathway for Optimization of HF, which now recommends ARNI therapy as preferred for first line treatment of chronic HF. Earlier this year, the FDA expanded the Entresto package insert, which now states the drug is indicated to decrease the risk of cardiovascular death and HF hospitalization in adults with chronic heart failure, with the benefits most evident in patients with LVEF below normal. The PARAGON trial results in patients with heart failure and preserved ejection fraction (HFpEF) were also reviewed. MHS cardiology providers have requested expanded access to Entresto.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the current PA criteria for sacubitril/valsartan, recognizing that guideline directed medical therapies (GDMT) for chronic HF, including Entresto are underutilized, and also acknowledging the 2021 ACC consensus pathway recommendations and updated FDA package labeling. Follow-up monitoring for Entresto utilization will be ongoing to evaluate usage patterns.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 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.

- **Oncological Agents**
 - **Lung Cancer – crizotinib (Xalkori)**—The manual PA criteria were updated to allow for the new indication for treatment of relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase-positive (ALK+) in pediatric patients one year of age and older, and young adults. There is a limitation of use in older adults for this new indication as safety and efficacy of Xalkori is not established in older adults with relapsed or refractory, systemic ALK+ ALCL.
 - **Lung Cancer – lorlatinib (Lorbrena)**—Manual PA criteria now allow use as first-line treatment of adults with ALK+ metastatic non-small cell lung cancer (NSCLC) when tumors are ALK+ as detected by an FDA-approved test.
- **Targeted Immunomodulatory Biologics (TIBs)**

- **adalimumab (Humira)**—Manual PA criteria now allow use in pediatric patients 5 years of age and older as well as adults for moderately to severely active ulcerative colitis (UC).
- **tocilizumab subcutaneous (Actemra SQ)**—Includes the new FDA-approved indication for slowing the rate of decline in pulmonary function in systemic sclerosis-associated interstitial lung disease (SSc-ILD) in adults.
- **Parkinson’s Disease Agents – amantadine (Gocovri)**—Includes the new indication for use as adjunctive treatment to levodopa/carbidopa for add-on therapy for “off” episodes of Parkinson’s Disease (PD).
- **Pulmonary Arterial Hypertensions: prostacyclin nebulized – treprostinil (Tyvaso)** — Includes the new FDA-approved indication for treatment of pulmonary hypertension associated with interstitial lung disease (WHO Group 3) to improve exercise ability.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Xalkori, Lorbrena, Humira, Actemra SQ, Gocovri, and Tyvaso. See Appendix C for the full PA criteria.

B. Quantity Limits

General QLS: QLS were reviewed for 7 drugs from drug classes where there are existing QLS, and for some of the new drugs, including the TIBs, methotrexate, antineoplastic and premalignant lesion agents, OAB drugs and oncological agents.

COMMITTEE ACTION: QLS—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLS for Arcalyst, Reditrex, Klisyri, Vesicare LS, Fotivda, Tepmetko, and Ukoniq. See Appendix D for the QLS.

C. PA and QLS Implementation Periods

COMMITTEE ACTION: PA AND QLS IMPLEMENTATION PERIOD—The P&T Committee recommended the following implementation periods:

- (17 for, 0 opposed, 0 abstained, 1 absent) The new PA for methylphenidate 72 mg extended release tablets (Relexxii) will become effective in new and current users the first Wednesday 90 days after the signing of the minutes and DHA will send letters to affected patients (May 18, 2022).

- (16 for, 0 opposed, 1 abstained, 1 absent) The new PA for Arcalyst will become effective in new users the first Wednesday 30 days after the signing of the minutes (March 16, 2022).
- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria in new users for the oncology drugs Xalkori and Lorbreña; the TIBs Humira and Actemra SQ; the Parkinson’s Disease Agent Gocovri; the pulmonary arterial hypertension drug Tyvaso will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2022)
- (17 for, 0 opposed, 0 abstained, 1 absent) Updates to the current PA criteria in new users for Amitiza, the updates to the Rasuvo and Otrexup PA criteria in new users, updates to the PA for Myrbetriq in new users, and the removal of the Entresto PA criteria will become effective the first Wednesday 30 days after the signing of the minutes (March 16, 2022).
- (17 for, 0 opposed, 0 abstained, 1 absent) the QLs listed in Appendix D will become effective the first Wednesday 2 weeks after the signing of the minutes in all POS (March 2, 2022).

VIII. 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. COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMPI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (March 2, 2022).

- **Oncological Agents: 2nd-Gen Antiandrogens**—designating **enzalutamide (Xtandi) 40 mg and 80 mg tablets** as UF, with the same Tier 1 co-pay, same manual PA criteria requirements, QL, and same specialty status as Xtandi 40 mg capsule. (Note that neither the Xtandi caps or tabs will be on the specialty program.)
- **Targeted Immunomodulatory Biologics: Miscellaneous**—designating **tofacitinib oral solution (Xeljanz)** as UF, with the same step therapy and PA criteria, QL, specialty status, and EMMPI List status, similar to Xeljanz 5 mg and 10 mg tablets. (Note that Xeljanz XR tablets are on the specialty program).

- **Diabetes Non-Insulin: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**—designating **semaglutide (Ozempic) 1 mg/0.75 mL injection** as NF and Non-step-preferred, with the same MN criteria, same PA criteria, and EMMPI List status, similar to the existing Ozempic injection strengths.
- **Parkinson’s Disease Agents**—designating **opicapone (Ongentys) 25 mg capsules** as UF, similar to Ongentys 50 mg capsules.

IX. RE-EVALUATION OF NF GENERICS: CALCIUM CHANNEL BLOCKERS (CCBs)

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs that are now available in generic formulations needs to be readdressed. The P&T Committee’s process for the reevaluation of NF agents was established at the May 2007 meeting and approved by the Director, of the then TRICARE Management Agency (now DHA), on July 24, 2007. A summary of the criteria is available in Appendix E of the November 2012 P&T Committee minutes available online at <https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Operations/Pharmacy-Division/DoD-Pharmacy-and-Therapeutics-Committee-2021/Meeting-Minutes>.

CCBs: The P&T Committee re-evaluated the UF status of the six NF CCBs, all of which are now available in generic formulations: verapamil capsule 24 hr (Verelan PM); verapamil capsule (Verelan); diltiazem tablet ER 24h (Cardizem LA); isradipine capsule (generic only); nifedipine (generic only); and nisoldipine tablet ER 24h (Sular).

Verelan PM has been designated as NF since the CCB drug class review in August 2005. The P&T Committee re-evaluated the formulary status of Verelan PM due to price reductions in generic verapamil capsule 24 hour formulations available across all three points of service (POS). There was no new clinical data to change the conclusion that the CCBs are highly therapeutically interchangeable.

Current utilization trends, numbers of generic products on the market from different manufacturers, and relative cost-effectiveness, including the weighted average cost per unit for generic verapamil capsule 24 hour were also reviewed. The unit cost of generic verapamil capsule 24 hour formulations has dropped significantly from the previous generic and brand cost, and the generic supply appears stable. The other NF CCB products have not shown a significant decline in cost.

COMMITTEE ACTION: FORMULARY STATUS, AND EMMPI RECOMMENDATION AND IMPLEMENTATION —The P&T Committee recommended (17 for, 0 opposed, 0 abstained, and 1 absent) the following, effective the first Wednesday 30 days after signing of the minutes:

- Returning generic verapamil capsule 24 hour (Verelan PM) to formulary status
- Removing generic verapamil capsule 24 hour from the EMMPI program
- The remaining NF CCBs, Verelan, Cardizem LA, isradipine, nifedipine, and nisoldipine will remain NF, and remain subject to the requirement that they be generally available only at mail order, regardless of generic status.

X. 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 May 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 May 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 (17 for, 0 opposed, 0 abstained, 1 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.

XI. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFs: MELATONIN

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

Factors influencing whether a particular OTC product is retained or removed from the MHS GENESIS OTC List include volume and utilization across multiple MTFs; feedback from MTF stakeholders to include primary care providers, pediatricians, and other providers, DHA Clinical Community advisory groups, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

- **Melatonin**—The FDA classifies melatonin as a dietary supplement, therefore it is not FDA-approved for any indication. Melatonin is commonly used as a sleep aid or for treating circadian rhythm disorders. There is little risk of harm and few adverse effects associated with its use.

The most utilized strengths of melatonin currently dispensed at MTFs include the 3 mg and 5 mg tablets. The average cost per month is less than \$1 per prescription, and 39% of all MTFs have dispensed at least one melatonin prescription in the last quarter. Providers consistently reported wanting the option to prescribe melatonin at MTFs.

1. COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—The P&T Committee recommended (15 for, 1 opposed, 0 abstained, 2 absent) the following:

- Retaining melatonin 3 mg (GCN 68738) and 5 mg (GCN 99671) tablets on the MHS GENESIS OTC list.
- Removing melatonin 1mg tablet (GC 94035), melatonin 5 mg SL tablet (GCN 13448) and the 10 mg mphase tablet (GCN 31649) from the MHS GENESIS OTC list.
- An implementation of 120 days following signing of the minutes for the products removed from the list. No patient letters are required due to the typically intermittent use of the products. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

XII. ITEMS FOR INFORMATION

A. Veterans Affairs Continuity of Care List

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

B. MHS and Commercial Pharmacy Trends

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

C. Post-Implementation Review: Utilization Management Actions

A retrospective review of several UM actions was presented to the Committee, including chlorzoxazone, doxycycline IR/DR, droxidopa (Northera), epinephrine injector (Auvi-Q), lidocaine-tetracaine 7%-7%, prenatal vitamins (Azesco, Trinaz, Zalvit), rotigotine (Neupro Patch), topical sulfacetamide, and venlafaxine ER 24 hour tablets. Overall trends in utilization and expenditures were reviewed since implementation.

XIII. ADJOURNMENT

The meeting adjourned at 1630 hours on May 6, 2021. The next meeting will be in August 2021.

Appendix A—Attendance: May 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 May 2021 DoD P&T Committee Meeting

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

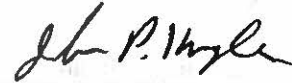
Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives

Appendix I—MHS GENESIS OTC Test List

Appendix J—Table of Abbreviations

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

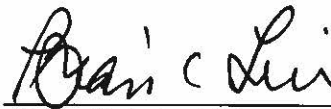
The Director, DHA:

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

11 Feb 2022

Date

Appendix A—Attendance: May 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	DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
MAJ Wendra Galfand, MC	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Christopher Janik for CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Matthew Kemm for Maj 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
Ms. Beth Days	Oncology Pharmacist
LCDR Joseph An, MSC	Navy, Oncologist
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Fakhrudin Valibhai, PharmD	COR TRICARE Pharmacy Program
Eugene Moore, PharmD	COR TRICARE Pharmacy Program
LCDR William Agbo	DLA Troop Support
Janet Dailey, PharmD (May 5 th) Kelly Echevarria, PharmD (May 6 th)	Department of Veterans Affairs

Appendix A—Attendance: May 2021 P&T Committee Meeting

Guests	
CPT Jennifer Weeks, MC	Army, Physician at Large alternate
Maj Angelina Escano, MC	Air Force physician
Mr. Jason Wray	DLA Troop Support
Ms. Pat Legra	DHA Contracting
Ms. Viktoria Reed	DHA Contracting
Mr. Dwight Bonham	DHA Contracting
Mr. Hudson Tompkins	DHA Contracting
Ms. Grace Steier	DHA Contracting
Mr. Monroe Porter	DHA Contracting
Others Present	
CDR Heather Rovey, 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
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
MAJ Triet Nguyen, MSC	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. Ebony Moore	DHA Formulary Management Branch Contractor
CPT Julian Rodriguez, MSC	BAMC Pharmacy Resident

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
Class Review MN Criteria	
<ul style="list-style-type: none"> • zolpidem sublingual (Intermezzo) • zolpidem sublingual (Edluar) • zolpidem oral spray (Zolpimist) <p>Sleep Disorders: Insomnia</p>	<ul style="list-style-type: none"> • No alternative formulary agent: patient has documented swallowing difficulties <p>Formulary alternatives: zolpidem IR tab, zaleplon</p>
<ul style="list-style-type: none"> • tasimelteon (Hetlioz/Hetlioz LQ) <p>Sleep Disorders: Insomnia</p>	<ul style="list-style-type: none"> • Two agents (OTC melatonin and ramelteon) have resulted in therapeutic failure <p>Formulary alternatives: melatonin OTC, ramelteon</p>
Newly Approved Drugs MN Criteria	
<ul style="list-style-type: none"> • ethinyl estradiol (EE) 20 mcg/levonorgestrel 0.1 mg chewable tablet (Tyblume) <p>Contraceptive Agents: Monophasics with 20 mcg estrogen</p>	<ul style="list-style-type: none"> • No alternative formulary agent: patient requires Tyblume chewable tablets due to established swallowing difficulties. <p>Formulary alternatives: levonorgestrel/EE tablets (generic Lutera, Sronyx, or equivalent)</p>
<ul style="list-style-type: none"> • levothyroxine sodium 100 mcg/ 5 mL oral solution (Thyquidity) <p>Thyroid Agents</p>	<ul style="list-style-type: none"> • No alternative formulary agent: patient is not able to swallow capsules or sprinkle capsules on food or chew a tablet <p>Formulary alternatives: Tirosint-SOL, Tirosint capsule, levothyroxine tabs (various)</p>
<ul style="list-style-type: none"> • mannitol inhalation powder (Bronchitol) <p>Respiratory Agents Miscellaneous</p>	<ul style="list-style-type: none"> • Use of two formulary agents (Pulmozyme, hypertonic saline 7% inhalation) are contraindicated • Two formulary agents (Pulmozyme, hypertonic saline 7% inhalation) resulted in therapeutic failure/inadequate response <p>Formulary alternatives: dornase alfa (Pulmozyme), hypertonic saline 7% inhalation (sodium chloride)</p>

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
<ul style="list-style-type: none"> methotrexate injection (Reditrex) <p>Antirheumatics: Injectable Methotrexate</p>	<ul style="list-style-type: none"> No alternative formulary agent: The patient requires a prefilled syringe due to decreased finger dexterity, or limited vision or impaired cognition <p>Formulary alternatives: generic methotrexate vials, generic methotrexate tablets</p>
<ul style="list-style-type: none"> solifenacin oral suspension (Vesicare LS) <p>Overactive Bladder Agents</p>	<ul style="list-style-type: none"> Patient has experienced or is likely to experience significant adverse effects from formulary agents Formulary agents result in therapeutic failure <p>Formulary alternatives: oxybutynin</p>
<ul style="list-style-type: none"> tirbanibulin 1% ointment (Klisyri) <p>Antineoplastic and Premalignant Lesion Agents</p>	<ul style="list-style-type: none"> Use of formulary agents is contraindicated Formulary agents result in therapeutic failure <p>Formulary alternatives: fluorouracil, imiquimod</p>
<ul style="list-style-type: none"> voclosporin (Lupkynis) <p>Immunosuppressives</p>	<ul style="list-style-type: none"> Patient has experienced significant adverse effects from formulary agents Formulary agents result in therapeutic failure Patient previously responded to the non-formulary agents and changing to a formulary agent would incur unacceptable risk <p>Formulary alternatives: tacrolimus, mycophenolate, corticosteroids, cyclophosphamide, Benlysta</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
<ul style="list-style-type: none"> • suvorexant (Belsomra) • lemborexant (Dayvigo) <p>Sleep Disorders: Insomnia</p>	<p><u>Updates from the May 2021 meeting are in bold.</u> Manual PA criteria apply to all new users of Belsomra and Dayvigo.</p> <p><u>Manual PA criteria:</u> Belsomra and Dayvigo are approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that the following agents are available without prior authorization: zolpidem IR and ER, zaleplon, eszopiclone • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), sleep hygiene, and the patient will continue with non-pharmacologic therapies throughout treatment • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release OR eszopiclone • Patient does not have a current or previous history of narcolepsy • Patient does not have a current or previous history of drug abuse <p>Non-FDA-approved uses are not approved. Prior authorization expires in 1 year.</p> <p><u>Renewal criteria</u> Note that initial TRICARE PA approval is required for renewal. PA will be renewed for an additional 1 year if the renewal criteria are met.</p> <ul style="list-style-type: none"> • Patient has not adequately responded to non-pharmacologic therapies • Patient agrees to continue with non-pharmacologic therapies including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), and/or sleep hygiene • Patient continues to respond to the drug

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • tasimelteon (Hetlioz/Hetlioz LQ) <p>Sleep Disorders: Insomnia</p>	<p><u>Updates from the May 2021 meeting are in bold. (Note that changes recommended at the Feb 2021 meeting in the UM section have been updated)</u></p> <p>Manual PA criteria apply to all new users of Hetlioz/Hetlioz LQ.</p> <p><u>Manual PA criteria:</u> Hetlioz or Hetlioz LQ is approved if <u>all</u> of the following criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that Hetlioz capsules are not approved for pediatrics or adolescents and are not approved for treating SMS; and that Hetlioz LQ liquid is only approved for pediatrics with SMS and is not approved for Non-24 sleep wake disorder or for use in adults. • For the Hetlioz capsule formulation, the patient is 18 years of age or older and is totally blind and has a documented diagnosis of non-24 sleep wake disorder OR • For the Hetlioz LQ liquid formulation, the patient is 3 years of age up to 15 years of age and has a documented diagnosis of Smith-Magenis Syndrome (SMS) • The patient has had a trial of melatonin and either failed or had an adverse event • The patient has tried and failed ramelteon • The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) <p>Non-FDA-approved uses are not approved including insomnia, jet lag disorder, or other circadian rhythm disorders.</p> <p>PA Criteria will expire after 6 months (if patient has not responded after 6 months, they will be deemed a non-responder)</p> <p><u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal</p> <ul style="list-style-type: none"> • The patient has been receiving Hetlioz/Hetlioz LQ for 6 months and has had a documented response to therapy. Renewal approved for 6 months.

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • zolpidem sublingual (Intermezzo) • zolpidem sublingual (Edluar) • zolpidem oral spray (Zolpimist) <p>Sleep Disorders: Insomnia</p>	<p>Updates from the May 2021 meeting are in bold. Note that the current automation will be removed.</p> <p>Manual PA criteria apply to all new and current users of Intermezzo, Edluar, and Zolpimist.</p> <p><u>Manual PA criteria:</u> Intermezzo, Edluar, and Zolpimist are approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that the following agents are available without prior authorization: zolpidem IR, zolpidem ER, zaleplon, eszopiclone • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), sleep hygiene and the patient will continue with non-pharmacologic therapies throughout treatment • Patient has tried and failed or had clinically significant adverse effects to zolpidem immediate-release or zaleplon • Patient has tried and failed or had clinically significant adverse effects with an orexin antagonist (i.e., Belsomra or Dayvigo) • Patient has documented swallowing difficulties <p>Non-FDA-approved uses are not approved. Prior authorization expires after 1 year.</p> <p><u>Renewal criteria</u> Note that initial TRICARE PA approval is required for renewal. PA will be renewed for an additional 1 year if the renewal criteria are met.</p> <ul style="list-style-type: none"> • Patient has not adequately responded to non-pharmacologic therapies • Patient agrees to continue with non-pharmacologic therapies including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), and/or sleep hygiene • Patient continues to respond to the drug
Newly Approved Drug PAs	
<ul style="list-style-type: none"> • ethinyl estradiol (EE) 20 mcg/levonorgestrel 0.1 mg chewable tablets (Tyblume) <p>Contraceptive Agents: Monophasics with 20 mcg estrogen</p>	<p>Manual PA criteria apply to all new users of Tyblume.</p> <p>PA does not apply to patients younger than 12 years of age (age edit)</p> <p><u>Manual PA criteria:</u> Tyblume is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that other formulations of EE 20 mcg/levonorgestrel 0.1 mg (e.g., Sronyx, Lutera, or equivalent) do not require prior authorization. • Patient has been counseled that this medication needs to be taken on an empty stomach with a full glass of water • Patient requires chewable tablets and cannot swallow due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, developmental disability, etc. and not due to convenience <p>Non-FDA approved uses are not approved, including migraine headache Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • levothyroxine sodium 100 mcg/5 mL oral solution (Thyquidity) <p>Thyroid Agents</p>	<p>Manual PA criteria apply to all new users of Thyquidity.</p> <p>PA does not apply to patients younger than 6 years of age (age edit)</p> <p><u>Manual PA criteria:</u> Thyquidity is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is not able to chew a levothyroxine tablet • The patient is not able to swallow a levothyroxine capsule or tablet • Thyquidity is prescribed by or in consultation with an endocrinologist <p>Non-FDA-approved uses are not approved. Prior authorization expires after 12 months. No renewal allowed; must fill out a new PA.</p>
<ul style="list-style-type: none"> • mannitol inhalation powder (Bronchitol) <p>Respiratory Agents Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Bronchitol.</p> <p><u>Manual PA criteria:</u> Bronchitol is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The provider is aware and acknowledges that dornase alfa (Pulmozyme) and hypertonic saline 7% inhalation (sodium chloride) are formulary alternatives available to DoD beneficiaries without the need of PA. Providers are encouraged to consider changing the prescription to Pulmozyme or hypertonic saline 7% inhalation • The patient is 18 years of age or older • The patient has a diagnosis of cystic fibrosis (CF) • Bronchitol is prescribed by or in consultation with a pulmonologist • The provider has performed a Bronchitol Tolerance Test (BTT) AND the patient did not have a severe reaction • The patient has been counseled on how to appropriately use Bronchitol • The patient has or will be prescribed a short-acting bronchodilator (i.e., ProAir is TRICARE's formulary short-acting beta agonists [SABA]) to use before treatment with Bronchitol • The patient has tried and had an inadequate response to dornase alfa (Pulmozyme) and hypertonic saline OR has a contraindication to both products • The patient will not use Bronchitol in combination with hypertonic saline <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • methotrexate subcutaneous injection (Reditrex) • methotrexate subcutaneous injection (Otrexup, Rasuvo) <p>Antirheumatics: Injectable Methotrexate</p>	<p>Manual PA criteria apply to all new users of Reditrex, Otrexup and Rasuvo</p> <p>Updates to Rasuvo and Otrexup from the May 2021 meeting are in bold</p> <p><u>Manual PA criteria:</u> Reditrex, Otrexup, or Rasuvo is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient has a diagnosis of active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis or severe, recalcitrant, disabling psoriasis in adults • The patient has tried and failed ORAL methotrexate. AND • The patient has experienced intolerance or significant adverse effects from generic injectable methotrexate OR • Patient has decreased finger dexterity, limited vision or impaired cognition resulting in the inability to utilize generic injectable methotrexate. <p>Non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • ponesimod (Ponvory) <p>Multiple Sclerosis Agents: Oral Miscellaneous</p>	<p>Manual PA is required for all new users of Ponvory.</p> <p><u>Manual PA Criteria:</u> Ponvory is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by a neurologist • Patient has a documented diagnosis of relapsing forms of multiple sclerosis (MS) • Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunamide [Aubagio]) • Patient has not previously failed a treatment course of fingolimod (Gilenya) • Patient has not previously failed a treatment course of siponimod (Mayzent) • Patient has not previously failed a treatment course of ozanimod (Zeposia) • Provider acknowledges that all recommended Ponvory monitoring has been completed and the patient will be monitored throughout treatment as recommended in the package insert. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), pulmonary function tests (PFTs), blood pressure, skin assessments and macular edema screening as indicated. • Ponvory will not be used in patients with significant cardiac history, including: <ul style="list-style-type: none"> ○ Patients with a recent history (within the past 6 months) of class III/IV heart failure, myocardial infarction, unstable angina, stroke, transient ischemic attack, or decompensated heart failure requiring hospitalization ○ Patients with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless they have a functioning pacemaker <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • solifenacin oral suspension (Vesicare LS) <p>Over Active Bladder Agents</p>	<p>Manual PA criteria apply to all new users of solifenacin oral suspension (Vesicare LS).</p> <p><u>Automated PA Criteria:</u> PA does not apply to patients younger than 12 years of age (age edit) AND if the patient has filled a prescription for oxybutynin tablets or oral syrup at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days. If automated criteria are not met:</p> <p><u>Manual PA criteria:</u> Vesicare LS is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The provider acknowledges that oxybutynin oral syrup is available for patients with neurogenic detrusor overactivity and does not require prior authorization • Prescribed by or in consultation with a urologist or nephrologist • Patient has a diagnosis of neurogenic bladder secondary to detrusor overactivity and/or myelomeningocele • Patient cannot swallow due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience OR • Patient requires a dose that cannot be achieved without splitting a solifenacin tablet • Patient has tried and failed or has a contraindication to oxybutynin <p>Non-FDA-approved uses are not approved including for overactive bladder. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • tepotinib (Tepmetko) <p>Oncological Agents: Lung Cancer</p>	<p>Manual PA criteria apply to all new users of Tepmetko.</p> <p><u>Manual PA criteria:</u> Tepmetko is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Tepmetko is prescribed by or in consultation with a hematologist/oncologist • The patient has metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to laboratory-confirmed mesenchymal-epithelial transition (MET) exon 14 skipping. • The provider will monitor for interstitial lung disease (ILD)/pneumonitis and hepatotoxicity • Female patients of childbearing age are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment • 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 • 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: _____. <p>Non-FDA-approved uses are not approved, except as noted above. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • tirbanibulin 1% ointment (Klisyri) <p style="text-align: center;">Antineoplastic and Premalignant Lesion Agents</p>	<p>Manual PA criteria apply to all new users of Klisyri.</p> <p><u>Manual PA criteria:</u> Klisyri is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Klisyri is prescribed by or in consultation with a dermatologist • The patient is 18 years of age or older • The patient has a diagnosis of actinic keratosis of the face or scalp • The patient has tried and failed or has a contraindication to fluorouracil and imiquimod <p>Non-FDA-approved uses are not approved.</p> <p>Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • tivozanib (Fotivda) <p style="text-align: center;">Oncological Agents: Renal Cell Carcinoma</p>	<p>Manual PA criteria apply to all new users of Fotivda.</p> <p><u>Manual PA criteria:</u> Fotivda is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • The patient has laboratory evidence of relapsed or refractory advanced renal cell carcinoma with clear cell histology following two or more prior systemic therapies including at least one VEGFR kinase inhibitor other than sorafenib (Nexavar) (e.g., Sutent, Votrient, Cabometyx, or Lenvima). • The patient will be monitored for hypertensive crisis, cardiac ischemia, arterial and venous thromboembolism, hemorrhage, proteinuria, thyroid dysfunction, and reversible posterior leukoencephalopathy syndrome • Fotivda is prescribed by or in consultation with a hematologist/oncologist • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 month after cessation of therapy • 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: _____. <p>Non-FDA-approved uses are not approved, except as noted above</p> <p>Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • umbralisib (Ukoniq) <p>Oncological Agents</p>	<p>Manual PA criteria apply to all new users of Ukoniq.</p> <p><u>Manual PA criteria:</u> Ukoniq is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Ukoniq is prescribed by a hematologist/oncologist • The patient has a diagnosis of: <ul style="list-style-type: none"> ○ Relapsed or refractory marginal zone lymphoma (MZL) AND has received at least one prior anti-CD20-based regimen [e.g., rituximab (Rituxan) obinutuzumab (Gazyva)] OR ○ Relapsed or refractory follicular lymphoma (FL) AND has received at least three prior lines of systemic therapy including an anti-CD20 based regimen and an alkylating agent • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Female patients of childbearing potential and male patients with female partners of childbearing potential agree to use contraception during treatment and for at least 1 month after the cessation of treatment • Male patients are aware that Ukoniq may cause male infertility • 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: _____ <p>Non-FDA-approved uses are NOT approved, except as noted above Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • vericiguat (Verquvo) <p>Cardiovascular Agents Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Verquvo.</p> <p><u>Manual PA criteria:</u> Verquvo is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Initial prescription is written by or in consultation with a cardiologist • Patient has a documented diagnosis of chronic HF (NYHA II-IV) • Patient has a left ventricular ejection fraction (LVEF) < 45% • Patient has worsening heart failure symptoms defined as one of the following: <ul style="list-style-type: none"> ○ History of previous heart failure hospitalization within the past 6 months OR ○ Outpatient IV diuretics for heart failure (without hospitalization) within the past 3 months • Patient's systolic blood pressure is at least 100 mmHg • Patient is receiving appropriate guideline-directed medical therapy (GDMT), including the following: ACE/ARB/ARNI, BB, MRA, SGLT2 inhibitor, hydralazine plus nitrate, Corlanor, and/or diuretic <ul style="list-style-type: none"> ○ Unless contraindicated or unable to tolerate due to adverse effects • Patient is not receiving concomitant treatment with long-acting nitrates, other sGC stimulators (riociguat [Adempas], or PDE5 inhibitors (sildenafil [Viagra, Revatio], tadalafil [Cialis, Adcirca]) • For women of childbearing age: <ul style="list-style-type: none"> ○ Patient is not pregnant AND ○ Provider is aware and the patient has been counseled on the teratogenicity risks with Verquvo and will comply with the contraceptive requirements listed in the package insert. <p>Non-FDA-approved uses are not approved including HFpEF, acute decompensated HF, PAH. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • vibegron (Gemtesa) <p>Overactive Bladder Agents</p>	<p>Manual PA criteria apply to all new users of Gemtesa.</p> <p><u>Manual PA criteria:</u> Gemtesa is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 2 formulary step-preferred products (oxybutynin IR, oxybutynin ER, tolterodine ER) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with at least one oral OAB medication OR is at increased risk for such central nervous system effects due to comorbid conditions or other medications, • The patient's creatinine clearance (CrCl) is greater than 15 mL/min <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • voclosporin (Lupkynis) <p>Immunosuppressives</p>	<p>Manual PA criteria apply to all new users of Lupkynis.</p> <p><u>Manual PA criteria:</u> Lupkynis is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Lupkynis is prescribed by or in consultation with a nephrologist • The patient has a documented diagnosis of active lupus nephritis (LN) • The patient has tried and failed previous therapy with mycophenolate • The patient has tried and failed previous therapy with either tacrolimus or cyclosporine • Lupkynis will not be used concomitantly with cyclophosphamide, as evidence for this combination has not been established • Due to drug interactions, the patient agrees to avoid eating grapefruit or drinking grapefruit juice while taking Lupkynis • The patient will not receive live vaccines • The provider agrees to monitor renal function, blood pressure, ECG, electrolytes, and monitor for neurotoxicity including risk of posterior reversible encephalopathy syndrome (PRES) • The provider is aware and patient is informed of the increased risk for developing malignancies and serious infections with Lupkynis or other immunosuppressants that may lead to hospitalization or death • For women of childbearing age: the provider is aware and patient is informed of the risk of fetal harm <p>Non-FDA-approved uses are not approved including kidney transplantation. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
New PAs	
<ul style="list-style-type: none"> methylphenidate extended release 72 mg tablets (Relexxii) <p>Attention Deficit/Hyperactivity Disorder: Stimulant</p>	<p>Manual PA criteria apply to all new and current users of methylphenidate extended release 72 mg tablets (Relexxii).</p> <p><u>Manual PA criteria:</u> Relexxii is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Provider is aware and acknowledges that several other long-acting methylphenidate ER formulations, including generic Concerta, generic Metadate CD, generic Methylin ER, generic Aptensio XR, generic Ritalin, and Quillivant XR are available to DoD beneficiaries without requiring prior authorization The provider must explain why the patient requires Relexxii 72 mg ER tablets and cannot take the available alternatives. <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> rilonacept injection (Arcalyst) <p>Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitor</p>	<p>Manual PA criteria apply to all new users of rilonacept (Arcalyst).</p> <p><u>Manual PA criteria:</u> Arcalyst is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> Patient has one of the following diagnoses: <ul style="list-style-type: none"> Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) <ul style="list-style-type: none"> Patient is 12 years of age or older Recurrent pericarditis <ul style="list-style-type: none"> Patient is 12 years of age or older Prescription is written by or in consultation with a cardiologist Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids Deficiency of Interleukin-1 Receptor Antagonist (DIRA) <ul style="list-style-type: none"> The patient weighs at least 10 kg (22 pounds) The patient is not concurrently receiving a TNF-inhibitor (e.g., Humira, Enbrel, Cimzia, and Simponi) due to the increased risk of serious infections. <p>Non-FDA-approved uses are not approved, including rheumatoid arthritis, neonatal-onset multisystemic inflammatory disease (NOMID), cardiovascular disease other than pericarditis (MI, acute coronary syndrome, atherosclerosis, heart failure, and Kawasaki disease), and gout.</p> <p>Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Updated PAs	
<ul style="list-style-type: none"> • lubiprostone (Amitiza) <p>Gastrointestinal-2 Agents: CIC/IBS-C</p>	<p>Updates from the May 2021 meeting are in bold.</p> <p>Manual PA criteria apply to all new users of Amitiza.</p> <p><u>Manual PA Criteria:</u> Coverage is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient is 18 years of age or older OR is prescribed in consultation with a pediatric gastroenterologist for pediatric patients • Patient has documented symptoms for ≥ 3 months • Patient has diagnosis of constipation predominant irritable bowel syndrome (IBS-C) or chronic idiopathic constipation (CIC) or opioid induced constipation (OIC) in adults with chronic, non-cancer pain <ul style="list-style-type: none"> ○ Patient is currently taking an opioid if used for OIC ○ Patient is female if used for IBS-C • Patient has documentation of failure of an increase in dietary fiber/dietary modification to relieve symptoms • Patient has absence of GI obstruction • Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as <ul style="list-style-type: none"> ○ osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories) ○ bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids; ○ stool softener (e.g., docusate); ○ stimulant laxative (e.g., bisacodyl, sennosides) • Patient has tried and failed linaclotide (Linzess) • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik) <p>Non-FDA-approved uses are NOT approved Prior authorization expires after 1 year.</p> <p><u>Renewal PA Criteria:</u> Note that initial TRICARE PA approval is required for renewal. PA will be approved for 1 year for continuation of therapy if:</p> <ul style="list-style-type: none"> • Patient has had improvement in constipation symptoms and • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • mirabegron (Myrbetriq) <p>Overactive Bladder Agents</p>	<p><u>Updates from the May 2021 meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of mirabegron (Myrbetriq).</p> <p><u>Manual PA criteria:</u> Myrbetriq is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 2 formulary step-preferred products (oxybutynin IR, oxybutynin ER, tolterodine ER) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such central nervous system effects due to comorbid conditions or other medications, • Patient has tried and failed or has a contraindication to vibegron (Gemtesa) • The patient does not have a CrCl < 15 mL/min • If the CrCl is between 15-29 mL/min, the dosage does not exceed 25 mg QD <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

<ul style="list-style-type: none"> • adalimumab (Humira) <p>Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors</p>	<p><u>Changes from the May 2021 meeting are in bold.</u></p> <p>Manual PA criteria applies to all new users of adalimumab (Humira).</p> <p><u>Manual PA Criteria:</u> Humira is approved if <u>all</u> criteria are met:</p> <p>Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication:</p> <ul style="list-style-type: none"> • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy • Moderate to severely active Crohn's disease (CD) • Moderate to severely active ulcerative colitis (UC) • Moderate to severe hidradenitis suppurativa (HS) • Non-infectious intermediate, posterior, and panuveitis • Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation • Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids <p>OR</p> <p>Coverage approved for pediatric patients 12-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Moderate to severe hidradenitis suppurativa (HS) <p>OR</p> <p>Coverage approved for pediatric patients 6-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Moderate to severely active Crohn's disease (CD) <p>OR</p> <p>Coverage approved for pediatric patients 5-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Moderately to severely active ulcerative colitis (UC) <p>OR</p> <p>Coverage approved for pediatric patients 4-17 years of age with diagnosis of:</p> <ul style="list-style-type: none"> • Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate <p>OR</p> <p>Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication:</p> <ul style="list-style-type: none"> • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) • Non-infectious intermediate, posterior, and panuveitis <p>Below criteria applies to AS indication only:</p> <ul style="list-style-type: none"> • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months <p>Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease, ankylosing spondylitis (AS), hidradenitis suppurativa and pyoderma gangrenosum (PG), and applies to pediatric patients with plaque psoriasis or non-fistulizing Crohn's disease:</p> <ul style="list-style-type: none"> • Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) <p>Below criteria applies to all patients (regardless of age):</p> <ul style="list-style-type: none"> • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)
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Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
	<p>Coverage for non-FDA-approved uses not listed above. Please provide a diagnosis and rationale for treatment. Supportive evidence will be considered.</p> <p>Prior authorization does not expire.</p> <p>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).</p>
<ul style="list-style-type: none"> • amantadine ER (Gocovri) <p>Parkinson’s Disease Agents</p>	<p><u>Changes from the May 2021 meeting are in bold.</u></p> <p>Manual PA criteria applies to all new users of amantadine ER (Gocovri).</p> <p><u>Manual PA Criteria:</u> Gocovri is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Patient has a diagnosis of Parkinson’s Disease (PD) • Patient is using requested medication for one of the following: <ul style="list-style-type: none"> ○ Treatment of dyskinesia and receiving levodopa-based therapy, with or without concomitant dopaminergic medications AND patient experienced therapeutic failure with a trial of amantadine immediate release of at least 300 mg daily in divided doses OR ○ Treatment of “off” episodes and receiving levodopa/carbidopa <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • crizotinib (Xalkori) <p>Oncological Agents: Lung Cancer</p>	<p><u>Updates from the May 2021 meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of crizotinib (Xalkori).</p> <p><u>Manual PA criteria:</u> Xalkori is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following diagnoses: <ul style="list-style-type: none"> ○ Metastatic non-small cell lung cancer (NSCLC) AND <ul style="list-style-type: none"> • Tumors are anaplastic lymphoma kinase (ALK) positive OR ROS1-positive (as detected by an approved test) ○ Relapsed or refractory systemic anaplastic large cell lymphoma (ALK) positive AND <ul style="list-style-type: none"> • Patient is 1 year of age and older or a young adult (Note – limitation of use: safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory systemic ALK-positive anaplastic large cell lymphoma) • 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: _____ <p>Non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • iloprost inhalation (Ventavis) • treprostinil (Tyvaso) <p>Pulmonary Arterial Hypertension: Prostacyclin Nebulized</p>	<p><u>Changes from the May 2021 meeting are in bold.</u></p> <p>Manual PA criteria applies to all new users of iloprost inhalation (Ventavis) or treprostinil (Tyvaso).</p> <p><u>Manual PA Criteria:</u> Ventavis or Tyvaso are approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has a documented diagnosis of one of the following: <ul style="list-style-type: none"> ○ WHO group 1 pulmonary arterial hypertension (PAH) AND <ul style="list-style-type: none"> • Patient has had a right heart catheterization (documentation required) • Results of the right heart catheterization confirm the diagnosis of WHO group 1 PAH ○ Tyvaso only: Patient has a documented diagnosis of WHO group 3 pulmonary hypertension associated with interstitial lung disease (PH-ILD) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • lorlatinib (Lorbrena) <p>Oncological Agents: Lung Cancer</p>	<p><u>Updates from the May 2021 meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria apply to all new users of lorlatinib (Lorbrena).</p> <p><u>Manual PA criteria:</u> Lorbrena is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has metastatic non-small cell lung cancer (NSCLC) AND <ul style="list-style-type: none"> • Tumors are anaplastic lymphoma kinase (ALK) positive (as detected by an approved test) • Patient has disease progression on one of the following: <ul style="list-style-type: none"> • crizotinib (Xalkori) and at least one other ALK inhibitor • alectinib (Alecensa) as a first line agent • ceritinib (Zykadia) as a first line agent • 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: _____ <p>Non-FDA-approved uses are not approved including neoplastic diseases. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • tocilizumab subcutaneous (Actemra SQ) <p>Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors</p>	<p><u>Changes from the May 2021 meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria applies to all new users of tocilizumab subcutaneous (Actemra SQ).</p> <p><u>Manual PA Criteria:</u> Actemra SQ is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication: <ul style="list-style-type: none"> • Moderate to severe active rheumatoid arthritis (RA) AND have had an inadequate response to at least 1 or more disease modifying anti-rheumatic drugs (DMARDs) non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • Giant cell arthritis (GCA) (Trial of Humira not required) • Slowing the rate of decline in pulmonary function in systemic sclerosis-associated lung disease (SSc-ILD) (Trial of Humira not required) <p>OR</p> <ul style="list-style-type: none"> • Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication: <ul style="list-style-type: none"> • Active polyarticular juvenile idiopathic arthritis (pJIA) • Systemic juvenile idiopathic arthritis (SJIA) <ul style="list-style-type: none"> • Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications • The patient has a contraindication to Humira (adalimumab) OR • The patient had an inadequate response to Humira OR • The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent <ul style="list-style-type: none"> • Patient has been stable on an IV Actemra with continuous use in the last 3 months and needs to transition to the SQ formulation of Actemra • Patient's platelet count is greater than or equal to 100,000 per mm³ AND ALT/AST is less than or equal to 1.5 times UNL (for adult patients only with RA, GCA, or SSc-ILD) • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) (all patients) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p> <p>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).</p>

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • methotrexate subcutaneous injection (Reditrex) <p>Antirheumatics: Injectable Methotrexate</p>	<ul style="list-style-type: none"> ▪ Retail: 4 injectors per fill ▪ MTF/Mail: 12 injectors per fill
<ul style="list-style-type: none"> • rilonacept injection (Arcalyst) <p>Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitors</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • solifenacin oral suspension (Vesicare LS) <p>Overactive Bladder Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 2 bottles/30 days ▪ MTF/Mail: 6 bottles/90 days
<ul style="list-style-type: none"> • tasimelteon (Hetlioz) • tasimelteon oral liquid (Hetlioz LQ) <p>Sleep Disorders: Insomnia</p>	<ul style="list-style-type: none"> ▪ MTF/Mail/Retail: 30 day supply ▪ Note that implementation will occur 60 days after signing of the minutes
<ul style="list-style-type: none"> • tepotinib (Tepmetko) <p>Oncological Agents: Lung Cancer</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • tirbanibulin 1% ointment (Klisyri) <p>Antineoplastic and Premalignant Lesion Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 5 day supply
<ul style="list-style-type: none"> • tivozanib (Fotivda) <p>Oncological Agents: Renal Cell Carcinoma</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 28 day supply
<ul style="list-style-type: none"> • tofacitinib oral solution (Xeljanz) <p>Targeted Immunomodulatory Biologics: Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply
<ul style="list-style-type: none"> • umbralisib (Ukoniq) <p>Oncological Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • enzalutamide (Xtandi) <p>Oncological Agents: 2nd-Gen Antiandrogens</p>	<ul style="list-style-type: none"> ▪ Retail: 30 day supply ▪ MTF/Mail: 60 day supply

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
<p>cabotegravir (Vocabria)</p> <p>Antiretrovirals: Integrase strand transfer inhibitors (INSTI)</p>	<ul style="list-style-type: none"> dolutegravir/rilpivirine dolutegravir/lamivudine 	<ul style="list-style-type: none"> 30mg film coated tablets 	<p>HIV</p>	<ul style="list-style-type: none"> Vocabria is the 5th INSTI for adults with HIV-1 who are on stable antiretroviral (ARV) therapy, who are virologically suppressed, and have no documented history of virologic failure Indicated with rilpivirine (Edurant) once daily x 4 weeks as oral lead-in therapy to evaluate tolerance before initiating long-acting injectable cabotegravir/rilpivirine (Cabenuva) Final dose of Vocabria and Edurant should be taken together on the same day as the first injection of Cabenuva Overall, well tolerated No compelling evidence that Vocabria offers a clinical advantage over other oral INSTIs in its class (non-inferior) The long-acting combination injectable (Cabenuva) has the potential to increase adherence and treatment success for those with HIV-1 	<ul style="list-style-type: none"> UF Do not add to EMMI list
<p>ethinyl estradiol (EE) 20 mcg/levonorgestrel 0.1 mg chewable tablet (Tyblume)</p> <p>Contraceptive Agents: Monophasics with 20 mcg estrogen (Sronyx, Lutera or equivalent)</p>	<ul style="list-style-type: none"> LNG 0.1mg/EE 20mcg tablet (Sronyx) Norethindrone 1mg/EE 20mcg + Fe chewable tablet (Minastrin) 	<ul style="list-style-type: none"> Chewable tablet 	<p>Low dose oral contraceptive</p>	<ul style="list-style-type: none"> levonorgestrel/EE chewable tablet contains the same doses and same hormones as BCF Sronyx, Lutera, and generics; only difference is that this product is chewable Multiple other chewable oral contraceptive products exist in addition to other forms of contraception that bypass the oral route (IUD, patch, vaginal ring, etc.) Among the chewable oral contraceptives, this is the only product that contains levonorgestrel Needs to be taken on an empty stomach which is a clinical disadvantage and raises concerns for reduced efficacy if taken incorrectly No new clinical data Provides little to no clinical benefit over existing formulary agents 	<ul style="list-style-type: none"> NF Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
levetiracetam 1000 mg and 1500 mg ER tablets (Elepsia XR) Anticonvulsant/Antimania Agents	<ul style="list-style-type: none"> levetiracetam extended release (Keppra XR) 	<ul style="list-style-type: none"> 1000 mg extended release tablet 1500 mg extended release tablet 	Adjunctive therapy in the treatment of partial-onset seizures in patients 12 years and older	<ul style="list-style-type: none"> Elepsia XR is a new formulation of extended release levetiracetam available in a higher strength (1000mg and 1500mg) than Keppra 500 mg and 750 mg ER tabs Elepsia XR is indicated for adjunctive therapy in the treatment of partial-onset seizures in patients 12 years and older No new clinical trials were conducted with Elepsia XR Elepsia XR demonstrated bioequivalence to Keppra XR tablets Elepsia XR is not recommended in patients with moderate to severe renal impairment Other than a theoretical decreased pill burden, Elepsia XR offers no clinically compelling advantage relative to existing agents 	<ul style="list-style-type: none"> Tier 4/Not covered
levothyroxine sodium 100 mcg/5 mL oral solution (Thyquidity) Thyroid agents	<ul style="list-style-type: none"> levothyroxine solution (Tirosint-SOL) levothyroxine tabs (Synthroid, various) levothyroxine caps (Tirosint) 	<ul style="list-style-type: none"> Oral solution 	Hypothyroidism and TSH suppression	<ul style="list-style-type: none"> Thyquidity is the second FDA-approved levothyroxine oral solution (after Tirosint – Sol) Tirosint-SOL reviewed May 2019 and designated UF No new clinical data Thyquidity provides little to no clinical benefit relative to similar agents on the formulary 	<ul style="list-style-type: none"> NF Add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
mannitol inhalation powder (Bronchitol) Respiratory Agents Miscellaneous	<ul style="list-style-type: none"> hypertonic saline, sodium chloride 3% and 7% solution (Nebusal, Pulmosol, Hyper-Sal) 	<ul style="list-style-type: none"> 40 mg capsule for inhalation 400 mg (10 capsules) twice a day by oral inhalation, in the morning and evening, with later dose take 2-3 hours before bedtime 	Add-on inhalation therapy for cystic fibrosis in adults	<ul style="list-style-type: none"> Bronchitol is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adults with cystic fibrosis (CF) Dosing can be burdensome requiring patient to inhale the contents of 10 capsules twice a day; a short-acting bronchodilator (i.e., ProAir) must be given before every dose Patient must pass a Bronchitol Tolerance Test (BTT) under the supervision of a healthcare provider before Bronchitol can be prescribed Offers convenience in that it doesn't require refrigeration, nebulization, or routine equipment sterilization like other therapies Efficacy was based on three, phase 3, randomized, double-blind, controlled, 26-week pivotal studies comparing study drug, at recommended dose, to control (inhaled mannitol 50 mg BID) which is a sub therapeutic dose Primary efficacy endpoint in all three studies was improvement of lung function as determined by the mean change from baseline in pre-dose FEV₁ (mL) Two studies involved patients ≥ 6 years of age and one included ≥ 18 years of age All other CF therapies were allowed to be continued during studies except hypertonic saline Inhaled short-acting bronchodilator (albuterol or equivalent) was given 5 to 15 minutes before Bronchitol dosing to help prevent bronchospasm Overall for efficacy, Bronchitol had a modest effect in terms of improvements in lung function; clinical significance is hard to determine Clinical place in therapy is unclear 	<ul style="list-style-type: none"> NF Add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
methotrexate SQ injection (Reditrex) Antirheumatics: Injectable methotrexate	<ul style="list-style-type: none"> Generic methotrexate injectable solution Otrexup autoinjector Rasuvo autoinjector 	<ul style="list-style-type: none"> Prefilled syringe 7.5 to 30 mg subcutaneously once weekly 	<ul style="list-style-type: none"> Rheumatoid arthritis (RA) Polyarticular juvenile idiopathic arthritis (pJIA) Psoriasis 	<ul style="list-style-type: none"> Reditrex is a new injectable formulation of methotrexate (MTX) in a prefilled syringe Indications include RA, pJIA, and psoriasis however Reditrex is not approved for neoplastic diseases No new clinical trial data Efficacy and safety data relied on old MTX clinical trials Generic formulations of injectable MTX are available as well as two other methotrexate autoinjector formulations (Otrexup and Rasuvo) Reditrex has no compelling advantages over existing agents 	<ul style="list-style-type: none"> NF Add to EMMPI list
ponesimod (Ponvory) Multiple sclerosis agents: oral miscellaneous	<ul style="list-style-type: none"> fingolimod (Gilenya) siponimod (Mayzent) ozanimod (Zeposia) 	<ul style="list-style-type: none"> Tablets: 2, 3, 4, 5, 6, 7, 8, 9, 10, and 20 mg; Titration to 20 mg daily 	For the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	<ul style="list-style-type: none"> Ponvory is another option for treatment of relapsing forms of MS and is the fourth sphingosine 1-phosphate (S1P) receptor modulator Indirect comparison to other S1PRMs shows similar efficacy Overwhelming majority of study population with RRMS (fewer with CIS or SPMS) Safety profile comparable to teriflunomide (Aubagio) Dose monitoring required for arrhythmias, heart block, and/or a history of MI or CHF 	<ul style="list-style-type: none"> UF Do not add to EMMPI list
solifenacin oral suspension (Vesicare LS) Overactive Bladder agents	<ul style="list-style-type: none"> Oxybutynin syrup 	<ul style="list-style-type: none"> 5mg/mL oral suspension 	Overactive bladder (OAB) in pediatric patients aged ≥ 2 years	<ul style="list-style-type: none"> Vesicare LS is a new oral suspension formulation of solifenacin approved for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 2 years old Convenient once daily dosing compared to up to three times a day dosing with oxybutynin syrup Pivotal trials were open-label and did not directly compare Vesicare LS to other antimuscarinic agents; however, when compared indirectly, it appears to have similar efficacy to oxybutynin syrup No new safety signals noted compared to solifenacin Guidelines do not yet address the role of Vesicare LS, although they do strongly encourage the use of antimuscarinic medications for NDO Vesicare LS offers a second child-friendly antimuscarinic formulation for the treatment of NDO 	<ul style="list-style-type: none"> NF Add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
tepotinib (Tepmetko) Oncological Agents: Lung Cancer	<ul style="list-style-type: none"> • Capmatinib (Tabrecta) 	<ul style="list-style-type: none"> • 450 mg once daily with food • 225 mg tablets 	METex14 positive metastatic Non-small cell lung cancer (NSCLC)	<ul style="list-style-type: none"> • Second drug FDA-approved for the treatment of patients with NSCLC and a mutation that leads to MET exon 14 skipping. (capmatinib; Tabrecta was the 1st) • Tepmetko is a preferred agent for first-line and subsequent therapy in patients with NSCLC and METex14 skipping mutations according to NCCN guidelines. • Among patients with advanced NSCLC with a confirmed MET exon 14 skipping mutation, tepotinib was associated with an overall response rate in 43% of patients. • Serious adverse events occurred in 45% of patients treated with Tepmetko. Edema occurred in 70% of patients and caused a grade 3 or higher adverse reaction in 9% of patients. • MET exon 14 skipping mutations occur in 3% to 4% of patients with NSCLC and the approval of Tepmetko provides another option for treatment of patients with these tumors. 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list
tirbanibulin 1% ointment (Klisyri) Antineoplastic and premalignant lesion agents	<ul style="list-style-type: none"> • Fluorouracil • Imiquimod • Diclofenac 	<ul style="list-style-type: none"> • 1% ointment 	Actinic keratosis	<ul style="list-style-type: none"> • Klisyri is a new, well-tolerated topical treatment for AK of the face or scalp • Several treatment options exist for the management of AK including other topical medications • Klisyri has a unique mechanism of action and a short treatment duration (5 days) • Only studied against vehicle in clinical trials • When indirectly compared to other topical treatments, Klisyri appears to have similar rates of AK clearance and higher rates of AK recurrence at 12 months • Not yet mentioned in the NCCN squamous cell skin cancer guidelines • Klisyri is an additional topical option for the treatment of AK with little to no clinical benefit over existing agents 	<ul style="list-style-type: none"> • NF • Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
tivozanib (Fotivda) Oncological Agents: Renal Cell Carcinoma	<ul style="list-style-type: none"> • sunitinib (Sutent) • sorafenib (Nexavar) • axitinib (Inlyta) • pazopanib (Votrient) • cabozantinib (Cabometyx) • lenvatinib (Lenvima) • bevacizumab (Avastin, Mvasi, Zirabev) 	<ul style="list-style-type: none"> • 1.34 mg and 0.89 mg capsules: take 1.34 mg qday for 21 days on followed by 7 days off (28 day cycle) 	Treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies	<ul style="list-style-type: none"> • Tivozanib offers a slight progression-free survival advantage over sorafenib; however, tivozanib and sorafenib offer identical overall survival rates • Tivozanib is less-well tolerated than sorafenib • Tivozanib has a significant amount of serious warnings and precautions • Tivozanib is an additional treatment option in an already crowded drug class 	<ul style="list-style-type: none"> • UF • Add to EMMPI list
umbralisib (Ukoniq) Oncological Agents	<ul style="list-style-type: none"> • duvelisib (Copiktra) • idelalisib (Zydelig) Medical benefit <ul style="list-style-type: none"> • copanlisib (Aliqopa) 	<ul style="list-style-type: none"> • 200 mg tablet • 800 mg orally once daily with food 	Relapsed or refractory marginal zone lymphoma (MZL) if patient received at least one prior anti-CD20-based regimen and follicular lymphoma (FL) if patient has received at least three prior lines of systemic therapy	<ul style="list-style-type: none"> • Ukoniq is the 4th phosphatidylinositol 3-kinase (PI3K) inhibitor and has dual activity against δ and ϵ isoforms • Ukoniq is indicated for: • Relapsed or refractory marginal zone lymphoma (MZL) in adults who have received at least one prior anti-CD20-based regimen • First PI3K FDA-approved for relapsed or refractory MZL (NCCN guidelines recommend other PI3K but after 2 prior therapies) and relapsed or refractory follicular lymphoma (FL) in adults who have received at least three prior lines of systemic therapy • Fourth PI3K inhibitor FDA-approved for relapsed or refractory follicular lymphoma and other PI3K only require 2 prior therapies • Approval was based on limited available data (one, phase 2, open label, pivotal study with no control group for two different indications [MZL, FL]) • Provides alternative treatment for MZL and FL with no boxed warning(s) or REMS Program, however it currently has minimal studies and due to FDA accelerated approval, further adequate and well-controlled clinical trials to verify and describe the clinical benefit are required 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
vericiguat (Verquvo) Cardiovascular Agents Miscellaneous	<ul style="list-style-type: none"> • sacubitril/valsartan (Entresto) • empagliflozin (Jardiance) • ACE/ARBs • Beta blockers • spironolactone • hydralazine/isosorbide dinitrate 	<ul style="list-style-type: none"> • 2.5 mg po QD • titrate to target dose of 10 mg QD 	Reduce risk of CV death and HF hospitalization following a HF hospitalization or need for outpatient IV diuretics, in adults with symptomatic chronic HF and LVEF <45%	<ul style="list-style-type: none"> • New drug class for HF, soluble guanylate cyclase (sGC) stimulator, an enzyme in the nitric oxide signaling pathway • Another sGC stimulator riociguat (Adempas) is approved for PAH • Increases production of cyclic guanosine monophosphate (cGMP), leading to smooth muscle relaxation and vasodilation, which preserves myocardial function • In the VICTORIA clinical trial used to gain FDA approval it showed a 10% reduction in the composite of death from CV cause or first hospitalization for HF • Compared to other treatments, was studied in high-risk patients with recently decompensated heart failure with reduced ejection fraction (HFrEF) (40% of pts were NYHA Class III HF with mean LVEF 29%) • Drug interaction with PDE-5 inhibitors – risk of hypotension • Contraindicated in pregnancy • Potential place in therapy as an add-on option to guideline-directed medical therapy (GDMT) • Listed as an “emerging therapy” in the 2021 American College of Cardiology Consensus Pathway 	<ul style="list-style-type: none"> • UF • Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
vibegron (Gemtesa) Overactive Bladder Agents	<ul style="list-style-type: none"> mirabegron (Myrbetriq) 	<ul style="list-style-type: none"> 75mg tablet 	OAB	<ul style="list-style-type: none"> 2nd β-3 adrenergic receptor agonist approved for the treatment of overactive bladder, after mirabegron (Myrbetriq) OAB guidelines, published before the approval of vibegron, recommend either antimuscarinics or β3-adrenergic receptor agonists as 2nd-line therapy after behavioral therapies Compared to antimuscarinics, β3-adrenergic receptor agonists avoid the side effects of constipation and dry mouth and are not associated with increased risk of dementia with long-term use Vibegron offered statistically significant improvements in primary and secondary endpoints when compared to placebo and was well-tolerated Not directly compared against mirabegron, but indirect comparisons suggest similar efficacy Benefits of vibegron compared to mirabegron, include its ability to be crushed, fewer drug interactions, and lack of clinically significant effects on blood pressure Vibegron is a therapeutic alternative to mirabegron; most patients could use either drug, and formulary tools preferring one over the other would not be inappropriate 	<ul style="list-style-type: none"> UF and step-preferred Do not add to EMMPI list

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Clinical Summary	Recommended UF Status
voclosporin (Lupkynis) Immuno-suppressives	<ul style="list-style-type: none"> • tacrolimus • mycophenolate mofetil (MMF) • belimumab (Benlysta) 	<ul style="list-style-type: none"> • 7.9 mg caps • Starting dose = 23.7 mg (3 caps) BID = 6 caps/day total • Must use in combo with MMF and corticosteroids 	Active lupus nephritis (LN)	<ul style="list-style-type: none"> • Another oral calcineurin inhibitor approved for use in adults with active lupus nephritis (LN); must be used in combination with corticosteroids and mycophenolate (MMF; Cellcept) • Approval based on 2 placebo controlled studies • Primary endpoint of complete renal response showed a greater response with voclosporin (41%) vs placebo (23%) • Primary and secondary endpoints were statistically significant compared to placebo • Voclosporin has not been compared head-to-head to tacrolimus or Benlysta for active LN • BBW: an increased risk for developing malignancies and serious infections or other immunosuppressants that may lead to hospitalization or death • Warnings: monitor renal function, BP, ECG and electrolytes due to risk of hyperkalemia, monitor for neurologic abnormalities including risk of posterior reversible encephalopathy syndrome (PRES) • Lupkynis offers another option in the treatment of LN, however place in therapy is currently unclear 	<ul style="list-style-type: none"> • NF • Do not add to EMMPI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 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)
May 2021	<p>Sleep Disorders: Insomnia UF (brand maintenance only) <i>Maintain current status:</i></p> <ul style="list-style-type: none"> • lemborexant (Dayvigo) <p>Sleep Disorders: Insomnia NF <i>No reason to exempt from NF-2 Mail requirement:</i></p> <ul style="list-style-type: none"> • zolpidem nasal (Zolpimist) • zolpidem SL (Edluar, Intermezzo) <p>Menopausal Hormone Therapy: Vaginal Agents UF (brand maintenance only) <i>Maintain current status:</i></p> <ul style="list-style-type: none"> • estradiol acetate vaginal ring (Femring) • estradiol vaginal insert (Imvexxy) • estradiol vaginal insert (Vagifem) <p>Menopausal Hormone Therapy: Oral Single Agents UF (brand maintenance only) <i>Maintain current status:</i></p> <ul style="list-style-type: none"> • estradiol tablet (Estrace) <p>Menopausal Hormone Therapy: Oral Combination Agents UF (brand maintenance only) <i>Maintain current status:</i></p> <ul style="list-style-type: none"> • estradiol/progesterone capsule (Bijuva) • estradiol/norethindrone acetate tablet (Activella, Amabelz, Mimvey) • ethinyl estradiol/norethindrone acetate tablet (Femhrt, Jinteli, Fyavolv) • estradiol/drospirenone (Angeliq) 	<p>Sleep Disorders: Insomnia UF (brand maintenance only) <i>Maintain current status and do not add to EMMPI Program due to comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • suvorexant (Belsomra) <p>Sleep Disorders: Insomnia NF <i>Exempt from NF-2 Mail requirement due to being unavailable at mail:</i></p> <ul style="list-style-type: none"> • tasimelteon (Hetlioz/Hetlioz LQ) <p>Menopausal Hormone Therapy: Vaginal Agents UF (brand maintenance only) <i>Maintain current status and do not add to EMMPI Program due to package size and day supply issues:</i></p> <ul style="list-style-type: none"> • conjugated equine estrogens vaginal cream (Premarin) • estradiol vaginal cream (Estrace) <p><i>Remove from EMMPI Program due to comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • estradiol vaginal ring (Estring) <p>Menopausal Hormone Therapy: Oral Single Agents UF (brand maintenance only) <i>Remove from EMMPI Program due to comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • conjugated equine estrogens tablet (Premarin) • esterified estrogens (Menest) <p>Menopausal Hormone Therapy: Oral Combination Agents UF (brand maintenance only) <i>Remove from EMMPI Program due to comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • conjugated equine estrogens/medroxy-progesterone acetate tablet (Prempro) • conjugated equine estrogens/medroxy-progesterone acetate tablet (Premphase) • estradiol/norgestimate (Prefest) <p><i>Maintain current status and do not add to EMMPI Program due to not being an FDA-approved product:</i></p> <ul style="list-style-type: none"> • esterified estrogens/methyltestosterone (Covaryx, Covaryx HS, Eemt, Eemt HS)

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the May 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)
	<p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Add to EMMPI List pending availability at mail:</i></p> <ul style="list-style-type: none"> • tivozanib (Fotivda) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated NF: <i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending availability at mail:</i></p> <ul style="list-style-type: none"> • levothyroxine sodium 100 mcg/ 5 mL oral solution (Thyquidity) • mannitol inhalation powder (Bronchitol) • methotrexate SQ injection (Reditrex) • solifenacin oral suspension (Vesicare LS) <p>Line Extensions Designated UF <i>Similar/parent agent already on list:</i></p> <ul style="list-style-type: none"> • tofacitinib oral solution (Xeljanz) <p>Line Extensions Designated NF <i>No reason to exempt from NF-2-Mail requirement, similar/parent agent already on list:</i> semaglutide injection (Ozempic)</p>	<p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • tepotinib (Tepmetko) • umbralisib (Ukoniq) <p><i>Drugs in class not currently represented on EMMPI List:</i></p> <ul style="list-style-type: none"> • cabotegravir (Vocabria) • ponesimod (Ponvory) <p><i>Comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • vericiguat (Verquvo) • vibegron (Gemtesa) <p>Designated NF: <i>Contraceptive exception/existing exclusion applies:</i></p> <ul style="list-style-type: none"> • levonorgestrel 0.1 mg & EE 0.02 mg (Tyblume) <p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> • voclosporin (Lupkynis) <p><i>Exception due to acute use/limited duration of use and comparable pricing at mail order vs MTFs or retail:</i></p> <ul style="list-style-type: none"> • tirbanibulin 1% ointment (Klisyri)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2021	Menopausal Hormone Therapy: Single Agents, Combination Agents, and Vaginal Agents	UF Class Review	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs must not have on formulary Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None 		<ul style="list-style-type: none"> ▪ None 	<p>Pending signing of the minutes: 30 days</p> <p>The effective date is March 16, 2022</p>	<ul style="list-style-type: none"> ▪ No PAs or QLs for any agents in any of the three subclasses ▪ Current PA for Imvexxy was removed 	<ul style="list-style-type: none"> ▪ Premarin and Prempro removed from the BCF ▪ Estradiol vaginal cream and estradiol oral tablets added to the BCF ▪ Estradiol vaginal cream BCF addition specifies this product, as previously MTFs could choose
			<p><i>Vaginal Agents</i></p> <ul style="list-style-type: none"> ▪ estradiol vaginal cream (generic) <p><i>Oral Single Agents</i></p> <ul style="list-style-type: none"> ▪ estradiol oral tablet (generic) <p><i>Oral Combination Agents</i></p> <ul style="list-style-type: none"> ▪ None 	<p><i>Vaginal Agents</i></p> <ul style="list-style-type: none"> ▪ conjugated equine estrogens vaginal cream (Premarin) ▪ estradiol vaginal cream (Estrace, generics) ▪ estradiol vaginal ring (Estring) ▪ estradiol acetate vaginal ring (Femring) ▪ estradiol vaginal tablet (Vagifem, generics) ▪ estradiol vaginal insert (Imvexxy) <i>moves from NF to UF</i> <p><i>Oral Single Agents</i></p> <ul style="list-style-type: none"> ▪ conjugated equine estrogens tablets (Premarin) ▪ estradiol tablets (Estrace, generics) ▪ esterified estrogens (Menest) <p><i>Oral Combination Agents</i></p> <ul style="list-style-type: none"> ▪ conjugated equine estrogens/medroxyprogesterone acetate tablets (Prempro) ▪ conjugated equine estrogens plus medroxyprogesterone acetate tablets (Premphase) ▪ ethinyl estradiol/norethindrone acetate tablets (Jinteli, Femhrt, Fyavolv, generics) ▪ estradiol/norethindrone acetate tablets (Activella, Amabelz, Jinteli, Mimvey, Mimvey Lo, generics) ▪ esterified estrogens/ methyltestosterone (Covaryx, Covaryx HS, Eemt, Eemt HS, generics) ▪ estradiol/drospirenone (Angeliq) ▪ estradiol/norgestimate (Prefest) ▪ estradiol/progesterone caps (Bijuva) <i>moves from NF to UF</i> 				

Appendix G—Table of Implemented Status of UF Recommendations/Decision Summary

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
May 2021	Sleep Disorders: Insomnia	UF Class Review Class last reviewed May 2012	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None 			<p>Pending signing of the minutes: 60 days</p> <p>The effective date is April 20, 2022</p>	<ul style="list-style-type: none"> ▪ PA criteria were removed for doxepin tablets and ramelteon ▪ Manual PA criteria for Belsomra and Dayvigo require a generic first ▪ Updated manual PA criteria for new users of Hetlioz/Hetlioz LQ, requires a trial of ramelteon and melatonin ▪ Updated PA criteria for new and current users of Edluar, Intermezzo, Zolpimist requires a generic agent and a DORA first ▪ PAs for all brand agents expire yearly, with renewal criteria required 	<ul style="list-style-type: none"> ▪ See Appendices B and C for MN and PA criteria. ▪ Melatonin OTC 3 mg and 5 mg added to the MHS GENESIS OTC test list in order to standardize dispensing of melatonin at MTFs
			<ul style="list-style-type: none"> ▪ zolpidem IR ▪ zolpidem ER 	<p><u>UF step-preferred generics</u></p> <ul style="list-style-type: none"> ▪ zolpidem IR (Ambien, generics) ▪ zolpidem ER (Ambien CR, generics) ▪ eszopiclone (Lunesta, generics) ▪ zaleplon (Sonata, generics) ▪ ramelteon (Rozerem, generics) <i>moves from NF to UF</i> ▪ doxepin 3 mg, 6 mg tablets (Silenor, generics) <p><u>UF step-preferred brands</u></p> <ul style="list-style-type: none"> ▪ suvorexant (Belsomra) <i>moves from NF to UF</i> ▪ lemborexant (Dayvigo) 	<p><u>NF and non-step-preferred brands</u></p> <ul style="list-style-type: none"> ▪ zolpidem IR 1.75 mg, 3.5 mg sublingual tabs (Intermezzo, generics) ▪ zolpidem IR 5 mg, 10 mg sublingual tabs (Edluar) ▪ zolpidem oral spray (Zolpimist) ▪ tasimelteon capsules (Hetlioz) ▪ tasimelteon oral suspension (Hetlioz LQ) 			

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives (Last 12 months)*†

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
May 2021	Anticonvulsants-Antimania Agents	<ul style="list-style-type: none"> levetiracetam (Elepsia XR) 	<ul style="list-style-type: none"> levetiracetam ER lamotrigine XR topiramate ER 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Corticosteroids-Immune Modulators: High Potency	<ul style="list-style-type: none"> clobetasol propionate 0.05% lotion metered dose pump (Impeklo) 	<ul style="list-style-type: none"> betamethasone/propylene glycol 0.05% lotion betamethasone dipropionate 0.05% gel clobetasol propionate/emollient 0.05 % (emulsion) foam clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo fluocinonide 0.05% solution and gel 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Feb 2021	Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene/betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora) 	<ul style="list-style-type: none"> 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 fluocinonide 0.05% cream, gel, and solution calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary] 	<ul style="list-style-type: none"> June 15, 2022 (120 days)
Nov 2020	Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) methylphenidate long-acting (Ritalin LA, generics) methylphenidate controlled delivery (CD) (Metadate CD, generics) dexmethylphenidate ER (Focalin XR, generics) mixed amphetamine salts ER (Adderall XR, generics) 	<ul style="list-style-type: none"> Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	<ul style="list-style-type: none"> budesonide ER 9 mg capsules (Ortikos) 	<ul style="list-style-type: none"> budesonide ER tablets (Entocort EC, generics) other corticosteroids 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Corticosteroids	<ul style="list-style-type: none"> dexamethasone 20 mg tables (Hemady) 	<ul style="list-style-type: none"> dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs 	<ul style="list-style-type: none"> June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	<ul style="list-style-type: none"> fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) 	<ul style="list-style-type: none"> fluticasone (Flovent Diskus) fluticasone (Flovent HFA) fluticasone furoate (Arnuity Ellipta) [non formulary] beclomethasone (QVAR) [non formulary] budesonide (Pulmicort Flexhaler) [non formulary] ciclesonide (Alvesco) [non formulary] flunisolide (Aerospan) [non formulary] mometasone (Asmanex Twisthaler) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	<ul style="list-style-type: none"> fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) 	<ul style="list-style-type: none"> fluticasone/salmeterol (Advair Diskus) fluticasone/salmeterol (Advair HFA) fluticasone/vilanterol (Breo Ellipta) [non formulary] mometasone/formoterol (Dulera) [non formulary] budesonide/formoterol (Symbicort) [non formulary] fluticasone/salmeterol (AirDuo Respiclick) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Calcium Channel Blockers	<ul style="list-style-type: none"> levamlodipine (Conjupri) 	<ul style="list-style-type: none"> amlodipine felodipine nifedipine diltiazem verapamil 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	GI-2 Agents	<ul style="list-style-type: none"> metoclopramide nasal spray (Gimoti) 	<ul style="list-style-type: none"> metoclopramide oral tablet (Reglan generics) metoclopramide oral solution (Reglan, generics) metoclopramide orally disintegrating tablet (Reglan ODT) 	<ul style="list-style-type: none"> June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% solution clobetasol 0.05% solution, shampoo fluocinonide 0.05% solution calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% ointment, cream, solution clobetasol 0.05% ointment, cream fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> betamethasone propylene glycol 0.05% cream clobetasol propionate 0.05% cream and ointment clobetasol propionate/emollient 0.05% cream desoximetasone 0.25% cream and ointment fluocinonide 0.05% cream and ointment fluocinonide/emollient base 0.05% cream halobetasol propionate 0.05% ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> adapalene 0.1% lotion, gel, cream adapalene 0.3% gel clindamycin phosphate 1% gel, cream, lotion, and solution clindamycin/ benzoyl peroxide 1.2% - 5% gel tazarotene 0.1% cream tretinoin 0.025%, 0.05%, and 0.1% cream tretinoin 0.01% and 0.025% gel 	<ul style="list-style-type: none"> February 24, 2021

* 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>. 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. 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.

† For a cumulative list of previous Tier 4 recommendations, refer to the November 2020 DoD P&T Committee minutes, found at health.mil/pandt

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
Analgesics and NSAIDs		
May 2019 (May 2021 update)	ADD these GCNs <ul style="list-style-type: none"> • 16965 –acetaminophen 500mg, due to shortage of acetaminophen 325 mg tablets (May 2019 meeting update) 	
Melatonin		
May 2021	Retain these GCNs: <ul style="list-style-type: none"> • 68738 – melatonin 3 mg tablets • 99671 – melatonin 5 mg tablets 	Remove these GCNs: <ul style="list-style-type: none"> • 94035 – melatonin 1 mcg tablet spray • 13448 – melatonin 5 mg SL tablet • 31649 – melatonin 10 mg mphase

*GCN Additions will be implemented the first Wednesday two weeks after signing of the minutes, with the deletions implemented at 120 days.

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
AACE/ACE	American Association of Clinical Endocrinologist and American College or Endocrinology	MHS	Military Health System
ACC	American College of Cardiology	MHT	Menopausal hormone therapy
ADR	Adverse reaction	MN	Medical Necessity
AE	Adverse event	MS	Multiple Sclerosis
AK	Actinic keratosis	MTF	Military Treatment Facility
BCF	Basic Core Formulary	MZL	Marginal zone lymphoma
BIA	Budget impact analysis	NAMS	North American Menopause Society
CCBs	Calcium channel blockers	NCCN	National Comprehensive Cancer Network
CBT-I	Cognitive behavioral therapy - Insomnia	NDAA	National Defense Authorization Act
CEE	Conjugated equine estrogens	NDC	National Drug Codes
CFR	Code of Federal Regulations	NDO	Neurogenic detrusor overactivity
CMA	Cost minimization analysis	NSCLC	Non-small cell lung cancer
CV	Cardiovascular	NYHA	New York Heart Association
DHA	Defense Health Agency	OAB	Overactive bladder
DoD	Department of Defense	ODT	Orally Disintegrating Tablet
DORA	Dual orexin receptor antagonist	OTC	Over the counter
DR	Delayed release	PA	Prior authorization
ECF	Extended Core Formulary	PAH	Pulmonary artery hypertension
EE	Ethinyl estradiol	PH-ILD	Pulmonary hypertension associated interstitial lung disease
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	POD	Pharmacy Operations Division
ER	Extended release	POS	Point of service
FDA	U.S. Food and Drug Administration	PRN	As needed
FL	Follicular lymphoma	RCC	Renal cell carcinoma
GDMT	Guideline directed medical therapy	RRMS	Relapsing remitting multiple sclerosis
GSM	Genitourinary syndrome of menopause	QL	Quantity limits
HF	Heart failure	SC	Subcutaneous
HFpEF	Heart failure with preserved ejection fraction	SMS	Smith-Magenis Syndrome
LN	Lupus nephritis	SL	Sublingual
LVEF	Left ventricular ejection fraction	TIB	Targeted Immunomodulatory Biologics

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

February 2021

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0900 hours on February 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.

A. Review Minutes of Last Meetings

1. **Approval of November 2020 Minutes**—Mr. Guy Kiyokawa, Deputy Director, DHA, approved the minutes from the November 2020 DoD P&T Committee meeting on January 27, 2021.

- a) **Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA)-risdiplam (Evrysdi) PA criteria:** The Deputy Director requested the DoD P&T Committee review the age limit restrictions on the risdiplam (Evrysdi) prior authorization criteria (see pp. 14, 16, 37).

2. **Clarification of Previous Minutes**

- a) **February 2019 Meeting—Migraine Agents: CGRP Preventative: Expanded MTF/Mail Pharmacy Initiative (EMMPI):** Erenumab (Aimovig) was recommended for removal from the EMMPI program, but this was inadvertently omitted from the meeting minutes. Aimovig will no longer remain on the EMMPI program.

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. Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the CDK inhibitor subclass used for advanced or metastatic hormone receptor-positive (HR(+)), human epidermal growth factor receptor 2-negative (HER2(-)) breast cancer. The drugs include abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali). Ribociclib is also co-packaged with the aromatase inhibitor letrozole (Kisqali Femara Co-Pack), which is a convenience formulation.

The Committee comprehensively reviewed the evidence including what was analyzed when Verzenio, Kisqali, and Kisqali Femara were presented as innovators in November, May, and August of 2017, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Efficacy

- A comprehensive review of the evidence shows that each CDK inhibitor offers a statistically and clinically significant advantage in objective response rate (ORR) and progression free survival (PFS), relative to the respective controls used in the individual clinical trials.
- There is no clear efficacy superiority of any one CDK inhibitor over another, and no clear superiority of the sequencing of when to use the CDK inhibitors. Overall, efficacy considerations do not drive selection of one particular agents.
- There are no head-to-head trials available directly comparing one CDK inhibitor with another.
- Indirect comparison of the hazard ratios of various efficacy endpoints (including ORR and PFS) from systematic reviews and network meta-analyses show that no one particular CDK inhibitor exhibits superiority over any other.

Guidelines

- The National Comprehensive Cancer Network (NCCN) guidelines recommend abemaciclib, palbociclib, and ribociclib as preferred first-line,

second-line or subsequent therapy, supported by the highest level of evidence.

- Abemaciclib (Verzenio) is also recommended as monotherapy for disease that has progressed on chemotherapy, but this is supported by a lower level of evidence (e.g., useful in certain circumstances).
- Other guidelines (e.g., American Society of Clinical Oncology, European Society for Medical Oncology) are in agreement with one another and make no distinction in the choice of a particular agent. Each CDK inhibitor has the same preference and strength of recommendation.

Safety

- There is no one clearly superior CDK inhibitor in terms of safety or tolerability.
- The safety profiles of the CDK inhibitors overlap, however, there are unique adverse events associated with each agent. Hematologic adverse events (e.g. neutropenia, anemia, and thrombocytopenia) are considered class effects.
 - Palbociclib (Ibrance) has the highest absolute risk of neutropenia, and a unique warning for the risk of pulmonary embolism.
 - Abemaciclib's (Verzenio's) safety profile includes a lower relative risk of neutropenia, but higher relative risk for diarrhea and unique warnings (amongst these agents) for hepatotoxicity and venous thromboembolism (VTE).
 - Ribociclib (Kisqali) has a lower relative risk of anemia, thrombocytopenia, and VTE, but higher relative risk for QT-prolongation and a unique warning (amongst these agents) for hepatobiliary toxicity.

Overall Clinical Conclusion

- Choice of treatment in HR(+)/HER2(-) advanced or metastatic breast cancer depends on several factors, including the safety profile of the individual CDK inhibitor, patients' preference, comorbidities, and disease burden.

Relative Cost-Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA) and budget impact analysis (BIA) were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that ribociclib (Kisqali), ribociclib/letrozole (Kisqali Femara Co-Pack) abemaciclib (Verzenio) and palbociclib (Ibrance) were all cost-effective.

- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating all CDK inhibitors as UF demonstrated significant cost avoidance for the Military Health System (MHS).
1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:
 - UF
 - abemaciclib (Verzenio)
 - palbociclib (Ibrance)
 - ribociclib (Kisqali)
 - ribociclib/letrozole (Kisqali Femora Co-Pack)
 - NF – None
 - Tier 4 – None
 - Note that no CDK inhibitors were added to the BCF
 2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—Manual PA currently apply to all four CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent), updating the PA criteria to follow the NCCN guidelines, with the additional indication for Verzenio noted, and including all four drugs on one PA form. The unique safety and monitoring factors will be outlined for each drug. See Appendix C for the full criteria.
 3. **COMMITTEE ACTION: QLS**—QLs currently apply to the CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) applying a 28 day supply at all points of service for Ibrance, Verzenio, Kisqali, and Kisqali Femara Co-Pack. See Appendix D for the full criteria.
 4. **EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM AND NON-FORMULARY TO MAIL REQUIREMENTS**—The CDK inhibitors are not currently included on the EMMPI program, due to the likelihood of dosage reduction from adverse events. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 2 absent) maintaining the current status (do not include Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack on the EMMPI program).
 5. **COMMITTEE ACTION: UF, PA, QL, and EMMPI IMPLEMENTATION PERIOD**—The P&T Committee recommended

(18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30-days after signing of the minutes in all points of service. Based on the P&T Committee's recommendation, the effective date is March 16, 2022.

Addendum to the UF recommendation: After the P&T meeting, a review of the bids submitted by one manufacturer showed that a re-calculation of the cost analysis was required. The new cost model was presented to the DoD P&T Committee via electronic means. An electronic vote was taken to determine whether to maintain the UF recommendation originally determined at the February 2021 meeting.

COMMITTEE ACTION: ADDENDUM TO UF

RECOMMENDATION: The P&T Committee reaffirmed (14 for, 0 opposed, 0 abstained, 2 absent) the recommendation made at the meeting, which maintains all four CDK inhibitors (Verzenio, Ibrance, Kisqali, and Kisqali Femora Co-Pack) on the UF.

B. Pulmonary 3 Agents: Combinations Subclass

Background—The Pulmonary 3 agents contain a fixed-dose triple combination of inhaled corticosteroid, long-acting muscarinic antagonist, and long-acting beta agonist (ICS/LAMA/LABA) in one inhaler. A triple combination regimen can also be achieved using a variety of multiple inhalers, including single ingredient inhalers used separately, or by using various fixed dose dual combination inhalers, such as, an ICS/LABA or LAMA/LABA.

The two drugs in the class are fluticasone/umeclidinium/vilanterol (Trelegy) and budesonide/glycopyrrolate/formoterol (Breztri). Triple combination therapy is used in severe chronic obstructive pulmonary disease (COPD) and severe asthma after failure with dual therapy ICS/LABA or LAMA/LABA. Both Trelegy and Breztri are approved for maintenance treatment of COPD, while Trelegy has an additional indication for maintenance treatment of asthma in adults.

Although this is the first time the Pulmonary 3 Agents have been reviewed as a class, both Trelegy and Breztri were originally reviewed as new drugs, in November 2017 and November 2020, respectively.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Asthma

- The National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) Expert Panel Working Group guidelines recommend adding a LAMA to ICS/LABA in patients with uncontrolled asthma to improve symptom control and quality of life. Triple combination therapy does not affect asthma exacerbations requiring corticosteroids or rescue medication use.
- Although Trelegy was shown to improve forced expiratory volume in one second (FEV1) Trelegy lacks an indication in the label to reduce asthma exacerbations.

COPD

- The Global Initiative for Chronic Obstructive Lung Disease (GOLD 2020), strategy recommends reserving triple therapy for highly symptomatic patients after failure of dual therapy with LAMA/LABA or ICS/LABA.
- In the individual clinical trials used to gain FDA approval, both Trelegy and Breztri demonstrated statistically significant improvements in trough FEV1, and in the Saint George Respiratory Questionnaire (SGRQ) quality of life instrument, however these results did not reach the minimally clinically important difference threshold.
- Although varying results were shown in the clinical trials with regard to a reduction in COPD exacerbations, neither Trelegy nor Breztri are indicated to reduce COPD exacerbations.
- For COPD, despite the lack of head-to-head trials, indirect comparisons suggest there is not a clinically relevant difference in the drugs' effects on improving FEV1.

Safety

- The GOLD strategy and American Thoracic Society guidelines recommend withdrawing ICS in patients receiving triple therapy (ICS/LAMA/LABA), if the patient has had no exacerbations in the preceding year, due to the risk of pneumonia.
- In studies with longer treatment durations, there was a higher rate of pneumonia with Trelegy, Breztri and ICS-containing regimens, compared to regimens lacking an ICS component.
- Overall drug discontinuation due to adverse events was low in the individual clinical trials with Trelegy and Breztri, versus respective comparators.

Clinical Considerations

- Breztri advantages include that it is less reliant on a patient’s inspiratory flow rate to activate the inhaler; however, it is dosed twice daily, and is only indicated for COPD. The Breztri Aerosphere metered dose inhaler requires patient breath-hand coordination to activate. Clinical trials evaluating Breztri in adults with asthma are ongoing.
- Trelegy’s advantages include FDA-approval for both asthma and COPD, and once daily dosing. The Ellipta inhaler device is breath-activated, requiring the patient to have a higher minimum inspiratory flow rate, however, it does not require patient breath-hand coordination.

Overall Clinical Conclusion

- The triple combination inhalers provide a convenience to patients by offering three drugs in one inhaler for one copay. However there is no data to show the triple combination inhalers result in improved outcomes compared to taking multiple inhalers to comprise a regimen of LABA/ICS/LAMA [ICS/LABA (e.g., Advair) plus LAMA (e.g., Spiriva)].
- In order to meet the needs of Military Health System (MHS) patients with COPD, at least one option for the triple ingredients of ICS/LAMA/LABA is required on the formulary; however, it does not have to be a three-ingredients-in-one inhaler.

Relative Cost-Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that budesonide/glycopyrrolate/formoterol (Breztri) and fluticasone/umeclidinium/vilanterol (Trelegy) were both cost-effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or Tier 4 on the UF. BIA results showed that designating Breztri and Trelegy as UF demonstrated the greatest cost avoidance for the Military Health System (MHS).

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - fluticasone/umeclidinium/vilanterol (Trelegy)
 - budesonide/glycopyrrolate/formoterol (Breztri)
- NF: None

- Tier 4/Not Covered: None
 - Note that a pulmonary 3 agent will not be included on the Basic Core Formulary. Advair and Spiriva Respimat remain on the BCF.
2. **COMMITTEE ACTION: QUANTITY LIMITS (QL)**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) standardizing the current Quantity Limits for Trelegy, and Breztri to allow for one inhaler per fill at Retail Network pharmacies, and three inhalers per fill at the MTF and TRICARE Mail Order pharmacy. See Appendix D for the full criteria.
 3. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) REQUIREMENTS**— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining only Trelegy on the program. Breztri will not be included on the program. *(See the August 2021 P&T Committee meeting minutes where Breztri was added to the EMMPI program.)*
 4. **COMMITTEE ACTION: UF, QL, EMMPI PROGRAM AND IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service. Based on the P&T Committee’s recommendation, the effective date is March 2, 2022.

(Note: See the August 2021 P&T Committee meeting minutes for the recommendation for the Tier 1 copay for Breztri.)

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed for group 1: (18 for, 0 opposed, 1 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 0 absent), with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 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: (18 for, 0 opposed, 1 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 0 absent) the following:

- UF:
 - berotralstat (Orladeyo) – Corticosteroids-Immune-modulators; for hereditary angioedema (HAE)
 - hydrocortisone oral sprinkle capsules (Alkindi) – Adrenocortical insufficiency in children
 - lonafarnib (Zokinvy) – Miscellaneous metabolic agent for Hutchinson-Gilford Progeria Syndrome or processing-deficient Progeroid Laminopathies
 - pegfilgrastim-apgf syringe (Nyvepria) – White Blood Cell Stimulants. Note that as part of this recommendation, Nyvepria will be designated as step-preferred.
 - setmelanotide injection (Imcivree) – Weight loss agent for obesity due to deficiencies of proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR)
- NF:
 - clascoterone 1% cream (Winlevi) – Acne Agents: Topical acne and rosacea agents
 - loteprednol 0.25% ophthalmic solution (Eysuvis) - Ophthalmic: Corticosteroid for short term use in dry eye disease
 - relugolix (Orgovyx) – Luteinizing hormone-releasing hormone (LHRH) agonists-antagonists for advanced prostate cancer
 - sodium sulfate/magnesium sulfate/potassium chloride (Sutab) – Laxatives-Cathartics-Stool Softeners: Bowel Preparation for colonoscopy
 - tramadol oral solution (Qdolo) – Narcotic analgesics and combinations
- Tier 4/Not Covered: See Appendix H for additional detail regarding Tier 4 agents and formulary alternatives.
 - calcipotriene/betamethasone dipropionate 0.005%/0.064% topical cream (Wynzora) - Topical Psoriasis agent.
 - Wynzora was recommended for Tier 4 status as it has little to no clinical benefit relative to other formulations of calcipotriene/betamethasone dipropionate formulations, and the needs of TRICARE beneficiaries are met by alternative agents.

- Formulary alternatives to Wyzora include using a 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; fluocinonide 0.05% cream, gel and solution), or calcipotriene 0.005% and betamethasone 0.064% foam (Enstilar) [Nonformulary].
- clobetasol propionate 0.05% lotion metered dose pump (Impeklo) – High Potency Topical Corticosteroid for steroid-responsive dermatoses.
 - Impeklo was recommended for Tier 4 status as it has little to no clinical benefit relative to other formulations of clobetasol propionate, and the needs of TRICARE beneficiaries are met by alternative agents.
 - Formulary alternatives to Impeklo include betamethasone/propylene glycol 0.05% lotion; betamethasone dipropionate 0.05% gel; clobetasol propionate/emollient 0.05 % (emulsion) foam; clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo, and fluocinonide 0.05% solution and gel

B. COMMITTEE ACTION: MN CRITERIA—The P&T Committee recommended group 1: (17 for, 0 opposed, 2 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 1 absent) MN criteria for Eysuvis, Orgovyx, Qdolo, Sutab, Winlevi. See Appendix B for the full criteria.

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

- Pegfilgrastim: No PA is required for Nyvepria, however, note that Nyvepria will be step-preferred, along with Udenyca and Fulphila (which were reviewed at the August 2020 meeting); new patients receiving a non-step-preferred Pegfilgrastim (Neulasta, Neulasta Onpro, and Ziextenzo) will be required to have a trial of Nyvepria, Udenyca and Fulphila first. The PA forms for the non-step-preferred products will be updated accordingly.
- LHRH agonists-antagonists for advanced prostate cancer: Applying manual PA criteria to new users of Orgovyx.
- HAE drugs: applying manual PA criteria to new users of Orladeyo. See the Utilization Management Section on pages 14 and 28 for updates to the PAs for all the HAE prophylaxis drugs.

- Applying manual PA criteria to new users of Alkindi Sprinkle, Imcivree, Qdolo, and Zokinvy.
- Applying manual PA criteria to new and current users of Eysuvis and Winlevi.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Tier 1 Co-Pay for pegfilgrastim (Nyvepria)

The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) lowering the current Tier 2 cost-share for Nyvepria 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.

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.

E. COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION

PERIOD—The P&T Committee recommended group 1: (17 for, 0 opposed, 2 abstained, 0 absent); group 2: (18 for, 0 opposed, 1 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF or NF Status:** An effective date of the first Wednesday upon two weeks after signing of the minutes in all points of service, on March 2, 2022. Note that the updated PAs for the HAE drugs will also occur at this time.
- **New Drugs Recommended for Tier 4/Not Covered Status:** 1) An effective date upon 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

- a) **Skeletal Muscle Relaxants and Combinations – orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte)**—The non-opioid combination product containing orphenadrine 50 mg, aspirin 770 mg, and caffeine 60 mg is indicated for mild to moderate acute musculoskeletal pain. The fixed dose combination generic Norgesic and Orphengesic products are not cost effective relative to the individual components, which are all available in low-cost formulations. Several other cost-effective prescription and OTC non-opioid alternatives (i.e., baclofen, cyclobenzaprine, NSAIDs, acetaminophen) are also available.

COMMITTEE ACTION: NEW PA CRITERIA FOR NORGESIC, ORPHENGESIC FORTE—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria for orphenadrine-aspirin-caffeine Norgesic and Orphengesic Forte in new users, to ensure that other therapies for musculoskeletal pain are tried first. See Appendix C for the full criteria.

- b. **Narcotic Analgesics and Combinations-levorphanol tartrate tablets**—Levorphanol tartrate is reserved for patients who require an opioid for severe pain where alternative options (i.e., non-opioid analgesics, opioid combination products) are ineffective, not tolerated, or otherwise inadequate. It is not a first line treatment for pain, due to safety concerns related to the long half-life. Provider feedback mentioned unfamiliarity with this product and supported PA criteria. Numerous other appropriate pain management options are available.

COMMITTEE ACTION: NEW PA CRITERIA FOR LEVORPHANOL TARTRATE TABS—The P&T Committee recommended (17 for, 0 opposed, 2 abstained, 0 absent) manual PA criteria for levorphanol tartrate tablets in new users, to ensure that other therapies for pain are tried first. See Appendix C for the full criteria.

2. Updated PA Criteria, Step Therapy, and MN Criteria

The P&T Committee recommended (17 for, 0 opposed, 2 abstained, 0 absent) updates to the PA criteria for several drugs, based on new clinical trial data, clinical practice guidelines, or MTF provider requests. The updated PA criteria discussed below apply to new users of an SGL2-inhibitor, Xhance, Symbicort/Dulera, and Evrysdi. See Appendices B and C for the full criteria.

- a) **Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors-empagliflozin (Jardiance), dapagliflozin (Farxiga), canagliflozin (Invokana), ertugliflozin (Steglatro) and their combinations with metformin**—The SGLT2 inhibitors were originally approved for treating type 2 diabetes mellitus (T2DM) when the class was reviewed for formulary status in 2015. Empagliflozin (Jardiance) is currently the preferred SGLT2 inhibitor; canagliflozin (Invokana), dapagliflozin (Farxiga), and ertugliflozin (Steglatro) are nonformulary and non-

step-preferred, requiring a trial of empagliflozin first. The SGLT2 inhibitors are also available in fixed-dose combinations with metformin.

Recently published trials provide evidence for the SGLT2 inhibitors in patients with heart failure with reduced ejection fraction (HFrEF) or chronic kidney disease (CKD), regardless of DM status. Clinical practice guidelines from the American College of Cardiology (ACC) (2021 ACC Consensus Decision Pathway for HFrEF Optimization) and the American Heart Association (AHA) (2020 Scientific Statement on cardiorenal protection in patients with DM and CKD) support a class effect for the SGLT2 inhibitors for improving cardiovascular outcomes. At the time of the February 2021 meeting, some of the package inserts for the SGLT2 inhibitors had not yet been updated to reflect the new clinical trial data. *Note that Jardiance received FDA approval for treating HFrEF on August 18, 2021.*

Provider input from MHS cardiologists and nephrologists overwhelmingly supported maintaining empagliflozin as the preferred SGLT2 inhibitor for T2DM, HFrEF and CKD, based on professional guidelines and clinical trial data, regardless of diabetes status or formal FDA-approval.

COMMITTEE ACTION: SGLT2 INHIBITORS UPDATED PA

CRITERIA—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) removing the current PA criteria for empagliflozin and empagliflozin/metformin. The PA criteria for canagliflozin, dapagliflozin, and ertugliflozin and their respective combinations with metformin were revised to require a trial of empagliflozin first for patients with T2DM, HFrEF and CKD. The nonformulary SGLT2 inhibitors will be allowed if the patient has a contraindication or has experienced adverse effects from empagliflozin. See Appendix C for the full criteria.

- b) Nasal Allergy Agents: Corticosteroids - fluticasone propionate 93 mcg nasal spray (Xhance)**—An MTF provider requested the Committee review the current PA and MN criteria for Xhance, which was designated NF at the February 2018 meeting. Xhance is the fourth fluticasone nasal product marketed, but it is only indicated for adults with nasal polyps and is not approved for allergic rhinitis.

A review of the evidence shows that Xhance may provide enhanced penetration of medication into the nasal cavity, but there is no evidence that this results in improved outcomes for the patient. Xhance provides no confirmed benefit in reducing nasal polyp size compared to alternative intranasal corticosteroids or steroid lavage. However, changes to the Xhance manual PA criteria were made to align with current rhinosinusitis guidelines for treating nasal polyps, and to follow DHA Specialist recommendations.

Additions to the criteria include a new requirement for nasal saline irrigation. The option of nasal corticosteroid lavage (e.g., irrigation/rinse) was added to list of treatments that are required prior to Xhance (patients must still try two nasal

steroids before Xhance). The MN criteria were also updated to require a trial of one formulary alternative prior to Xhance.

- c) **Pulmonary-1 Agents: Combinations: budesonide/formoterol (Symbicort) and mometasone/formoterol (Dulera)**—Manual PA criteria for Symbicort and Dulera were originally recommended in February 2014, requiring a trial of fluticasone/salmeterol (Advair) first. The PA criteria were most recently revised in November 2019, allowing ICS-formoterol (e.g., budesonide/formoterol, or mometasone/formoterol) as a rescue inhaler, based on the 2019 Global Initiative for Asthma (GINA) evidence-based strategy.

In 2020, the U.S. based National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) focused update to the Asthma Management Guidelines now prefers combination ICS-formoterol for daily (maintenance) and as needed use (PRN or quick-relief therapy) for moderate persistent asthma (Steps 3 and 4 in the algorithm) over other ICS and ICS/LABA combinations. The traditional regimens of ICS with PRN short-acting beta agonist (SABA) or ICS/long acting beta agonist (LABA) with PRN SABA are now considered alternate treatments. However, no changes are needed if a patient's current regimen of maintenance ICS/LABA with SABA as quick-relief therapy is providing adequate asthma control.

This approach of using ICS-formoterol for maintenance and PRN use was based on 10 studies comparing ICS-formoterol dual combination inhalers with the same dose ICS or higher dose ICS single ingredient inhalers. A reduction in asthma exacerbations was noted with ICS-formoterol therapy. Limitations to the studies were the inclusion of ICS-formoterol and SABA inhalers that are not commercially available in the U.S. and significant industry funding. Also note that the current FDA labeling for Symbicort and Dulera does not include quick-relief use.

Provider feedback was solicited regarding the NAEPPCC recommendations, and overall, providers supported increased access to ICS/formoterol combinations for DoD beneficiaries. Current contracting commitments preclude changing the formulary status for Symbicort and Dulera at this time. However, manual PA criteria and MN criteria for both drugs were updated in accordance with the 2020 NAEPPCC recommendations.

- d) **Miscellaneous Neurologic Agent for spinal muscular atrophy (SMA): risdiplam (Evrysdi) oral solution**—Manual PA criteria for Evrysdi were added when it was first reviewed as a new drug at the November 2020 meeting. The Director, DHA recommended that the P&T Committee re-review the criteria. The Committee re-evaluated the current age restriction, which limits use to patients younger than 25. After further review, despite a lack of clinical evidence supporting Evrysdi in patients older than 25 years of age, for humanistic reasons the age restriction was

removed from the PA. Patients meeting all the other criteria will be allowed to use Evrysdi, regardless of age. See Appendix C for revised criteria.

COMMITTEE ACTION: UPDATED PA CRITERIA—The P&T Committee recommended (17 for, 0 opposed, 2 abstained, 0 absent) updated PA criteria for Xhance, Symbicort, Dulera, the HAE drugs, and Evrysdi, and the updated MN criteria for Symbicort and Dulera. See Appendix B for the full MN criteria and see Appendix C for the full PA criteria.

3. Updated PA Criteria, Step Therapy, and MN Criteria for New FDA-Approved Indications, NCCN Guideline Updates, or Age Ranges

The P&T Committee (17 for, 0 opposed, 2 abstained, 0 absent) recommended updates to the manual PA criteria and step therapy for several drugs due to expanded age indications, and new FDA-approved indications, or other reasons. The updated PAs, MN criteria and step therapy outlined below will apply to new users. See Appendix C for full criteria.

- **Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis: plasma-derived human C1 Esterase Inhibitor IV (Cinryze), plasma-derived human C1 Esterase Inhibitor SC (Haegarda), lanadelumab (Takhzyro) SC injection**—The prophylactic HAE drugs were evaluated for formulary status in August 2017, and new drug review for Orladeyo was presented previously at this meeting (see 10). The manual PA criteria for the HAE prophylactic drugs were updated to reflect the 2020 U.S. Hereditary Angioedema Association guidelines which do not recommend a trial of anabolic androgens prior to other available prophylactic agents.
- **Targeted Immunomodulatory Biologics (TIBs) - anakinra (Kineret)**—Manual PA criteria now allow for the new indication of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).
- **Immunosuppressives - belimumab (Benlysta)**—belimumab injection SQ and IV (Benlysta)—Manual PA criteria were updated to include the new indication of active lupus nephritis in adults who are receiving standard therapy.
- **Cystic Fibrosis Agents - ivacaftor (Kalydeco), elexacaftor/tezacaftor/ivacaftor (Trikafta), and tezacaftor/ivacaftor (Symdeko)**—The PA criteria for the cystic fibrosis drugs were revised to standardize the wording for all three drugs, and to reflect the new indications allowing for mutation types that are responsive to Kalydeco or Symdeko, based on clinical and/or *in vitro* assay data.
- **Weight Loss Agents - liraglutide 3 mg (Saxenda)**—Manual PA criteria now allow use in patients as young as 12 years for weight loss. Patients age 16 years and older must first try phentermine, consistent with the requirements for adults, however

patients between the ages of 12 to 15 years are allowed to use Saxenda without first trying phentermine.

- **Oncological Agents**

- **Breast Cancer - neratinib (Nerlynx)**—Includes the new FDA-approved indications for advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer in adults, when used in combination with capecitabine, and when the patient has received two or more prior anti-HER2-based regimens in the metastatic setting. The previous lifetime duration of one year was removed, since the new indication of HER2+ breast cancer does not limit length of the treatment course.
- **Multiple Myeloma - selinexor (Xpovio)**—Updated the manual PA criteria to allow for the new indication for multiple myeloma, when used in combination with bortezomib and dexamethasone, and when the patient has received at least one prior therapy.
- **Multiple Myeloma - ixazomib (Ninlaro)**—Updated the manual PA for NCCN recommended (category 1) use as a single-agent maintenance therapy for multiple myeloma when patients will receive Ninlaro following primary therapy and hematopoietic cell transplant (HCT).

- **Sleep Disorders**

- **Wakefulness Promoting Agents - pitolisant (Wakix)**—The new indication of cataplexy in adults with narcolepsy is now included in the criteria.
- **Sleep Disorders: Insomnia Agents - tasimelteon capsule and liquid (Hetlioz, Hetlioz LQ)**—tasimelteon capsule and liquid (Hetlioz/Hetlioz LQ)—Updated the manual PA criteria to include the new indication of Smith-Magenis Syndrome (SMS) for the capsules in patients 16 years of age and older, and for the liquid in patients 3 to 15 years of age.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA—

The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for the CF drugs, Kineret, Benlysta, Saxenda, Nerlynx, Xpovio, Ninlaro, Wakix, Hetlioz, and Hetlioz LQ. See Appendix C for the full PA criteria.

B. Quantity Limits

General QLS: QLS were reviewed for five newly approved drugs.

COMMITTEE ACTION: QLS—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) QLS for Alkindi Sprinkle, Zokinvy, Imcivree, Orladeyo, and Winlevi. See Appendix D for the QLS.

C. PA and QLS Implementation Periods

COMMITTEE ACTION: PA AND QLS IMPLEMENTATION

PERIOD—The P&T Committee recommended the following implementation periods:

- (18 for, 0 opposed, 1 abstained, 0 absent) The new PA for orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte); the updated SGLT2 inhibitor PA criteria; and the removal of the age restriction for Evrysdi will become effective in new users the first Wednesday 30 days after the signing of the minutes (March 16, 2022). *Note that due to the BAP meeting delay and subsequent delay of the signing of the February 2021 P&T Committee meeting minutes, the PA for Evrysdi was updated in June 2021, based on the direction of the Director, DHA from the November 2020 DoD P&T Committee minutes' signing.* .
- (17 for, 0 opposed, 2 abstained, 0 absent) Updates to the current PA criteria in new users for Xhance; the LAMA/LABA inhalers Symbicort and Dulera; Kineret; Benlysta; the CF drugs Kalydeco, Symdeko, and Trikafta; Saxenda; the oncology drugs Nerlynx, Xpovio, and Ninlaro, and the sleep disorder drugs Wakix, Hetlioz, and Hetlioz LQ, along with MN criteria updates for Xhance, Symbicort, and Dulera will become effective the first Wednesday 60 days after the signing of the minutes (April 20, 2022). *Note that due to the BAP meeting delay and subsequent delay of the signing of the February 2021 P&T Committee meeting minutes, and the fact that the PA updates expand the potential patient eligible to receive the drugs listed above, the PAs were updated in June 2021.*
- (17 for, 0 opposed, 2 abstained, 0 absent) The new PA for levorphanol tartrate tablets will become effective in new users the first Wednesday 90 days after the signing of the minutes (May 18, 2022).
- (18 for, 0 opposed, 1 abstained, 0 absent) QLS listed in Appendix D will become effective the first Wednesday 2 weeks after the signing of the minutes in all POS (March 2, 2022).
- Note that the implementation for the updated PAs for the HAE drugs Cinryze, Haegarda, Takhzyro and Orladeyo will occur at two weeks after signing of the minutes, as outlined in the new drug section on p 10.

VII. 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. COMMITTEE ACTION: LINE EXTENSIONS, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 0 absent) clarifying the formulary status of the following products to reflect the current formulary status and applicable step therapy, MN criteria, PA criteria, QLs, and EMMI List status, and specialty status for the parent compound. Implementation will occur the first Wednesday two weeks after signing of the minutes (March 2, 2022).

- **Hepatitis C Agents: Direct Acting Agents**—designating **sofosbuvir/velpatasvir tablets (Epclusa) 200 mg-50 mg tablet** as UF, with the same manual PA requirements, QLs, and specialty reporting requirements similar to Epclusa 400 mg-100 mg tablet.
- **Gastrointestinal-2 Agents: Miscellaneous—fidaxomicin granules for oral suspension (Dificid)**—designating Dificid granules for oral suspension as UF with similar QLs as currently applies to the Dificid oral tablet. See Appendix D for the QL.

VIII. 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 February 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 February 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.

1. **COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS**—The P&T Committee recommended (groups 1: 17 for, 0 opposed, 1 abstained, 1 absent; group 2: 18 for, 0 opposed, 1 abstained, 0 absent), adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMI List) for the reasons outlined in the table. See Appendix F.

IX. CHANGES TO THE MHS GENESIS OTC LIST: ALIGNING OTC FORMULARIES AT MTFs: NASAL COLD AND ALLERGY PRODUCTS

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

Factors influencing whether a particular OTC product is retained or removed from the MHS GENESIS OTC List include volume and utilization across multiple MTFs; feedback from MTF stakeholders to include primary care providers, pediatricians, and other providers, DHA Clinical Community advisory groups, pharmacists, and pharmacy personnel; clinical considerations; and comparative cost.

- A. OTC Nasal Cold and Allergy Products**—OTC nasal cold and allergy products include nasal corticosteroids (budesonide, fluticasone furoate, fluticasone propionate, and triamcinolone), cromolyn sodium, nasal decongestants (oxymetazoline and phenylephrine), and saline nasal products.

Legend products in this category include nasal steroids (beclomethasone, ciclesonide, flunisolide, fluticasone propionate, and mometasone), nasal anticholinergics (ipratropium) and nasal antihistamines (azelastine and olopatadine). By far the most commonly used products across these categories are legend fluticasone propionate 50 mcg, OTC oxymetazoline 0.05% spray, and the four OTC saline products noted below. These products are also consistently lower in cost compared to alternative products. Clinicians at MHS GENESIS sites that dispensed less commonly used OTC products (e.g., budesonide, the OTC version of fluticasone propionate 50 mcg, cromolyn, or phenylephrine) did not express an overwhelming need to retain any of these OTC products on formulary.

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

- Retaining oxymetazoline 0.05% spray, sodium chloride, bicarbonate/squeeze bottle (e.g., Ayr, Neilmed Sinus) pack w/dev; sodium chloride/sodium bicarbonate (Ayr, Neilmed Sinus Rinse) packet; sodium chloride (Ayr Saline, Baby Ayr Saline) 0.65% drops; and sodium chloride (Ayr Saline, Deep Sea, Ocean) 0.65% spray.
- Removing budesonide 32 mcg spray, fluticasone propionate 50 mcg spray, cromolyn sodium 5.2 mg spray, and phenylephrine 0.125%, 0.25% and 0.5% sprays, which are rarely used by MTFs.
- An implementation date of the first Wednesday 120 days following signing of the minutes for the products removed from the list. No patient letters are required due to the typically intermittent use of

the products. Appendix I outlines specific products retained or added to the MHS GENESIS OTC List.

X. ITEMS FOR INFORMATION

A. Tier 4/Not Covered Re-Review: Proton Pump Inhibitor (PPI) — dexlansoprazole (Dexilant) and esomeprazole strontium:

The Committee was briefed on the Tier 4 PPIs (dexlansoprazole and esomeprazole strontium) selected at the May 2019 meeting, with implementation occurring November 28, 2019 (with some MTFs implementing in January 2020). For dexlansoprazole (Dexilant), there was no new clinical data to change the May 2019 conclusion that it does not have a significant clinically meaningful therapeutic advantage in terms of effectiveness, safety, and clinical outcomes compared to other PPI drugs currently included on the UF. Dexlansoprazole remains significantly more costly than the remainder of the class. Esomeprazole strontium was discontinued from the market in 2020.

In the future, after a medication in any drug class has been recommended for Tier 4 placement by the DoD P&T Committee, the Committee will only review the drug again if significant clinical or cost-effectiveness updates or changes have occurred that may necessitate a change in Tier 4 status.

B. Annual Review of Newly Approved Drugs

The Committee was briefed on the utilization and cost trends for the newly approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015. Since the start of the program, 351 drugs have been reviewed, including 77 in calendar year 2020 alone. Updates on the metrics for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

C. Post-Implementation Review: Migraine Agents: Calcitonin Gene-related Peptide (CGRP) Preventatives

The CGRP migraine prophylaxis drugs [erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality)] were evaluated for formulary status in February 2019. Overall trends in utilization and expenditures were reviewed since implementation in November 2019.

XI. ADJOURNMENT

The meeting adjourned at 1619 hours on February 4, 2021. The next meeting will be in May 2021.

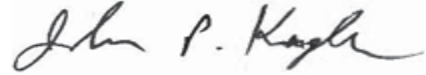
Appendix A—Attendance: February 2021 DoD P&T Committee Meeting

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 February 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—MHS GENESIS OTC Test List**
- Appendix J—Table of Abbreviations**

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

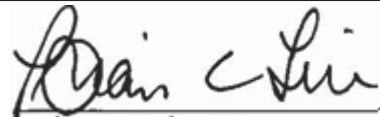
The Director, DHA:

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 Feb 2022
Date

Appendix A—Attendance: February 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, BCACP	DHA Formulary Management Branch (Recorder)
LTC John Poulin, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Officer
LTC Rosco Gore, MC	Army, Internal Medicine Physician
MAJ Wendra J Galfand, MC	Army, Family Medicine Physician
LCDR Sean Stuart, MC	Navy, Physician at Large
CDR Bradley Gotto for CAPT Brandon Hardin, MSC	Navy, Pharmacy Officer
LCDR Danielle Barnes, MC	Navy, Pediatrics Representative
CDR Austin Parker, MC	Navy, Internal Medicine Physician
CDR Jason Foote for CAPT Paul Michaud, USCG	Coast Guard, Pharmacy Officer
Maj Jeffrey Colburn, MC	Air Force, Internal Medicine Physician
Col James Jablonski, MC	Air Force, Physician at Large
Lt Col Larissa Weir, MC	Air Force, OB/GYN Physician
Col Corey Munro, BSC	Air Force, Pharmacy Officer
COL Clayton Simon, MC	TRICARE Regional Office Representative
Dr. Lara Au	Oncology Pharmacist
LTC Jason Burris	Army, Oncologist
Nonvoting Members Present	
Bryan Wheeler, DHA	Deputy General Counsel, DHA
Beth Days, PharmD	Oncology Pharmacist
LCDR William Agbo CPT Hope Shen	DLA Troop Support

Appendix B—Table of Medical Necessity (MN) Criteria

Elaine Furmaga (February 3 rd) Mitchell Nazario (February 4 th)	Department of Veterans Affairs
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Guests	
Ms. Hilary Meckel	DHA Contracting Officer
Ms. Yvette Dluhos	DHA Contracting
Mr. Dwight Bonham	DHA Contracting
Mr. Hudson Tompkins	DHA Contracting
Ms. Grace Steier	DHA Contracting
Mr. Monroe Porter	DHA Contracting
Ms. Madison Northen	DHA Contracting
Others Present	
Lt Col Ronald Khoury, MC	Chief, DHA Formulary Management Branch POD
CDR Heather Rovey, 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
MAJ Adam Davies, MSC	DHA Formulary Management Branch
LCDR Elizabeth Hall, BCPS	DHA Formulary Management Branch
Ellen Roska, PharmD, MBA, PhD	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
MAJ Triet Nguyen, MSC	DHA Formulary Management Branch
Maj Gregory Palmrose, BSC	DHA Market Management Branch
CDR Eric Parsons	DHA Purchased Care 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. Ebony Moore	DHA Formulary Management Branch Contractor
Ms. Rachel Lai	University of Texas PharmD Student

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
Newly Approved Drugs MN Criteria	
<ul style="list-style-type: none"> • clascoterone cream (Winlevi) <p>Acne Agents: Topical Acne and Rosacea</p>	<ul style="list-style-type: none"> • Use of formulary agents is contraindicated • Patient has tried AND failed or experienced significant adverse effects from at least 3 formulary agents, including 1 oral product and 1 clindamycin/benzoyl peroxide combination product. <p>Formulary alternatives: adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, gel), spironolactone</p>
<ul style="list-style-type: none"> • loteprednol 0.25% ophthalmic solution (Eysuvis) <p>Ophthalmic: Dry Eye</p>	<ul style="list-style-type: none"> • Patient has experienced significant adverse effects from formulary agents • A trial of two formulary agents has resulted in therapeutic failure (one of which must be loteprednol 0.5%) <p>Formulary alternatives: loteprednol 0.5% gel, ointment, or suspension (Lotemax, generics); loteprednol 0.38% gel (Lotemax SM); loteprednol 1% suspension (Inveltys); loteprednol 0.2% suspension (Alrex, generics); fluorometholone (Flarex, FML)</p>
<ul style="list-style-type: none"> • relugolix (Orgovyx) <p>Luteinizing Hormone-Releasing Hormone Agonists-Antagonists for Prostate Cancer</p>	<ul style="list-style-type: none"> • At least one formulary agent (Lupron Depot, Eligard, Firmagon) resulted in therapeutic failure. • No alternative formulary agent – Patient is not able to use a intramuscular injection, subcutaneous injection or implant <p>Alternatives: leuprolide acetate IM (Lupron Depot), leuprolide acetate SQ (Eligard), degarelix SQ (Firmagon), goserelin SQ implant (Zoladex), histrelin SQ implant (Vantas), triptorelin IM (Trelstar Mixject)</p>
<ul style="list-style-type: none"> • sodium sulfate/ magnesium sulfate/ potassium chloride (Sutab) <p>Laxatives-Cathartics-Stool Softeners: Bowel Preparations</p>	<ul style="list-style-type: none"> • No alternative formulary agent – the patient requires a bowel prep formulated as a tablet and cannot take OsmoPrep. <p>Formulary alternatives: GoLytely, Suprep, MoviPrep</p>
<ul style="list-style-type: none"> • tramadol oral solution (Qdolo) <p>Narcotic Analgesics & Combinations</p>	<ul style="list-style-type: none"> • No alternative formulary agent - Patient cannot swallow tablets <p>Formulary alternatives: tramadol IR tablets, acetaminophen liquid, ibuprofen liquid</p>

Appendix B—Table of Medical Necessity (MN) Criteria

Drug / Drug Class	Medical Necessity Criteria
Utilization Management Updated MN Criteria	
<ul style="list-style-type: none"> • fluticasone propionate 93 mcg nasal spray (Xhance) <p>Nasal Allergy Agents: Corticosteroids</p>	<p><u>Updates from the February 2021 meeting are in bold and strikethrough.</u></p> <ul style="list-style-type: none"> • Use of at least two one formulary and nonformulary nasal allergy drugs has resulted in therapeutic failure <p>Formulary Alternatives: azelastine 137 mg nasal inhaler, flunisolide (generic Nasarel), fluticasone propionate 50 mcg nasal inhaler (generic Flonase), mometasone (generic Nasonex), beclomethasone (Beconase AQ), budesonide (generic Rhinocort Aqua)</p>
<ul style="list-style-type: none"> • mometasone/formoterol (Dulera) • budesonide/formoterol (Symbicort) <p>Pulmonary I Agents – Combinations</p>	<p><u>Updates from the February 2021 meeting are in bold and strikethrough.</u></p> <ul style="list-style-type: none"> • Use of formulary agents (Advair Diskus and Advair HFA) is contraindicated • Patient has experienced significant adverse effects from Advair that is not expected to occur with the non-formulary ICS/LABA medication • Formulary agents (Advair Diskus and Advair HFA) result or are likely to result in therapeutic failure • Patient previously responded to the non-formulary agent and changing to a formulary agent (Advair Diskus and Advair HFA) would incur unacceptable risk • No alternative formulary agent: <ul style="list-style-type: none"> • For Symbicort and Dulera: patient has asthma and requires rescue therapy or intermittent and daily ICS-LABA with an ICS-formoterol combination • Symbicort: Patient requires an MDI because they have decreased inspiratory effort and cannot use a DPI (Advair Diskus) • Breo-Ellipta: patient has complicated drug regimen and requires once daily dosing <p>Formulary Alternatives: Advair Diskus and Advair HFA</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • Ibrance • Verzenio • Kisqali • Kisqali Femara Co-Pack <p>Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors</p>	<p>The PA criteria below replaces the current PA criteria for the CDK inhibitors.</p> <p>Manual PA criteria apply to all new users of Ibrance, Verzenio, Kisqali, and Kisqali Femara Co-Pack.</p> <p><u>Manual PA Criteria:</u> Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack is approved if <u>all</u> of the following criteria are met:</p> <ul style="list-style-type: none"> • Drug is prescribed by or in consultation with an oncologist • The patient is not currently taking another cyclin-dependent kinase inhibitor • For Verzenio only: The patient has hormone receptor HR(+)/HER2(-), node(+), early breast cancer at high risk of recurrence and a Ki67 score ≥ 20% as determined by an FDA approved test. (new indication from Oct 2021) • The patient has advanced or metastatic hormone receptor (HR(+))/HER2(-) breast cancer • If the patient is female, the patient meets one of the following criteria: <ul style="list-style-type: none"> ▪ Ibrance, Verzenio, Kisqali, or Kisqali Femara Co-Pack will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR ▪ Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR ▪ For Verzenio only: Will be used as monotherapy following metastatic progression on chemotherapy • If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation. • Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease • For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism • For Verzenio only: provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity • For Kisqali and Kisqali Femara Co-Pack only: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only • Male patients have been informed of the risk of infertility • For Kisqali Femara Co-Pack only, female patients have been informed of the risk of infertility from letrozole • 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:_____. <p>Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Newly Approved Drug PAs	
<ul style="list-style-type: none"> • berotralstat (Orladeyo) • lanadelumab-flyo (Takhzyro) • C1-INH (Cinryze IV) • C1-INH (Haegarda SC) <p>Corticosteroids- Immune-modulators: Hereditary Angioedema Agents</p>	<p>The PA criteria below replace the current PA criteria for the drugs.</p> <p>Manual PA criteria apply to all new users of Orladeyo, Takhzyro, Cinryze, and Haegarda.</p> <p><u>Manual PA criteria:</u> Orladeyo, Takhzyro, Cinryze, or Haegarda is approved if all apply:</p> <ul style="list-style-type: none"> • Patient Age <ul style="list-style-type: none"> ○ For Orladeyo, the patient is 12 years of age or older ○ For Takhzyro, the patient is 12 years of age or older ○ For Cinryze, the patient is 13 years of age or older • The patient has a diagnosis of hereditary angioedema (HAE) • Orladeyo, Takhzyro, Cinryze or Haegarda is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist • The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., ≥2 HAE attacks/month, laryngeal attacks, etc.) • The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly) <p>Non-FDA-approved uses NOT approved. Prior Authorization does not expire.</p>
<ul style="list-style-type: none"> • clascoterone cream (Winlevi) <p>Acne Agents: Topical Acne and Rosacea</p>	<p>Manual PA is required for all new and current users of clascoterone cream (Winlevi).</p> <p><u>Manual PA Criteria:</u> Coverage is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider is aware and acknowledges that adapalene (cream, gel, lotion), clindamycin (cream, gel, lotion, solution), clindamycin/benzoyl peroxide (combination) gel, tretinoin (cream, gel), and spironolactone (tablets) are available to DoD beneficiaries without requiring prior authorization • Patient has a diagnosis of acne vulgaris • Patient is 12 years of age or older • The drug is prescribed by or in consultation with a dermatologist. • Provider acknowledges a potential increased risk of hypothalamic-pituitary-adrenal axis suppression in adolescents compared to adults • Patient has tried and failed or has contraindications to a topical retinoid product and to a combination of topical clindamycin and benzoyl peroxide product. The provider must fill in the dates of when the patient previously tried these agents or document the contraindication that exists. <ul style="list-style-type: none"> • Topical retinoid: Date _____ Contraindication _____ • Combination topical clindamycin with benzoyl peroxide: Date _____ Contraindication _____ • Patient has tried and failed or has contraindications to at least one oral medication (i.e., spironolactone, a combined oral contraceptive, OR isotretinoin) for acne. The provider must fill in the dates of when the patient previously tried these agents or document the contraindication that exists <ul style="list-style-type: none"> • Oral medication: _____ Date _____ Contraindication _____ <p>Non-FDA-approved uses are not approved, including for hair loss Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • hydrocortisone oral sprinkle (Alkindi Sprinkle) <p>Corticosteroids- Immune Modulators</p>	<p>Manual PA criteria apply to all new users of Alkindi Sprinkle</p> <p>PA is not required for patients 6 years of age and younger (age edit).</p> <p><u>Manual PA criteria:</u> Alkindi Sprinkle is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • The provider is aware and acknowledges that 5 mg generic hydrocortisone tablets and prednisone Intensol oral syrup are available to DoDbeneficiaries without requiring prior authorization • Patient is between the ages of 6 and 18 years of age. • Patient has a documented diagnosis of adrenocortical insufficiency • Provider acknowledges that the patient’s dosing regimen requires small doses of hydrocortisone and cannot accurately split the dose using 5 mg hydrocortisone tablets or use the Intensol oral syrup <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • lonafarnib (Zokinvy) <p>Metabolic Agents: Miscellaneous</p>	<p>Manual PA criteria apply to all new users of Zokinvy.</p> <p><u>Manual PA criteria:</u> Zokinvy is approved if <u>all</u> criteria are met:</p> <ul style="list-style-type: none"> • Patient is 12 months of age or older • Patient has a body surface area (BSA) of 0.39 m² and greater • Patient has a documented diagnosis of Hutchinson-Gilford Progeria Syndrome or the following processing deficient Progeroid Laminopathies: <ul style="list-style-type: none"> ○ Heterozygous LMNA mutation with progerin-like protein accumulation ○ Homozygous or compound heterozygous ZMPSTE24 mutations • Patient is not concomitantly receiving strong or moderate CYP3A inhibitors or inducers, midazolam, lovastatin, simvastatin, or atorvastatin • Patient’s renal function, electrolytes, complete blood counts, and liverenzymes will be monitored at regular intervals • Female patients with reproductive potential have been advised of the risk to a fetus and effective contraception is used <p>Non-FDA approved uses are NOT approved including for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies.</p> <p>Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> loteprednol 0.25% ophthalmic solution (Eysuvis) <p>Ophthalmic: Corticosteroid</p>	<p>Manual PA criteria apply to all new and current users of Eysuvis</p> <p><u>Manual PA criteria</u>—Coverage will be approved if all criteria are met:</p> <ul style="list-style-type: none"> The provider is aware and acknowledges that generic loteprednol 0.5%, and other loteprednol formulations, Lotemax SM, Lotemax FML and Inveltys, are available to DoD beneficiaries without requiring prior authorization Eysuvis is prescribed by an optometrist or ophthalmologist Patient has a diagnosis of dry eye disease as evidenced by at least one diagnostic test (e.g., Tear Film Break Up Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) Patient has tried and failed or had an adverse event to a two week course of generic loteprednol 0.5% Patient has tried and failed or had an adverse event to a two week course of at least one low-dose ophthalmic steroid formulation (e.g. Lotemax SM, Inveltys, Alrex, and FML) Use of Eysuvis will not exceed 14 days per course of therapy for dry eye disease <p>Non-FDA-approved uses are NOT approved, including allergic conjunctivitis and for post-operative use to decrease inflammation PA expires in 6 months.</p> <p>Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Eysuvis will be approved for an additional 6 months if the following is met</p> <ul style="list-style-type: none"> The patient has experienced improvement in dry eye signs and symptoms.
<ul style="list-style-type: none"> relugolix (Orgovyx) <p>Luteinizing Hormone- Releasing Hormone Agonists-Antagonists</p>	<p>Manual PA is required for all new users of relugolix (Orgovyx).</p> <p><u>Manual PA Criteria:</u> Orgovyx is approved if all criteria are met:</p> <ul style="list-style-type: none"> The provider is aware and acknowledges that leuprolide acetate IM (Lupron Depot), leuprolide acetate SQ (Eligard), and degarelix SQ (Firmagon) are available to DoD beneficiaries without requiring prior authorization Patient is 18 years of age or older Orgovyx is prescribed by or in consultation with an oncologist or urologist Patient has advanced prostate cancer Patient has tried and failed OR is unable to use injectable leuprolide formulations (i.e., subcutaneous injection or implant, subcutaneous injection) <p>Non-FDA-approved uses are not approved including cancers other than prostate cancer, and in women for endometrial thinning, endometriosis, and uterine leiomyomata (fibroids).</p> <p>Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • setmelanotide (Imcivree) <p>Weight Loss Agents</p>	<p>Manual PA criteria apply to all new users of Imcivree.</p> <p><u>Manual PA criteria:</u> Imcivree is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is 6 years of age or older • Patient has a confirmed diagnosis (via genetic testing) of POMC-, PCSK1-, or LEPR-deficiency that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) • Patient and provider agree to evaluate weight loss after 12-16 weeks of treatment. Imcivree should be discontinued if a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential <p>Initial prior authorization expires in 4 months.</p> <p><u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Imcivree is approved for 1 year for continuation of therapy if all criteria are met:</p> <ul style="list-style-type: none"> • The patient has a documented improvement (a decrease from baseline) in at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential. <p>Non-FDA approved uses are NOT approved including Alström Syndrome, Bardet-Biedl Syndrome (BBS), POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity.</p>
<ul style="list-style-type: none"> • tramadol oral solution (Qdolo) <p>Narcotic Analgesics & Combinations</p>	<p>Manual PA criteria apply to all new users of tramadol oral solution (Qdolo).</p> <p>Manual PA Criteria: Qdolo will be approved if all criteria are met:</p> <ul style="list-style-type: none"> • The provider is aware and acknowledges that several opioid analgesics are available to DoD beneficiaries without requiring prior authorization, including tramadol IR tablets, and codeine with acetaminophen tablets and solution. • Patient is 12 years of age or older • For patients less than 18 years of age, Qdolo will not be approved for pain following tonsillectomy or adenoidectomy • Patient has tried and failed or has a contraindication to liquid acetaminophen • Patient has tried and failed or has a contraindication to liquid ibuprofen • Patient has tried and failed or has a contraindication to tramadol IR tablets <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • pegfilgrastim (Neulasta) • pegfilgrastim (Neulasta Onpro) • pegfilgrastim-bmez (Ziextenzo) • WBC Stimulants Class: Pegfilgrastim subclass 	<p>Note that the Manual PA criteria for the Pegfilgrastims was updated to include a trial of Nyvepria before the non-step-preferred products. Updates from the Feb 2021 meeting are in bold.</p> <p>Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta Onpro), and pegfilgrastim-bmez (Ziextenzo)</p> <p>Note that Udenyca and Nyvepria are available at the Tier 1 copay at the Mail Order and Retail Network pharmacies.</p> <p><u>Manual PA Criteria:</u> Coverage will be approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) and pegfilgrastim-apgf (Nyvepria) are the TRICARE preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist or oncologist • For Neulasta OnPro: Patient requires use of an on-body injector because the patient and/or caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration <p>OR</p> <ul style="list-style-type: none"> • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-cbqv (Udenyca) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-apgf (Nyvepria) and is expected to respond to pegfilgrastim (Neulasta) or pegfilgrastim-bmez (Ziextenzo) <p>PA does not expire</p>
New PAs	
<ul style="list-style-type: none"> • orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte) <p>Skeletal Muscle Relaxants and Combinations</p>	<p>Manual PA criteria applies to all new users of orphenadrine-aspirin-caffeine 50 mg-770 mg-60 mg (Norgesic, Orphengesic Forte).</p> <p><u>Manual PA Criteria:</u> Norgesic, Orphengesic Forte is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider is aware and acknowledges that orphenadrine ER, baclofen, cyclobenzaprine, acetaminophen, and numerous NSAIDs are available to DoD beneficiaries without requiring prior authorization • The provider must explain why the patient requires orphenadrine-aspirin-caffeine tablets (Norgesic, Orphengesic Forte) and cannot take the available alternatives. <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> levorphanol tartrate tablets <p>Narcotic Analgesics and Combinations</p>	<p>Manual PA criteria applies to all new users of levorphanol tartrate tablets.</p> <p>Manual PA criteria: levorphanol tartrate is approved if all criteria are met:</p> <ul style="list-style-type: none"> Provider acknowledges that morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/ acetaminophen, and tapentadol IR are available to DoD beneficiaries without requiring prior authorization Patient has tried and failed at least one of the following short acting opioids: morphine sulfate IR, codeine IR, hydromorphone IR, meperidine IR, oxycodone IR, hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, tapentadol IR <p>Non-FDA approved uses are NOT approved. PA does not expire.</p>
Updated PAs	
<ul style="list-style-type: none"> fluticasone propionate 93 mcg nasal spray (Xhance) <p>Nasal Allergy Agents: Corticosteroids</p>	<p><u>Updates from the February 2021 meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria apply to all new users of fluticasone propionate 93 mcg nasal spray (Xhance).</p> <p>Manual PA Criteria: Xhance is approved if ALL criteria are met:</p> <ul style="list-style-type: none"> Patient has chronic rhinosinusitis with nasal polyposis confirmed by imaging or direct visualization Patient is 18 years of age or older The prescription is written by or in consultation with an allergist, immunologist, pulmonologist, or otolaryngologist The symptoms of chronic rhinosinusitis with nasal polyposis are inadequately controlled despite all of the following maximized treatments: <ul style="list-style-type: none"> Nasal saline irrigation Adequate duration of at least TWO of the following <ul style="list-style-type: none"> fluticasone propionate (generic Flonase) flunisolide (generic Nasarel) beclomethasone (Beconase AQ, QNASL) budesonide (Rhinocort Aqua, generic) mometasone (Nasonex, generics) nasal corticosteroid irrigation/rinse azelastine ipratropium nasal spray (Atrovent nasal spray) Patient has tried and failed mometasone (Nasonex) OR beclomethasone (Beconase) <p>Non-FDA-approved uses are NOT approved, including allergic rhinitis Prior Authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • canagliflozin (Invokana) • canagliflozin/metformin (Invokamet, Invokamet XR) • dapagliflozin (Farxiga) • dapagliflozin/metformin (Xigduo XR) • ertugliflozin (Steglatro) <p>Diabetes Non-Insulin: Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor</p>	<p>The criteria below replaces the current SGLT2 inhibitor PA criteria and apply to new users The previous automation requirements for the SGLT2 inhibitors no longer apply, and will be replaced with the manual PA criteria described below.</p> <p><u>Manual PA Criteria:</u> Invokana, Invokamet, Farxiga, Xigduo XR, or Steglatro will be approved if all criteria are met:</p> <p><i>For all indications :</i></p> <ul style="list-style-type: none"> • The patient is 18 years of age or older • Provider is aware and acknowledges that empagliflozin (Jardiance), empagliflozin/metformin (Synjardy, Synjardy XR) and empagliflozin/linagliptin (Glyxambi) are DoD's preferred SGLT2 inhibitor, and that PA is not required for empagliflozin <p><i>For Type 2 Diabetes Mellitus :</i></p> <ul style="list-style-type: none"> • Canagliflozin (Invokana, Invokamet), dapagliflozin (Farxiga, Xigduo XR), or ertugliflozin (Steglatro) are requested to improve glycemic control in patients with T2DM OR • Canagliflozin, (Invokana, Invokamet), dapagliflozin (Farxiga, Xigduo XR), or ertugliflozin (Steglatro) are requested to reduce the risk of cardiovascular death in patients with T2DM and established cardiovascular disease • Patient must have had an inadequate response or experienced significant adverse events, or have a contraindication to metformin • Patient must have tried one of the preferred SGLT2 inhibitors (Jardiance, Glyxambi, Synjardy, Synjardy XR) and had an inadequate response or experienced significant adverse reactions or have a contraindication. <p><i>For Heart Failure with reduced ejection fraction (HFrEF):</i></p> <ul style="list-style-type: none"> • Canagliflozin, (Invokana), dapagliflozin (Farxiga), or ertugliflozin (Steglatro) are requested for reduction in risk of heart failure hospitalization and/or cardiovascular death in patients with heart failure with reduced ejection fraction. • Patient has experienced significant adverse reactions has a contraindication to empagliflozin • Initial prescription is written by or in consultation with a cardiologist • Patient has a documented diagnosis of chronic HF (NYHA II-IV) with a left ventricular ejection fraction (LVEF) \leq 40% and with continued heart failure symptoms • Patient is receiving appropriate guideline-directed medical therapy including the following: angiotensin-converting enzyme inhibitor (ACEI), angiotensin II receptor blocker (ARB), or angiotensin receptor neprilysin inhibitor(ARNI); beta blocker; and aldosterone antagonist, unless contraindicated or if the patient has experienced adverse effects or could not tolerate these therapies <p><i>For Chronic Kidney Disease (CKD):</i></p> <ul style="list-style-type: none"> • Canagliflozin, (Invokana, Invokamet), dapagliflozin (Farxiga, Xigduo XR), or ertugliflozin (Steglatro) are requested to reduce kidney disease progression and improve cardiovascular outcomes in patients with CKD. • Patient has experienced significant adverse reactions or has a contraindication to empagliflozin • Initial prescription is written by or in consultation with a nephrologist • Patient's estimated glomerular filtration rate (eGFR) is higher than 25 ml/min/1.73m² AND the Urinary Albumin-to-Creatinine Ratio is greater than or equal to 200 mg/gram • Patient is receiving maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB), or is unable to use an ACEI or ARB <p>Non-FDA-approved uses are not approved, including type 1 diabetes mellitus, heart failure with preserved ejection fraction, or acute decompensated heart failure Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • mometasone/formoterol (Dulera) • budesonide/formoterol (Symbicort) <p>Pulmonary I Agents – Combinations</p>	<p><u>Updates from the February 2021 meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria apply to all new users of Symbicort and Dulera</p> <p>Note: fluticasone/salmeterol (Advair Diskus/Advair HFA) is DoD's preferred ICS/LABA and is available without a PA.</p> <p><u>Automated PA criteria:</u> Symbicort or Dulera is approved if:</p> <ul style="list-style-type: none"> • The patient has filled a prescription for Advair Diskus or Advair HFA at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. OR • The patient is 12 years of age and younger (age edit) <p><u>Manual PA criteria:</u> Symbicort or Dulera is approved (i.e., trial of Advair Diskus or Advair HFA is NOT required) if one of the options below applies:</p> <ul style="list-style-type: none"> • Use of formulary agents (Advair Diskus and Advair HFA) is contraindicated • Patient has experienced significant adverse effects from Advair that is not expected to occur with the non-formulary ICS/LABA medication • Formulary agents (Advair Diskus and Advair HFA) result or are like to result in therapeutic failure • Patient previously responded to non-formulary agent and changing to a formulary agent (Advair Diskus and Advair HFA) would incur unacceptable risk • The patient has asthma and requires rescue therapy or intermittent and daily ICS-LABA therapy with an ICS-formoterol combination in accordance with GINA Strategy <ul style="list-style-type: none"> ○ Symbicort: patient requires an MDI because they have decreased inspiratory effort and cannot use a DPI (Advair Diskus) ○ Breo-Ellipta: patient has complicated drug regimen and requires once-daily dosing <p>Non-FDA-approved uses are NOT approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • risdiplam (Evrysdi) <p>Neurological Agents Miscellaneous</p>	<p><u>Updates from the February 2021 meeting are in strikethrough.</u></p> <p>Manual PA criteria applies to all new users of risdiplam (Evrysdi).</p> <p><u>Manual PA Criteria:</u> Evrysdi is approved if all criteria are met:</p> <ul style="list-style-type: none"> • The patient is between the ages of 2 months to 25 years of age (Fill-in-the-blank) • The drug is prescribed by a pediatric or adult neurologist • Patient has genetic confirmation of homozygous deletion or compound heterozygosity predictive of loss of function of the SMN1 gene (documentation required) • Patient has confirmation of at least two SMN2 gene copies (documentation required) • Patient has a confirmed diagnosis of Spinal Muscular Atrophy Types 1, 2, or 3 (Fill-in-the-blank) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients of childbearing potential have been counseled to use effective contraception during treatment and for at least 1 month after the cessation of therapy • Male patients of reproductive potential are counseled about the potential effects on fertility • Patient does not have evidence of hepatic impairment • Patient does not have permanent ventilator dependence • Patient does not have complete paralysis of all limbs • Evrysdi will not be used concurrently with Spinraza (nusinersen injection for intrathecal use) • Patient weight must be documented (Fill-in-the-blank) – (Any answer acceptable) • Patient dose in total mg/day and mg/kg per day must be documented (Fill-in-the-blank) <ul style="list-style-type: none"> ▪ The dose must be 0.2 mg/kg if the patient is 2 months to < 2 years of age; OR 0.25 mg/kg for patients ≥ 2 years of age who weigh < 20 kg; OR 5 mg for patients ≥ 2 years of age who weigh ≥ 20 kg <p>Non-FDA-approved uses are not approved. Prior authorization expires in 6 months.</p> <p><u>Renewal criteria:</u> (Initial TRICARE PA approval is required for renewal)</p> <ul style="list-style-type: none"> • According to the prescriber, the patient's level of disease has improved or stabilized to warrant continuation on Evrysdi as determined by an objective measurement and/or assessment tool and/or clinical assessment of benefit. (documentation required) <p>Renewal criteria expires in 1 year.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • anakinra (Kineret) <p>Targeted Immunomodulatory Biologics (TIBs): Non-Tumor Necrosis Factor (TNF) Inhibitors</p>	<p>Updates from the February 2021 meeting are in bold.</p> <p>Manual PA criteria applies to all new users of anakinra (Kineret).</p> <p><u>Manual PA Criteria:</u> Kineret is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patients ≥ 18 years with moderate to severe active rheumatoid arthritis OR • Pediatric patients (all ages) with: <ul style="list-style-type: none"> • Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryopyrin Associated Period Syndrome (CAPS). (Trial of Humira not required). • Systemic Juvenile Idiopathic Arthritis (sJIA) (Trial of Humira not required). • Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (Trial of Humira not required). • Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications • The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent • The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • The patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • belimumab (Benlysta) <p>Immunosuppressives</p>	<p><u>Updates from the February 2021 meeting are in bold and strikethrough.</u></p> <p>Manual PA Criteria apply to all new users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta</p> <p><u>Manual PA criteria:</u> Coverage is approved for Benlysta if all of the following are met:</p> <ul style="list-style-type: none"> • Benlysta is prescribed by or in consultation with a specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist • The patient is 18 years of age or older for active lupus nephritis or the patient is 5 years of age or older for SLE • Must of one of the following documented diagnoses: <ul style="list-style-type: none"> • Active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE • Class III, IV, or V active lupus nephritis • For SLE, the patient is concurrently taking standard therapy (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) • For active lupus nephritis, patient is concurrently receiving either mycophenolate mofetil or cyclophosphamide followed by azathioprine • The patient does not have severe active lupus nephritis or severe active central nervous system lupus • The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide <p>Off-label uses are not approved</p> <p>Prior Authorization expires in 2 years.</p> <p><u>Renewal PA Criteria:</u> Benlysta will be approved on a yearly basis if all of the following are met:</p> <ul style="list-style-type: none"> • For SLE, treatment with Benlysta has shown documented clinical benefit (i.e., improvement in number/frequency of flares, improvement in Safety of Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.) • The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) • The patient does not have severe active lupus nephritis or severe active central nervous system lupus <p>The patient is not taking concomitant biologics (e.g., rituximab) and/or intravenous cyclophosphamide</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • elexacaftor/tezacaftor/ivacaftor (Trikafta) <p style="text-align: center;">Cystic Fibrosis Agents</p>	<p>Updates from the February 2021 meeting are in bold and apply to new patients.</p> <p>Manual PA criteria applies to all new users of elexacaftor/tezacaftor/ivacaftor (Trikafta).</p> <p><u>Manual PA Criteria:</u> Trikafta is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed for the treatment of cystic fibrosis (CF) for an FDA approved age • Prescribed by or in consultation with a pulmonologist • Patient has at least one <i>F508del</i> mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-approved CF mutation test OR a mutation in the CFTR gene that is responsive based on <i>in vitro</i> data AND if the genotype is unknown, an FDA-approved test should be used to detect the presence of at least one <i>F508del</i> mutation or a mutation that is responsive based on <i>in vitro</i> data • Not approved in combination therapy with Kalydeco, Symdeko, or Orkambi <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • ivacaftor (Kalydeco) <p style="text-align: center;">Cystic Fibrosis Agents</p>	<p>Updates from the February 2021 meeting are in bold and strikethrough and apply to new patients.</p> <p><u>Manual PA Criteria:</u> Kalydeco is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed for the treatment of cystic fibrosis (CF) for an FDA approved age • Prescribed by or in consultation with a pulmonologist • Patient is not homozygous for the <i>F508del</i> mutation in the has one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco potentiation based on clinical and/or <i>in vitro</i> assay data AND if the genotype is unknown, patient has a specific CF-related gene mutation that has been detected by an FDA-approved test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use • Not approved in combination therapy with Symdeko, Orkambi, or Trikafta • What is the gene mutation? (fill in the blank) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>
<ul style="list-style-type: none"> • tezacaftor/ivacaftor (Symdeko) <p style="text-align: center;">Cystic Fibrosis Agents</p>	<p>Updates from the February 2021 meeting are in bold and strikethrough and apply to new users</p> <p><u>Manual PA Criteria:</u> Symdeko is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Prescribed for the treatment of cystic fibrosis (CF) for an FDA approved age • Prescribed by or in consultation with a pulmonologist • Patient is homozygous for the <i>F508del</i> mutation OR have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Symdeko potentiation based on <i>in vitro</i> data and/or clinical evidence AND if the genotype is unknown, an FDA-approved test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use • Please enter the CF-related gene mutation based on FDA approved testing (fill in blank) _____ • Not approved in combination therapy with Kalydeco, Orkambi, or Trikafta • What is the gene mutation? (fill in the blank) <p>Non-FDA-approved uses are not approved. Prior authorization does not expire.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • ixazomib (Ninlaro) <p>Oncological Agents: Multiple Myeloma</p>	<p>Updates from the February 2021 meeting are in bold.</p> <p>Manual PA criteria applies to all new users of ixazomib (Ninlaro).</p> <p><u>Manual PA Criteria:</u> Ninlaro is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is greater than or equal to 18 years of age • Must be prescribed by or in consultation with a hematologist or oncologist • Patient is diagnosed with: <ul style="list-style-type: none"> • Multiple myeloma AND patient must not have progressed on bortezomib, <u>NOR</u> carfilzomib – containing regimen OR One or more of the following: <ul style="list-style-type: none"> • Patient must have failed or not be a candidate for bortezomib <u>AND</u> carfilzomib • Patient has failed or is not a candidate for carfilzomib and has high risk cytogenetics • Patient will be starting ixazomib as third (or higher) line of therapy • Must be used in combination with lenalidomide, pomalidomide, OR thalidomide • Must be used in combination with dexamethasone <p>OR</p> <ul style="list-style-type: none"> • Multiple myeloma and has received hematopoietic cell transplant (HCT) AND patient will receive Ninlaro as maintenance therapy following primary therapy and HCT • Must not be used concurrently with bortezomib <u>NOR</u> carfilzomib OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ <p>Other Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • neratinib (Nerlynx) <p>Oncological Agents: Breast Cancer</p>	<p><u>Updates from the February 2021 meeting are in bold and strikethrough.</u></p> <p>Manual PA criteria applies to all new users of neratinib (Nerlynx).</p> <p><u>Manual PA Criteria:</u> Nerlynx is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is greater than or equal to 18 years of age • Patient has early stage HER2-overexpressed/amplified breast cancer AND • Following adjuvant trastuzumab based therapy (preferably less than 1 year, but no more than 2 years after completion) OR • Patient has advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer AND • Used in combination with capecitabine AND • Patient has received two or more prior anti-HER2-based regimens in the metastatic setting OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ AND • Counseled on significant adverse event profile AND • Co-prescribed antidiarrheal to mitigate for at a minimum 2 months AND • Counseled on possibility of unproven survival benefit gain • Note: Place the following wording on the PA: This PA will expire in 18 months, NO renewal allowed, patient should not take more than 365 day lifetime supply <p>Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire expires after 18 months; No renewal allowed.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • selinexor (Xpovio) <p>Oncological Agents: Multiple Myeloma</p>	<p><u>Updates from the February 2021 meeting are in bold.</u></p> <p>Manual PA criteria applies to all new users of selinexor (Xpovio).</p> <p><u>Manual PA Criteria:</u> Xpovio is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Patient is greater than or equal to 18 years of age • Prescribed by or in consultation with an oncologist • Patient has: <ul style="list-style-type: none"> • relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody AND patient will use Xpovio in combination with dexamethasone OR • relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy OR • Multiple myeloma who have received at least one prior therapy AND patient will use Xpovio in combination with bortezomib and dexamethasone OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: <hr/> <ul style="list-style-type: none"> • Patient will be monitored for cytopenias including anemia, neutropenia, and thrombocytopenia • Patients will be monitored for electrolyte disturbances including hyponatremia and hypokalemia • Patients will be monitored for infection including upper respiratory infection and pneumonia • Patients will be monitored for dizziness and altered mental status • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • All patients (females AND males) of reproductive potential will use effective contraception during treatment and for at least 1 week after discontinuation <p>Non-FDA-approved uses are not approved, except as noted above Prior authorization does not expire</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • liraglutide 3 mg injection (Saxenda) <p>Weight Loss Agents</p>	<p>Updates from the February 2021 meeting are in bold.</p> <p>Manual PA criteria apply to all new and current users of Saxenda.</p> <p><u>Manual PA Criteria</u>—Saxenda is approved if ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • Patient is 12 years of age or older Or • Patient is 16 years of age or older and patient has tried and failed generic phentermine or has a contraindication to phentermine (Note: provider must include the date of use and duration of therapy or contraindication to the drug) • Phentermine: Date_____Duration of therapy_____Or • Patient is 18 years of age or older and patient has tried and failed all of the following (generic phentermine, Qsymia, Xenical, and Contrave) or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) • Phentermine: Date_____Duration of therapy _____ • Qsymia: Date_____Duration of therapy _____ • Xenical: Date_____Duration of therapy _____ • Contrave: Date_____Duration of therapy _____ • If the patient is diabetic, they must have tried and failed metformin and the preferred GLP1-RAs (Bydureon and Trulicity) <p>All of the following criteria apply to patients 12 years of age and older</p> <ul style="list-style-type: none"> • Concomitant use of Saxenda with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleepapnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy. • For Active Duty Service Members: The individual must be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy AND will remain engaged throughout course of therapy. • Patient is not pregnant. <p>Non-FDA-approved uses are not approved, including Diabetes Mellitus. Prior authorization expires after 4 months and then annually.</p> <p>Note: Renewal Criteria also applies to patients 12 years of age and older</p> <p><u>Renewal PA Criteria:</u> Saxenda will be approved for an additional 12 months if the following are met:</p> <ul style="list-style-type: none"> • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Saxenda will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks • The patient is not pregnant <p>Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • tasimelteon (Hetlioz/Hetlioz LQ) <p>Sleep Disorders: Insomnia</p>	<p><u>Updates from the February 2021 meeting are in bold.</u></p> <p>Manual PA criteria apply to all new users of Hetlioz and Hetlioz LQ.</p> <p><u>Manual PA criteria:</u> Hetlioz or Hetlioz LQ is approved if ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • For the capsule, the patient is 18 years of age or older and is totally blind and has a documented diagnosis of non-24 sleep wake disorder <p style="text-align: center;">Or</p> <ul style="list-style-type: none"> • For the liquid, the patient is 3 years of age up to 15 years of age and has a documented diagnosis of Smith-Magenis Syndrome (SMS) • The patient has had a trial of melatonin and either failed or had an adverse event • The patient is not taking a drug that will interact with tasimelteon (i.e., beta blockers or strong CYP3A4 inducers) <p>Non-FDA-approved uses are not approved including jet lag disorder or other circadian rhythm disorders.</p> <p>Note: Hetlioz capsules are not approved for pediatrics or adolescents and is not approved for SMS. Hetlioz LQ is only approved for pediatrics with SMS and is not approved for Non-24 or for used in adults.</p> <p>PA Criteria will expire after 6 months (if patient has not responded after 6 months, they will be deemed a non-responder)</p>

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
<ul style="list-style-type: none"> • pitolisant (Wakix) <p>Sleep Disorders: Wakefulness- Promoting Agents</p>	<p><u>Updates from the February 2021 meeting are in bold.</u></p> <p>Manual PA is required for all new users of Wakix.</p> <p><u>Manual PA Criteria:</u> Wakix is approved if all criteria are met:</p> <ul style="list-style-type: none"> • Provider acknowledges that PA is not required for modafinil or armodafinil. • Patient is 18 years of age or older • Wakix is not approved for use in children, adolescents, or pregnant patients. • Patient has a documented diagnosis of excessive daytime sleepiness associated with one of the following: <ul style="list-style-type: none"> ▪ narcolepsy and an Epworth Sleepiness Scale (ESS) score ≥ 14 and narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing ▪ cataplexy and an Epworth Sleepiness Scale (ESS) score of ≥ 12 and at least 3 cataplexies per week • Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Patient is not concurrently taking any of the following: <ul style="list-style-type: none"> ▪ Modafinil, armodafinil, or stimulant-based therapy, such as amphetamine or methylphenidate • Patient must have tried and failed and had an inadequate response to modafinil • Patient must have tried and failed and had an inadequate response to armodafinil • Patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) • Patient does not have a history of severe hepatic impairment • Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea <p>Non-FDA-approved uses are not approved (including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, cataplexy, obstructive sleep apnea, major depression, ADHD, or shift work disorder).</p> <p>PA expires in 1 year.</p> <p><u>Renewal PA criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.</p>

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
<ul style="list-style-type: none"> • abemaciclib (Verzenio) • palbociclib (Ibrance) • ribociclib (Kisqali) • ribociclib/letrozole (Kisqali Femara Co-Pack) <p>Breast Cancer Agents: Cyclin-Dependent Kinase Inhibitors Subclass</p>	<ul style="list-style-type: none"> ▪ Retail/Mail/MTF: 28 day supply <p>Note that implementation will occur 30 days after signing of the minutes.</p>
<ul style="list-style-type: none"> • budesonide/formoterol fumarate/ glycopyrrolate (Breztri Aerosphere) • fluticasone /umeclidinium/vilanterol (Trelegy Ellipta) <p>Pulmonary-3 Agents: Combinations Subclass</p>	<ul style="list-style-type: none"> ▪ Retail: 1 inhaler per fill ▪ MTF/Mail: 3 inhalers per fill <p>Note: no change to current status</p>
<ul style="list-style-type: none"> • hydrocortisone oral sprinkle (Alkindi Sprinkle) <p>Corticosteroids-Immune Modulators</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • lonafarnib (Zokinvy) <p>Metabolic Agents-Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • setmelanotide (Imcivree) <p>Weight Loss Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 30 day supply
<ul style="list-style-type: none"> • berotralstat (Orladeyo) <p>Corticosteroids-Immune Modulators: Hereditary Angioedema Agents</p>	<ul style="list-style-type: none"> ▪ Retail: 28 tabs per fill ▪ MTF/Mail: 84 tabs per fill
<ul style="list-style-type: none"> • clascoterone 1% cream (Winlevi) <p>Acne Agents: Topical Acne and Rosacea</p>	<ul style="list-style-type: none"> ▪ Retail: 1 tube/30 days ▪ MTF/Mail: 3 tubes/90 days
<ul style="list-style-type: none"> • sofosbuvir/velpatasvir (Epclusa) <p>Hepatitis C Agents: Direct Acting Agents</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 28 day supply
<ul style="list-style-type: none"> • fidaxomicin oral suspension (Dificid) <p>Gastrointestinal-2 Agents: Miscellaneous</p>	<ul style="list-style-type: none"> ▪ Retail/MTF/Mail: 1 bottle per fill ▪ Note if provider determines that there are circumstances that may qualify for patient to receive additional quantities, the provider may request coverage review through prior authorization

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
<p>berotralstat (Orladeyo)</p> <p>Corticosteroids-Immune-modulators: Hereditary Angioedema Agents</p>	<ul style="list-style-type: none"> • C1-INH, Pd (Cinryze) • C1-INH, Pd (Haegarda) lanadelumab-flyo (Takhzyro) 	<ul style="list-style-type: none"> • 110 mg, 150 mg oral capsules • Once daily 	<p>To prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older</p>	<ul style="list-style-type: none"> • Orladeyo is the 3rd kallikrein inhibitor for HAE and the first oral prophylaxis agent for treating HAE • Takhzyro and Orladeyo are both kallikrein inhibitors approved for prophylaxis, but are injections. Kalbitor is a medical benefit agent for treatment of acute HAE attacks. • Orladeyo showed a statistically significant and clinically relevant moderate benefit in reducing monthly HAE attack rates • Orladeyo offers a significant advantage for patient convenience as the first oral agent for HAE prophylaxis, however indirect comparison shows that the clinical efficacy is moderate compared to other prophylaxis agents 	<ul style="list-style-type: none"> • UF • Do not add to EMMI list
<p>calcipotriene/ betamethasone dipropionate 0.005%/0.064% topical cream (Wynzora)</p> <p>Psoriasis Agents</p>	<ul style="list-style-type: none"> • Calcipotriene 0.005%-betamethasone DP 0.064% (Taclonex) ointment • Calcipotriene 0.005%-betamethasone DP 0.064% (Enstilar) foam • Any topical vitamin D analogue used with any topical high-potency corticosteroid 	<ul style="list-style-type: none"> • Applied once daily for up to 8 weeks (maximum 100 g/week) 	<p>Topical treatment of plaque psoriasis in patients 18 years and older</p>	<ul style="list-style-type: none"> • Wynzora is a topical combination of calcipotriene and betamethasone cream approved for plaque psoriasis • Wynzora offers no therapeutic advantages over individual calcipotriene and a high-potency topical corticosteroid used concurrently other than patient convenience • Of note, calcipotriene (Dovonex) 0.005% cream is BCF • Wynzora is 10th agent in class offering little to no therapeutic advantage over already-existing agents (which include 2 combination products) 	<ul style="list-style-type: none"> • Tier 4/Not covered

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
clascoterone 1% cream (Winlevi) Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> spironolactone tretinoin cream clindamycin/benzoyl peroxide gel 	<ul style="list-style-type: none"> 1% cream given as 1 application (1 gram) BID 	Topical treatment of acne vulgaris in patients ≥ 12 years old	<ul style="list-style-type: none"> Winlevi is the 1st topical antiandrogen indicated for the treatment of acne vulgaris and is also approved for use in males Winlevi was compared to vehicle and showed statistically significant treatment benefit No head to head studies with other therapies No current guideline recommendations on topical antiandrogen therapy Numerous topical agents available for acne Providers recommend trying other topical acne drugs first Winlevi is the first topical antiandrogen for the treatment of acne, but offers no additional benefit relative to existing formulary agents 	<ul style="list-style-type: none"> NF Add to EMMI list
clobetasol propionate 0.05% lotion metered dose pump (Impeklo) Corticosteroids-Immune Modulators: High Potency	<ul style="list-style-type: none"> Other high-potency topical corticosteroids 	<ul style="list-style-type: none"> Applied BID for up to 2 weeks; maximum dose 50 g/week 	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years and older	<ul style="list-style-type: none"> Impeklo is a new formulation of clobetasol propionate 0.05% lotion in a metered dose pump No new clinical data, 24 alternative formulary agents available, and 11 scalp-friendly formulary options Lotions already in category of efficient vehicles; i.e., metered dose pump offers little to no value Impeklo provides no advantages in efficacy relative to existing topical high-potency topical corticosteroids and provides little to no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> Tier 4/Not covered
hydrocortisone oral sprinkle (Alkindi Sprinkle) Corticosteroids-Immune Modulators	<ul style="list-style-type: none"> hydrocortisone tablets 	<ul style="list-style-type: none"> Oral granules contained in capsules 50 caps/bottle 0.5, 1, 2, 5 mg 	Replacement therapy in pediatrics with adrenocortical insufficiency	<ul style="list-style-type: none"> Alkindi Sprinkle is another formulation of hydrocortisone indicated for replacement therapy in pediatric patients with adrenocortical insufficiency Alkindi Sprinkle was evaluated in 1 uncontrolled, open-label, single arm study in 18 pediatric patients This drug offers no advantages in clinical efficacy relative to existing hydrocortisone formulations on the formulary Other than availability of lower strengths, Alkindi provides little to no clinical benefit relative to existing formulary agents 	<ul style="list-style-type: none"> UF Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
<p>lonafarnib (Zokinvy)</p> <p>Metabolic Agents- Miscellaneous</p>	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> Capsules: 50 mg, 75 mg First 4 months: 115 mg/m² BID with morning and evening meals After 4 months: 150 mg/m² BID with morning and evening meals 	<ul style="list-style-type: none"> Reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS) <p>Treatment of processing-deficient Progeroid Laminopathies</p>	<ul style="list-style-type: none"> Zokinvy is the first approved treatment for Hutchinson-Gilford Progeria Syndrome and some Progeroid Laminopathies Zokinvy was evaluated in two phase 2 trials Mortality was statistically lower in treated patients vs untreated patients Most common ADRs included nausea, vomiting, diarrhea, infection, decreased appetite and fatigue Contraindications include use with strong or moderate CYP3A inhibitors or inducers, midazolam, lovastatin, simvastatin, and atorvastatin Additional safety concerns include periodic monitoring of electrolytes, CBCs, liver function, renal function, and ophthalmological evaluations Zokinvy provides the first treatment option for a rare disease 	<ul style="list-style-type: none"> UF Do not add to EMMI list
<p>loteprednol 0.25% ophthalmic solution (Eysuvis)</p> <p>Ophthalmic: Corticosteroids</p>	<ul style="list-style-type: none"> loteprednol 0.5% gel, ointment, or suspension (Lotemax, generics) loteprednol 0.38% gel (Lotemax SM) loteprednol 1% suspension (Inveltys) loteprednol 0.2% suspension (Alrex, generics) fluoromethalone (Flarex, FML) 	<ul style="list-style-type: none"> 0.25% ophth susp 1gtt QID 	<p>Short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease</p>	<ul style="list-style-type: none"> 5th loteprednol product approved for treating inflammatory conditions Eysuvis is the first ophthalmic steroid with an FDA approved indication for short-term treatment of dry eye Guidelines recommend short courses of up to 2 weeks for treating dry eye disease Loteprednol has evidence to show that it can be effective for treating dry eye disease for short durations but is not limited to Eysuvis Providers agree that there are other available alternative low-dose ophthalmic steroids that can be used for dry eye Eysuvis provides little to no clinical benefit over other ophthalmic steroid products 	<ul style="list-style-type: none"> NF Do not add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
<p align="center">pegfilgrastim-apgf (Nyvepria)</p> <p>White Blood Cell Stimulants</p>	<ul style="list-style-type: none"> • Neulasta • Udenyca • Fulphila • Ziextenzo 	<ul style="list-style-type: none"> • 6 mg/0.6 mL prefilled, syringe for subcutaneous use administered once per chemotherapy cycle 	<p>Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs</p>	<ul style="list-style-type: none"> • Nyvepria is the 4th biosimilar to Neulasta and 9th agent in the white blood cell stimulant subclass • No new clinical data • Nyvepria provides no compelling clinical advantages over existing pegfilgrastim formulary agents 	<ul style="list-style-type: none"> • UF, step preferred • Do not add to EMMI list • Tier 1 copay
<p align="center">relugoli (Orgovyx)</p> <p>Luteinizing Hormone-Releasing Hormone Agonists-Antagonists</p>	<ul style="list-style-type: none"> • leuprolide acetate (Lupron Depot, Eligard) • degarelix SQ (Firmagon) <p>Medical benefit:</p> <ul style="list-style-type: none"> • goserelin SQ implant (Zoladex) • histrelin SQ implant (Vantas) • triptorelin IM (Trelstar Mixject) 	<ul style="list-style-type: none"> • Available as 120 mg oral tablets • Dosed as 360 mg loading dose on the first day followed by 120 mg dose once a day 	<p>Treatment of adult patients with advanced prostate cancer</p>	<ul style="list-style-type: none"> • Orgovyx is the 1st oral gonadotropin-releasing hormone (GnRH) drug approved for adult patients with advanced prostate cancer • Efficacy based on one open-label study comparing Orgovyx (GnRH antagonist) to leuprolide acetate (GnRH agonist) • Orgovyx met the primary endpoint of lowering testosterone levels to castration levels and maintaining for 48 weeks • No surge of testosterone levels with Orgovyx compared with leuprolide • Adverse events were similar to leuprolide • MACE = nonfatal MI, nonfatal stroke, and death from any cause were lower with Orgovyx (2.9%) vs leuprolide (6.2%) • Offers convenience of an oral tablet with once daily dosing, after a loading dose • Several alternative agents are available, but require injections • Place in therapy remains to be determined 	<ul style="list-style-type: none"> • NF • Add to EMMI list

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

Generic (Trade) UF Class	Comparators	Dosage Form	Indications	Clinical Summary	Recommended UF Status
setmelanotide injection (Imcivree) Weight Loss Agents	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> Multidose vial 2 mg (0.2 mL) SubQ once daily x 2 weeks, then titrate up or down as tolerated Max 3 mg SubQ daily Start at 1 mg SubQ once daily for pediatrics 	Approved for rare forms of obesity <ul style="list-style-type: none"> Proopiomelano-cortin (POMC) deficiency Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency Leptin receptor (LEPR) deficiency 	<ul style="list-style-type: none"> Imcivree is a newly approved agent with a novel mechanism approved for rare forms of obesity in adults and peds 6 years and older Genetic testing is required for diagnosis FDA-Approved indications include <ul style="list-style-type: none"> proopiomelanocortin (POMC) deficiency proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency leptin receptor (LEPR) deficiency Setmelanotide is a melanocortin 4 (MC4) receptor agonist Imcivree is not approved for benign or likely-benign receptor variants Imcivree is the first approved agent for rare forms of obesity 	<ul style="list-style-type: none"> UF Do not add to EMMI list
sodium sulfate/magnesium sulfate/potassium chloride (Sutab) Laxatives-Cathartics-Stool Softeners: Bowel Preparations	<ul style="list-style-type: none"> OsmoPrep PEG based preps Suprep PrePopik ClenPiq 	<ul style="list-style-type: none"> Oral tablets Day 1 = 12 tabs + 48 ounces water Day 2 = repeat 	Cleansing of colon in preparation for colonoscopy in adults	<ul style="list-style-type: none"> 2nd available tablet-based bowel prep Similar ingredients to Suprep; same manufacturer Non-inferior efficacy to MoviPrep and PrePopik for bowel cleansing Sutab compared to OsmoPrep: 24 vs 32 tabs; 2.8 L vs 1.9 L total volume consumed No compelling clinical advantage relative to existing bowel prep formulary agents 	<ul style="list-style-type: none"> NF Do not add to EMMI list
tramadol oral solution (Qdolo) Narcotic Analgesics & Combinations	<ul style="list-style-type: none"> acetaminophen solution Ibuprofen solution tramadol IR tablets codeine/APAP solution hydrocodone/acetaminophen solution 	<ul style="list-style-type: none"> Oral solution 5 mg/mL clear liquid, grape flavor 473 mL bottle; 50-100 mg q 4-6 hrs PRN 	Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate	<ul style="list-style-type: none"> Qdolo is another formulation of tramadol as an oral solution indicated for management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate Qdolo was approved based on equivalence to tramadol IR tablets There are other narcotic analgesics available in alternate dosage forms but have different mechanisms of action and potency Other than being an alternate dosage form, Qdolo provides little to no compelling clinical advantage over existing agents 	<ul style="list-style-type: none"> NF Do not add to EMMI list

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the February 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)
February 2021	<p>Pulmonary-3 Agents: Combinations UF (brand maintenance only) <i>Maintain current status:</i></p> <ul style="list-style-type: none"> fluticasone furoate /umeclidinium/vilanterol (Trelegy Ellipta) <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated NF: <i>No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending availability at mail:</i></p> <ul style="list-style-type: none"> clascoterone 1% cream (Winlevi) relugolix (Orgovyx) 	<p>Breast Cancer Agents: Cyclin-Dependent Kinase Inhibitors UF <i>Maintain current status and exempt from EMMPI Program:</i></p> <ul style="list-style-type: none"> abemaciclib (Verzenio) palbociclib (Ibrance) ribociclib (Kisqali) ribociclib/letrozole (Kisqali Femara Co-Pack) <p>Pulmonary-3 Agents: Combinations UF <i>Maintain current status and exempt from EMMPI Program:</i></p> <ul style="list-style-type: none"> budesonide/formoterol fumarate/glycopyrrolate inhalation aerosol (Breztri Aerosphere) <i>(Note see the August 2021 P&T Committee meeting minutes where Breztri was added to the EMMPI program)</i> <p>Newly Approved Drugs per 32 CFR 199.21(g)(5) Designated UF: <i>Drugs in class not currently represented on EMMPI List (removed Aug 2020 subclass review) due to limited duration use/not maintenance medications:</i></p> <ul style="list-style-type: none"> pegfilgrastim-apgf (Nyvepria) <p><i>Not yet clear if feasible to provide through mail order:</i></p> <ul style="list-style-type: none"> berotralstat (Orladeyo) hydrocortisone oral sprinkle (Alkindi Sprinkle) lonafarnib (Zokinvy) setmelanotide (Imcivree) <p>Designated NF: <i>Exception due to acute use/limited duration of use and similar agents are not on the list:</i></p> <ul style="list-style-type: none"> sodium sulfate/magnesium sulfate/potassium chloride (Sutab) tramadol oral solution (Qdolo) <p><i>Exception due to acute use/limited duration of use and more cost advantageous to make exception:</i></p> <ul style="list-style-type: none"> loteprednol 0.25% ophthalmic solution (Eysuvis) <p>Line Extensions Designated UF <i>Drugs for limited duration use and similar agents are not on the list:</i></p> <ul style="list-style-type: none"> fidaxomicin oral suspension (Dificid) <p><i>Similar agents are not on the list:</i></p> <ul style="list-style-type: none"> sofosbuvir/velpatasvir (Epclusa)

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

Date	DoD PEC Drug Class	Type of Action	BCF/ECF Medications MTFs must have BCF meds on formulary	UF Medications MTFs may have on formulary	Nonformulary Medications MTFs may not have on formulary	Decision Date / Implement Date	PA and QL Issues	Comments
Feb 2021	Breast Cancer Agents – Cyclin-Dependent Kinases (CDK) Inhibitors Subclass	UF Class Review	<ul style="list-style-type: none"> ▪ None <p>Note: CDKI was not selected for the BCF.</p>	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> ▪ None <ul style="list-style-type: none"> ▪ palbociclib (Ibrance) ▪ abemaciclib (Verzenio) ▪ ribociclib (Kisqali) ▪ ribociclib/letrozole combo pack (Kisqali Femara Co-Pack) 	<ul style="list-style-type: none"> ▪ None 	<p>Pending signing of the minutes / 30 days The effective date is March 16, 2022</p>	<ul style="list-style-type: none"> ▪ Updated PA criteria. See Appendix C 	
Feb 2021	Pulmonary III Agents: Combinations	UF Class Review	<ul style="list-style-type: none"> ▪ None 	<p align="center">Tier 4/Not Covered Medications</p> <p align="center">MTFs <u>must not</u> have on formulary</p> <p align="center">Will not be available in the MTFs or Mail Order, patient to pay full cost at Retail Network pharmacies</p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> ▪ None 	<p>Pending signing of the minutes/2 weeks The effective date is March 2, 2022</p>	<ul style="list-style-type: none"> ▪ QLs updated. See Appendix D 	N/A

Appendix H—Tier 4/Not Covered Drugs and Therapeutic Alternatives (Last 12 months)*†

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Feb 2021	Corticosteroids -Immune Modulators: High Potency	<ul style="list-style-type: none"> clobetasol propionate 0.05% lotion metered dose pump (Impeklo) 	<ul style="list-style-type: none"> betamethasone/propylene glycol 0.05% lotion betamethasone dipropionate 0.05% gel clobetasol propionate/emollient 0.05 % (emulsion) foam clobetasol propionate 0.05% solution, lotion, gel, foam, spray, and shampoo fluocinonide 0.05% solution and gel 	<ul style="list-style-type: none"> June 15, 2022
Feb 2021	Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene/ betamethasone dipropionate 0.005% /0.064% topical cream (Wynzora) 	<ul style="list-style-type: none"> 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 fluocinonide 0.05% cream, gel, and solution calcipotriene 0.005% / betamethasone 0.064% foam (Enstilar) [Nonformulary] 	<ul style="list-style-type: none"> June 15, 2022
Nov 2020	Attention-Deficit/Hyperactivity Disorder (ADHD) Agents: Stimulants	<ul style="list-style-type: none"> methylphenidate ER sprinkle capsules (Adhansia XR) 	<ul style="list-style-type: none"> methylphenidate ER (Aptensio XR sprinkle capsule), for patients with swallowing difficulties methylphenidate ER oral suspension (Quillivant XR suspension), for patients with swallowing difficulties methylphenidate ER osmotic controlled release oral delivery system (OROS) (Concerta, generics) methylphenidate long-acting (Ritalin LA, generics) methylphenidate controlled delivery (CD) (Metadate CD, generics) dexmethylphenidate ER (Focalin XR, generics) mixed amphetamine salts ER (Adderall XR, generics) 	<ul style="list-style-type: none"> Currently Tier 4 from Aug 2019 meeting, implemented March 4, 2020
Nov 2020	GI-1 Agents	<ul style="list-style-type: none"> budesonide ER 9 mg capsules (Ortikos) 	<ul style="list-style-type: none"> budesonide ER tablets (Entocort EC, generics) other corticosteroids 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Corticosteroids	<ul style="list-style-type: none"> dexamethasone 20 mg tables (Hemady) 	<ul style="list-style-type: none"> dexamethasone generics 0.5, 0.75, 1, 1.5, 2, 4, 6 mg tabs 	<ul style="list-style-type: none"> June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Nov 2020	Pulmonary I Agents Inhaled Corticosteroids (ICS)	<ul style="list-style-type: none"> fluticasone propionate dry powder inhaler oral (ArmonAir Digihaler) 	<ul style="list-style-type: none"> fluticasone (Flovent Diskus) fluticasone (Flovent HFA) fluticasone furoate (Arnuity Ellipta) [non formulary] beclomethasone (QVAR) [non formulary] budesonide (Pulmicort Flexhaler) [non formulary] ciclesonide (Alvesco) [non formulary] flunisolide (Aerospan) [non formulary] mometasone (Asmanex Twisthaler) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Pulmonary I Agents ICS/Long-Acting Beta Agonists (LABA)	<ul style="list-style-type: none"> fluticasone propionate / salmeterol dry powder inhaler oral (AirDuo Digihaler) 	<ul style="list-style-type: none"> fluticasone/salmeterol (Advair Diskus) fluticasone/salmeterol (Advair HFA) fluticasone/vilanterol (Breo Ellipta) [non formulary] mometasone/formoterol (Dulera) [non formulary] budesonide/formoterol (Symbicort) [non formulary] fluticasone/salmeterol (AirDuo Respiclick) [non formulary] 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	Calcium Channel Blockers	<ul style="list-style-type: none"> levamlodipine (Conjupri) 	<ul style="list-style-type: none"> amlodipine felodipine nifedipine diltiazem verapamil 	<ul style="list-style-type: none"> June 2 2021
Nov 2020	GI-2 Agents	<ul style="list-style-type: none"> metoclopramide nasal spray (Gimoti) 	<ul style="list-style-type: none"> metoclopramide oral tablet (Reglan generics) metoclopramide oral solution (Reglan, generics) metoclopramide orally disintegrating tablet (Reglan ODT) 	<ul style="list-style-type: none"> June 2 2021

P&T Committee Meeting Date	Drug Class	Tier 4/Not Covered Product	Formulary Alternatives	Implementation
Aug 2020	Topical Psoriasis Agents	<ul style="list-style-type: none"> calcipotriene 0.005%-betamethasone 0.064% suspension (Taclonex, generic) 	<p><i>Scalp Psoriasis:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% solution clobetasol 0.05% solution, shampoo fluocinonide 0.05% solution calcipotriene 0.005%-betamethasone 0.064% foam (Enstilar) [Nonformulary] <p><i>Psoriasis involving areas other than the scalp:</i></p> <ul style="list-style-type: none"> calcipotriene 0.005% ointment, cream, solution clobetasol 0.05% ointment, cream fluocinonide 0.05% cream, ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	High-Potency Topical Corticosteroids	<ul style="list-style-type: none"> halcinonide 0.1% topical solution (Halog) 	<ul style="list-style-type: none"> betamethasone propylene glycol 0.05% cream clobetasol propionate 0.05% cream and ointment clobetasol propionate/emollient 0.05% cream desoximetasone 0.25% cream and ointment fluocinonide 0.05% cream and ointment fluocinonide/emollient base 0.05% cream halobetasol propionate 0.05% ointment 	<ul style="list-style-type: none"> February 24, 2021
Aug 2020	Acne Agents: Topical Acne and Rosacea	<ul style="list-style-type: none"> tazarotene 0.045% lotion (Arazlo) 	<ul style="list-style-type: none"> adapalene 0.1% lotion, gel, cream adapalene 0.3% gel clindamycin phosphate 1% gel, cream, lotion, and solution clindamycin/ benzoyl peroxide 1.2% - 5% gel tazarotene 0.1% cream tretinoin 0.025%, 0.05%, and 0.1% cream tretinoin 0.01% and 0.025% gel 	<ul style="list-style-type: none"> February 24, 2021
May 2020	Note that no drugs were recommended for Tier 4 status at the May 2020 meeting			

* 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>. 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. 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.

† For a cumulative list of previous Tier 4 recommendations, refer to the November 2020 DoD P&T Committee minutes, found at health.mil/pandt

Appendix I—MHS GENESIS OTC Test List

DoD P&T Meeting	RETAIN or ADD the following to the OTC MHS Genesis List	REMOVE the following from the OTC MHS Genesis List
OTC Nasal Cold and Allergy Products		
February 2021	<p>Retain these GCNs:</p> <ul style="list-style-type: none"> • 34062 – oxymetazoline 0.05% spray (e.g., Afrin) • 36878 – sodium chloride, bicarbonate /squeeze bottlepack w/dev (e.g., Ayr, Neilmed Sinus) • 24904 – sodium chloride/sodium packet bicarb (e.g., Ayr, Neilmed Sinus Rinse) • 34300 – sodium chloride 0.65% drops (e.g., Ayr Saline, Baby Ayr Saline) • 34291 – sodium chloride 0.65% spray (e.g., Ayr Saline, Deep Sea, Ocean) 	<p>Remove these GCNs:</p> <ul style="list-style-type: none"> • 40708 – budesonide 32 mcg spray(e.g., Rhinocort) • 37683 – fluticasone propionate 50 mcg spray susp (e.g., Flonase allergy) • 46790 – cromolyn sodium 5.2 mg spray (Nasalcrom) • 34182 – phenylephrine 0.125% drops (e.g., Little Noses) • 34122 – phenylephrine 0.25% spray (e.g., Neo-synephrine) • 34123 – phenylephrine 0.5% spray (e.g., Neo-synephrine)

*GCN Additions will be implemented the first Wednesday two weeks after signing of the minutes, with the deletions implemented at 120 days.

Appendix J—Table of Abbreviations

Term	Definition	Term	Definition
ACC	American College of Cardiology	MHS	Military Health System
ADR	Adverse reaction	MN	Medical Necessity
AE	Adverse event	MTF	Military Treatment Facility
AHA	American Heart Association	NAEPP	National Asthma Education and Prevention Panel
BCF	Basic Core Formulary	NAEPPCC	National Asthma Education and Prevention Panel Coordinating Committee
BIA	Budget impact analysis	NCCN	National Comprehensive Cancer Network
BSA	Body surface area	NDAA	National Defense Authorization Act
CDK	Cyclin-Dependent Kinase	NDC	National Drug Codes
CFR	Code of Federal Regulations	NOMID	Neonatal-Onset Multisystem Inflammatory Disease
CMA	Cost minimization analysis	ODT	Orally Disintegrating Tablet
COPD	Chronic obstructive pulmonary disease	ORR	Objective response rate
CV	Cardiovascular	OTC	Over the counter
DHA	Defense Health Agency	PA	Prior authorization
DIRA	Deficiency of Interleukin-1 Receptor Antagonist	PCSK1	Proprotein convertase subtilisin/kexin type 1
DoD	Department of Defense	PFS	Progression free survival
DR	Delayed release	POD	Pharmacy Operations Division
ECF	Extended Core Formulary	POMC	proopiomelanocortin
EMMPI	The Expanded MTF/Mail Pharmacy Initiative	POS	Point of service
ER	Extended release	PPI	Proton Pump Inhibitor
FDA	U.S. Food and Drug Administration	PRN	As needed
GINA	Global Initiative for Asthma	QL	Quantity limits
GOLD	Global Initiative for Chronic Obstructive Lung Disease	SC	Subcutaneous
HAE	Hereditary angioedema	SGLT2	Sodium-Glucose Co-Transporter 2
HCT	Hematopoietic cell transplant	SGRQ	Saint George Respiratory Questionnaire
HER2 (-)	Human epidermal growth factor receptor 2-negative breast cancer	SMA	Spinal muscular atrophy
HFrEF	Heart failure with reduced ejection fraction	SMS	Smith-Magenis Syndrome
HR(+)	Hormone receptor positive breast cancer	SMN2	Survival of motor neurons 2
ICS	Inhaled Corticosteroid	SLE	Systemic lupus erythematosus (SLE)
LABA	Long-acting beta agonist	T2DM	Type 2 diabetes mellitus
LAMA	Long-acting muscarinic antagonist	TIB	Targeted Immunomodulatory Biologics
LEPR	leptin receptor	VTE	Venous thromboembolism
LHRH	luteinizing hormone-releasing hormone		