DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
February 2024

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on February 8th and 9th, 2024.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of November 2023 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the November 2023 DoD P&T Committee meeting on January 29th, 2024.

B. Clarification of previous meeting minutes

- **May 2023**
  - **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors—adalimumab (Humira)—**The PA criteria for Humira were updated to allow for approval if the prescriber specialty is Rheumatology. The implementation has been delayed from the original date of August 30, 2023 to May 2024.
- **August 2023**
  - **dabigatran (Pradaxa) brand over generic Prior Authorization (PA):** The Tier 1 copay currently applies to the brand Pradaxa 75 mg and 150 mg capsules. The Tier 1 copay will also apply to the new brand Pradaxa 110 mg capsule.
  - **White Blood Cell Stimulants (filgrastims and PEG filgrastims):** The quantity limits (QLs) were removed and will default to the benefit design limits. Three copays for a 90-day supply will be allowed at Retail Network pharmacies.
- **November 2023**
  - **nonformulary methotrexate injectables (Otrexup, Rasuvo, Reditrex) – Medical Necessity (MN) criteria:** The Administrative Authorities were updated allowing administrative changes to medical necessity (MN) criteria for national supply shortages. The MN criteria for Otrexup, Rasuvo and Reditrex were updated to allow use if generic methotrexate vials cannot be procured due to national supply shortages.

- **amikacin liposome inhalation suspension (Arikayce)-MN criteria:** The MN criteria were updated to allow for use of Arikayce if IV amikacin cannot be procured.

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 completely excluded pharmaceutical agents were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and completely excluded pharmaceutical agent 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, permanently codified at 10 USC 1074g (a)(10). 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 in accordance with 10 USC 1074g (a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (a)(9), added by Section 702(c)(2) of the NDAA for FY 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

IV. UF DRUG CLASS REVIEWS

Growth-Stimulating Hormone Agents

Background—The P&T Committee evaluated the relative clinical effectiveness of the growth hormone-stimulating agents which are used for treating growth hormone deficiency and other conditions in children, including small for gestational age, chronic renal insufficiency, Prader Willi syndrome, Turner Syndrome, Noonan's Syndrome, and ShoX Homeobox Mutation. Additional FDA-labeled uses for adults include treating AIDS/HIV wasting cachexia and short bowel syndrome were also considered. The class was last reviewed for formulary status in May 2018. Since then, three long-acting agents entered the market, which were originally reviewed as innovator drugs. PA has applied to the class since 2007. Due to the weight-based dosing for this class, the QLs default to the benefit plan limits.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

Products

- The short-acting drugs all contain recombinant human growth hormone (somatropin) and are injected once daily. The long-acting products

lonapegsomatropin (Skytrofa), somapacitan (Sogroya), and somatrogon (Ngenla) are injected once weekly.

- There is no change from the 2018 conclusion that although products differ in terms of storage requirements, preservatives, available quantities, delivery devices, smallest delivery increment, reconstitution and assembly steps prior to delivery, and FDA indications, these differences do not impact treatment outcome.

Clinical Practice Guidelines

- Guidelines from the Pediatric Endocrine Society (2016), the Growth Hormone Research Society (2019), and the American Association of Clinical Endocrinology (2019) all recommend recombinant human growth hormone for the treatment of growth hormone deficiency, but do not recommend one product over another.
- For the long-acting products, guidelines mention a potential for improved adherence, and that early studies demonstrate comparable safety and efficacy to the short-acting growth hormone agents. However, there is no preference for the long-acting preparations over the short-acting products.

Efficacy

- All short-acting recombinant human growth hormone agents are bioidentical and therapeutically interchangeable.
- Systematic reviews and meta-analyses show the long-acting products are similar in efficacy and safety compared to the short-acting products, although limited head-to-head data is available.

Safety

- There is considerable overlap in terms of commonly reported adverse effects, however, specific differences between products are related to the different preservatives used and not due to differences in the active ingredient.

Individual Product Characteristics

- Short-Acting Agents
    - *Genotropin* is available in a vial formulation as well as a pre-filled reusable pen option. Genotropin can be stored at room-temperature and also provides a preservative-free option.
    - *Humatrope* is available in a vial formulation as well as a pre-filled cartridge and disposable pen option. It requires refrigeration and contains metacresol as a preservative as well as glycerin.
    - *Norditropin* is available in a pre-filled, pre-mixed multi-dose disposable pen and uses a non-benzyl alcohol preservative. It is stable at room temperature for up to 3 weeks.
    - *Nutropin* is available in a pre-filled, pre-mixed multi-dose disposable pen that requires refrigeration and contains phenol as a preservative.

- *Saizen* is available in a vial formulation and can be stored at room-temperature prior to reconstitution. Benzyl alcohol is used as a preservative. Additionally, it can be used with a needle-free device.
- *Serostim* is unique as it is labeled only for growth hormone deficiency due to HIV wasting and short bowel syndrome. It is packaged in individual vials and requires higher doses than the other preparations. Availability solely in vials is a limitation for use in terms of patient convenience.
- *Zomacton* is available in a vial formulation and can be used with a needle-free delivery device. It contains either benzyl alcohol or metacresol as a preservative. The needle-free device is associated with bruising.

- Long-acting Agents
  - *somapacitan-beco (Sogroya)* is available as a pre-filled, pre-mixed, multi-dose disposable pen. It requires refrigeration and has a phenol preservative.
  - *lonapegsomatropin-tcgd (Skytrofa)* is available as a pre-filled dual chamber cartridge that does not require reconstitution prior to being loaded into the single-dose reusable chargeable pen device. Prior to use, the cartridges can be stored at room-temperature for up to 6-months. Skytrofa does not contain a preservative.
  - *somatrogon-ghla (Ngenla)* is available as a pre-filled, pre-mixed, multi-dose disposable pen. It requires refrigeration and contains the preservative metacresol.

Other Factors

- MHS providers agreed that a prefilled device is preferred over a vial and diluent that requires reconstitution, in terms of patient ease of use.

Overall Clinical Conclusion

- The products offering a pre-filled, pre-mixed multi-dose pen delivery systems for ease of use include Norditropin, Omnitrope, Sogroya and Ngenla.
- The growth hormone-stimulating agents are highly therapeutically interchangeable.
- In order to meet the needs of MHS patients, both a short-acting and long-acting agent are required on the formulary, to allow for a variety of preservatives and preservative-free options, different devices, and to allow for potential manufacturer shortages.

Relative Cost Effectiveness Analysis and Conclusion—The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis. The P&T Committee concluded (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that somatropin (Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Saizen-Prep, Serostim, Zomacton), lonapegsomatropin-tcgd (Skytrofa), somapacitin-beco (Sogroya), and somatrogon-ghla (Ngenla) were all cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the growth stimulating hormone agents in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

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

    - UF and step-preferred
        - Short-acting agents
            - somatropin (Norditropin)
            - somatropin (Genotropin) – *moves from NF non-step-preferred to UF and step preferred*
            - somatropin (Zomacton) - *moves from UF non-step-preferred to UF and step preferred*
            - somatropin (Omnitrope) - *moves from UF non-step-preferred to UF and step preferred*
        - Long-acting agents
            - somatrogon-ghla (Ngenla) – *moves from NF non-step-preferred to UF and step preferred*
            - somapacitan-beco (Sogroya) – *moves from NF non-step-preferred to UF and step preferred*
    - NF and non-step-preferred
        - Short-acting agents
            - somatropin (Humatrope)
            - somatropin (Nutropin)
            - somatropin (Serostim)
            - somatropin (Saizen, Saizen Prep)
        - Long-acting agents
            - lonapegsomatropin-tcgd (Skytrofa)
    - Complete exclusion

- None

- Note that as part of this recommendation, a trial of two short-acting step-preferred drugs and two long-acting step-preferred products will be required prior to use of the non-step-preferred products in new and current users.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria have applied to the class since 2007, and PA was applied to the long-acting agents when they were reviewed individually as innovator drugs. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the existing PA for the new step therapy. A trial of two short-acting agents and two long-acting agents is required in all new and current users of the non-step-preferred products (Humatrope, Nutropin, Serostim, Saizen, Saizen Prep and Skytrofa), unless the patient has a contraindication to or has experienced an adverse event from the step-preferred products. For the step-preferred products, criteria will apply to new users. See Appendix C for full criteria.

   A growth hormone-stimulating agent is not allowed for use in idiopathic short stature, the normal ageing process, obesity, depression, or for other off-label uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment, etc.). Concomitant use of multiple growth hormone products is not allowed. Annual PA renewal is required, to ensure appropriate use.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) MN criteria for the non-step-preferred products, (Humatrope, Nutropin, Serostim, Saizen, Saizen Prep and Skytrofa). See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The growth-stimulating hormone agents were temporarily removed from the EMMPI program in March 2023, due to a nation-wide shortage of Norditropin. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) adding Omnitrope to the Specialty contingent EMMPI program (see p 20 and Appendix F). The non-step-preferred products will be exempt from the program requirements, as there is no cost advantage to DoD.

5. ***COMMITTEE ACTION: REMOVAL OF TIER 1 COPAY FOR NORDITROPIN—***Norditropin currently has a Tier 1 copay, implemented at the previous 2018 class review. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the Tier 1 copay for

Norditropin, as it is no longer the sole step-preferred growth-stimulating hormone agent. Norditropin will move to the Tier 2 copay.

6. ***COMMITTEE ACTION: REMOVAL OF NORDITROPIN FROM THE EXTENDED CORE FORMULARY—***Historically medications on the Basic Core Formulary (BCF) and Extended Core Formulary (ECF) were required to be available at MTFs. All MTFs are required to stock BCF drugs, but MTFs only with the appropriate specialist prescribers had to keep ECF drugs in stock. The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing Norditropin from the ECF.

7. ***COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM, TIER 1 COPAY REMOVAL, ECF REMOVAL and IMPLEMENTATION PERIOD—***The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) 1) An effective date of the first Wednesday 90 days after signing of the minutes in all points of service, and 2) that DHA will send letters to beneficiaries affected by the NF, non-step-preferred recommendation and to those patients affected by the change in copay for Norditropin. See Appendix G for the actual implementation date.

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

The products were divided into two groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Abrilada, Augtyro, Bimzelx, Cabtreo, Coxanto, Fruzaqla, Jesduvroq, Jylamvo, Likmez, Motpoly XR, Ogsiveo, Ojjaara, Truqap, Velsipity, Xalkori pellets, Xphozah and Zepbound, while Group 2 included Entyvio, Omvoh, Voquezna and Zurzuvae.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 16 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the February 2024 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.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 15 for, 0 opposed, 1 abstained, 0 absent) the following:

    - UF
        - capivasertib (Truqap) – Oncological Agents for breast cancer
        - crizotinib oral pellets (Xalkori) – Oncological Agents; a new formulation for non-small cell lung cancer (NSCLC), anaplastic

large cell lymphoma (ALCL) and inflammatory myofibroblastic tumors (IMT)

- etrasimod (Velsipity) – Sphingosine-1 phosphate (S1p) receptor modulators for ulcerative colitis
- fruquintinib (Fruzaqla) – Oncological Agents for colorectal cancer
- methotrexate oral solution (Jylamvo) – Antirheumatics; new formulation of methotrexate
- metronidazole oral suspension (Likmez) – Gastrointestinal-2 Agents; new formulation of metronidazole
- mirikizumab-mrkz (Omvoh) – Targeted Immunomodulatory Biologics (TIBs) for ulcerative colitis
- momelotinib (Ojjaara) – Oncological Agents for myelofibrosis
- nirogacestat (Ogsiveo) – Oncological Agents for desmoid tumors
- repotrectinib (Augtyro)– Oncological Agents for NSCLC
- tirzepatide (Zepbound) – Weight Loss Agents
- vedolizumab (Entyvio) – TIBs for ulcerative colitis
- zuranolone (Zurzuvae) – Antidepressants and Non-Opioid Pain Syndrome Agents for postpartum depression

- NF
  - adalimumab-afzb (Abrilada) – TIBs; Humira biosimilar
  - bimekizumab-bkzx (Bimzelx) – TIBs for plaque psoriasis
  - daprodustat (Jesduvroq) – Hematological Agents
  - lacosamide extended release (Motpoly XR) – Anticonvulsants-Antimania Agents
  - tenapanor (Xphozah) – Electrolyte Depleting Agents; phosphate absorption inhibitor for chronic kidney disease
  - vonoprazan (Voquezna) – Proton Pump Inhibitors: Potassium-Competitive Acid Blockers
- Complete Exclusion: See Appendix H for additional detail regarding excluded agents and formulary alternatives.
  - clindamycin 1.2%, adapalene 0.15%, and benzoyl peroxide 3.1% topical gel (Cabtreo)– Acne Agents: Topical Acne and Rosacea
    - Cabtreo was recommended for complete exclusion as it has little to no clinical benefit relative to other drugs for acne, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include

clindamycin/benzoyl peroxide gel, adapalene gel, and tretinoin cream.

- oxaprozin 300 mg capsules (Coxanto) – Pain Agents: NSAIDs
  - Coxanto was recommended for complete exclusion as it has little to no clinical benefit relative to other pain agents, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include meloxicam, oxaprozin 600 mg tablets, and naproxen ER (Naprelan ER).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 15 for, 0 opposed, 1 abstained, 0 absent) MN criteria for Abrilada, Bimzelx, Jesduvroq, Motpoly XR, Xphozah, and Voquezna. See Appendix B for the full criteria.

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

   - Applying manual PA criteria to new users of the oncology drugs Truqap, Xalkori, Fruzaqla, Ojjaara, Ogsiveo and Augtyro; and for new users of Jesduvroq, Motpoly XR, Jylamvo, Likmez, Voquezna and Zurzuvae.
   - Applying manual PA criteria to new and current users of the Humira biosimilar Abrilada, similar to what is in place for the other Humira biosimilars. A trial of the Humira branded product is required first as per the February 2023 P&T Committee meeting minutes.
   - Applying manual PA criteria to new users of Bimzelx, requiring a trial of Humira, Stelara and Cosentyx, similar to what is in place for the other TIBs approved for treating plaque psoriasis.
   - Applying manual PA criteria to new users of Velsipity and Omvoh, requiring a trial of Humira first, and for new users of Entyvio, requiring a trial of Humira or infliximab first, similar to what is in place for the other TIBs approved for treating ulcerative colitis.
   - Applying manual PA criteria to new and current users of Xphozah, requiring a trial of two traditional phosphate binders first.
   - Applying manual PA criteria to new users of Zepbound, requiring a trial of generic phentermine, Qsymia (or its generic components) and Contrave (or its generic components), similar to what is in place for the weight loss agents Saxenda and Wegovy.
   - Applying interim manual PA criteria in new and current users for Cabtreo and Coxanto prior to the complete exclusion implementation.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 15 for, 0 opposed, 1 abstained, 0 absent) QLs for Abrilada, Augtyro, Bimzelx, Entyvio, Fruzaqla, Ojjaara, Omvoh, Ogsiveo, Truqap, Xalkori pellets and Voquezna. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS***—The P&T Committee recommended (Group 1: 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 16 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the EMMPI program for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

6. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (Group 1 15 for, 0 opposed, 0 abstained, 1 absent and Group 2: 15 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 two weeks after signing of the minutes in all points of service; see Appendix G.
   - **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion recommendation at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

a) **Electrolyte-Mineral-Trace Element Replacement—potassium chloride (KCl) 10 mEq packet (Pokonza)—**Pokonza was identified as a high-cost potassium product in a class with many cost-effective alternatives, including alternate dosage formulations (liquid and packets). Many commercial health plans have chosen to not cover Pokonza or require a PA. PA criteria were recommended requiring providers to explain why the cost-effective alternatives cannot be used instead.

b) **Pain Agents: Pain Topical**—lidocaine 5% patch (DermacinRx, Lidocan, Lidocan II, Lidocan III)—Lidocan patches are manufactured by a single manufacturer and are not cost-effective compared to numerous other lidocaine

patches produced by generic manufacturers. PA criteria were recommended for these brands.

COMMITTEE ACTION: POTASSIUM CHLORIDE (KCL) 10 MEQ PACKET (POKONZA) AND LIDOCAINE 5% PATCH (DERMACINRX, LIDOCAN, LIDOCAN II, LIDOCAN III)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria in new and current users of Pokonza, DermacinRx, Lidocan, Lidocan II, and Lidocan III. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

2. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for three 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) **Diabetes Non-Insulin Drugs: Sulfonylureas—glipizide 2.5 mg immediate release (IR) tablet—**Numerous other glipizide IR (5 mg and 10 mg) and extended release (ER) (2.5 mg, 5 mg and 10 mg) formulations are more cost-effective than this 2.5 mg IR formulation made by a sole manufacturer.

b) **Corticosteroids-Immune Modulators: High-Potency Corticosteroids—amcinonide 0.1% ointment**—There are multiple topical steroids of similar potency and an amcinonide cream that is cost-effective relative to this amcinonide 0.1% ointment.

c) **Binders-Chelators-Antidotes-Overdose Agents—trientine 500 mg capsule—** Trientine is already available as a cost-effective 250 mg capsule. Patients requiring trientine 500 mg can take two capsules of the 250 mg formulation instead.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for glipizide 2.5 mg IR tablets, amcinonide 0.1% ointment, and trientine 500 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 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (15 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.

a) **Oncological Agents: Ovarian Cancer—olaparib (Lynparza)**—Lynparza's indication for the maintenance treatment of recurrent ovarian cancer is now restricted to those patients with a germline breast cancer (BRCA) mutation only. The manual PA criteria were updated accordingly.

b) **Oncological Agents—encorafenib (Braftovi) and binimetinib (Mektovi)**—The manual PA criteria for Braftovi and Mektovi were updated to allow for the treatment of metastatic NSCLC.

c) **Oncological Agents: Lung Cancer—entrectinib (Rozlytrek)—**The solid tumor indication for Rozlytrek was expanded to include children older than 1 month of age. The manual PA criteria were updated to remove age cutoff criteria.

d) **Oncological Agents: Prostate Cancer 2nd Generation Antiandrogens—enzalutamide (Xtandi)—**The manual PA criteria for Xtandi were updated to allow for the treatment of non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis.

e) **Oncological Agents—pirtobrutinib (Jaypirca)—**The manual PA criteria were updated to allow for the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) in adults who have received two or more prior lines of therapy, including a bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma- 2 (BCL-2) inhibitor.

f) **Oncological Agents: Acute Myelogenous Leukemia (AML) ivosidenib (Tibsovo)—**The manual PA criteria were updated to allow for the treatment of relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

g) **Oncological Agents—belzutifan (Welireg)—**The PA was updated to allow for the new indication of advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). Additionally, due to updated National Comprehensive Cancer Network (NCCN) guidelines that allow use in metastatic disease, the previous exclusion for metastatic disease was removed.

h) **Oncological Agents: Non-Bruton Tyrosine Kinase (BTK) Inhibitors for (CLL)—venetoclax (Venclexta)—**The PA was updated to allow for dose modification when Venclexta is used with a CYP3A inhibitor, based on updated FDA-labeling regarding drug interactions.

i) **Growth Stimulating Agents: Miscellaneous—vosoritide (Voxzogo)—**The age cutoff for Voxzogo was removed from the PA due to a recent FDA label update. In addition, minor edits were made to standardize wording in the safety section.

j) **Psoriasis Agents—roflumilast 0.3% cream (Zoryve)—**The manual PA criteria were updated to reflect the new expanded indication in children as young as 6 years old with plaque psoriasis.

k) **Atopy Agents—tralokinumab-ldrm (Adbry)—**The manual PA criteria were updated to reflect the new expanded indication for atopic dermatitis in children as young as 12 years of age. The PA criteria for children mirrors that of adults except it allows pediatric patients to use any topical steroid (as opposed to a high potency steroid as required for adults).

l) **TIBs—etanercept (Enbrel) and abatacept (Orencia)—**Enbrel and Orencia are both now approved for pediatric patients 2 years of age and older with psoriatic arthritis. A trial of non-biologic systemic therapy and Humira will be required before the patient can try Enbrel or Orencia.

m) **Targeted Immunomodulatory Biologics: Non-TNF Inhibitors—secukinumab (Cosentyx)—**The manual PA criteria were updated to allow for the treatment of moderate to severe hidradenitis suppurativa in adults.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Lynparza, Braftovi, Mektovi, Rozlytrek, Venclexta, Xtandi, Jaypirca, Tibsovo, Welireg, Voxzogo, Zoryve, Adbry, Enbrel, Orencia, and Cosentyx in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

4. Updated PA Criteria for Reasons other than New Indications

a) **Pulmonary 1-Agents: Inhaled Corticosteroids—NF, non-step-preferred products (QVAR, Pulmicort, Arnuity Ellipta, Alvesco, Aerospan, and Asmanex)—**The Flovent HFA and Diskus branded agents were discontinued from the market in late 2023 (see November 2023 DoD P&T Committee meeting minutes). Language in the PA criteria for the non-step-preferred inhaled corticosteroids was updated to require a trial of fluticasone propionate first, rather than Flovent HFA or Flovent Diskus.

b) **Oncological Agents: Prostate Cancer 2nd Generation Antiandrogens—darolutamide (Nubeqa)—**At the November 2022 P&T Committee meeting,

the Nubeqa PA was updated to allow for a new indication for the treatment of metastatic hormone-sensitive prostate cancer. The renewal criteria for Nubeqa was removed, as previously limited treatment to patients with non-metastatic disease, which no longer applies.

c) **Oncological Agents: Prostate Cancer CYP-17 Inhibitors—abiraterone acetate 500 mg (Zytiga)—**Step-therapy in the subclass currently requires a trial of micronized abiraterone (Yonsa) and generic abiraterone acetate 250 mg (Zytiga) prior to use of branded Zytiga 500 mg. Due to changes in pricing, the Zytiga 250 mg and Yonsa steps were removed from the Zytiga 500 mg PA.

d) **Hematological Agents—ropeginterferon alfa-2b-njft (Besremi)—**Besremi was reviewed at the February 2022 meeting and designated NF requiring PA. The PA currently restricts use to high-risk polycythemia vera (PV) patients and requires a trial of hydroxyurea first, unless there is therapeutic failure, intolerance or a contraindication. In December 2023, updated NCCN guidelines now list Besremi as a preferred treatment regimen for low-risk PV patients. Other options for low-risk PV patients including hydroxyurea are no longer preferred regimens. For high-risk PV patients, hydroxyurea and Besremi are now both listed as preferred regimens. Provider feedback and a review of other commercial healthcare plans support allowing Besremi use in low-risk PV patients and removing the hydroxyurea requirement. Additional updates to the PA were made based on provider feedback.

e) **Sphingosine-1 phosphate (S1-P) receptor modulators for ulcerative colitis—ozanimod (Zeposia)—**Zeposia was originally approved for treating multiple sclerosis in 2020 but gained an indication for ulcerative colitis (UC) in August 2021. The PA currently requires a trial of Humira first, consistent with the requirements for other drugs classes used for UC, including the TIBs. The PA for Zeposia was updated to also require a trial of Velsipity first, in addition to Humira, unless the patient has a contraindication to or has had an adverse reaction to Velsipity.

f) **Gastrointestinal-2 Agents: Constipation -predominant Irritable Bowel Syndrome (IBS-C)—tenapanor (Ibsrela)—**Ibsrela and Xphozah both contain the same active ingredient, tenapanor, and are marketed by the same manufacturer, but have different indications. Ibsrela is indicated for IBS-C, while Xphozah is approved for hyperphosphatemia in patients with CKD. The current Ibsrela PA excludes use for hyperphosphatemia. The Ibsrela PA was updated to allow use in hyperphosphatemia, due to the evidence supporting tenapanor use for this indication.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, MEDICAL NECESSITY CRITERIA, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Nubeqa, the non-step-preferred inhaled corticosteroids, Zytiga 500 mg, Besremi, Zeposia and

Ibsrela. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix C for the full criteria.

5. Removal of PA

Contraceptives—At the November 2023 meeting, seven contraceptive agents, including two chewable tablet formulations and two extended cycle products were moved from NF to UF status due to availability of cost-effective generic formulations. The PAs for these contraceptive agents will be removed, to support expanded access for these cost-effective contraceptives.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for the seven contraceptives listed below. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (chew tab) (e.g., Charlotte 24 Fe, Finzala, Mibelas 24 Fe) – Generic Code Number (GCN) 34725
- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (e.g., Aurovela 24 Fe, Blisovi 24 Fe, Hailey 24 Fe, Junel Fe 24, Larin 24 Fe, Microgestin 24 Fe, Tarina 24 Fe) – GCN 26629
- norethindrone 0.8mg/ethinyl estradiol 25 mcg (chew tab) (e.g., Kaitlib Fe, Layolis Fe) – GCN 29719
- norethindrone 0.4mg/ethinyl estradiol 35 mcg (e.g., Balziva, Briellyn, Philith, Vyfemla) – GCN 11470
- norethindrone 0.4mg/ethinyl estradiol 35 mcg/iron (chew tab) (e.g., Wymzya Fe) – GCN 97167
- levonorgestrel 0.15 mg/ethinyl estradiol 30 mcg 3-month dose pack (e.g., Amethia, Ashlyna, Camrese, Daysee, Jaimiess, Simpesse) – GCN 27096
- levonorgestrel 0.1 mg/ethinyl estradiol 20 mcg 3-month dose pack (e.g., Camrese Lo, Lojaimiess) – GCN 18167

B. Quantity Limits

Ophthalmic: Dry Eye Agents—perfluorohexyloctane ophthalmic solution (Miebo)—Miebo was reviewed at the August 2023 P&T meeting and was designated NF, with a PA; QLs were not recommended at that time. The Committee is now aware that Miebo eyedrops are smaller than traditional eye drops (11 microliters vs. 35 to50 microliters, respectively). This affects day supply calculations as pharmacists usually assume 20 drops/mL.

COMMITTEE ACTION: PERFLUOROHEXYLOCTANE OPHTHALMIC (MIEBO) QL AND IMPLEMENTATION—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) adding a QL of 1 bottle per 30-day supply at Retail and 3 bottles per 90-day supply at MTF/Mail to ensure that appropriate quantities of Miebo are dispensed. Implementation will occur the first Wednesday two weeks after signing of the minutes. See Appendix D for full criteria.

C. Line Extensions

The P&T Committee clarified the formulary status for three product line extensions 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) **Cystic Fibrosis Agents**—designating **ivacaftor (Kalydeco) 5.8 mg and 13.4 mg granule packets** with the same formulary status (UF), PA, QL, and Specialty status as the parent Kalydeco granule packets and tablets.

b) **Oncological Agents: Lung Cancer**—designating **entrectinib (Rozlytrek) oral pellet** with the same formulary status (UF), PA, QL, and Specialty status as the parent Rozlytrek capsules.

c) **Attention Deficit/Hyperactivity Disorder: Stimulant**—designating **methylphenidate ER (Relexxii) 18 mg, 27 mg, 36 mg, and 54 mg tablets** with the same formulary status (NF) and PA as the parent Relexxii 45 mg, 63 mg, and 72 mg tablets.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, Specialty program, and EMMPI program status of the line extension products, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. UTILIZATION MANAGEMENT: CONTINUOUS GLUCOSE MONITORING SYSTEMS (CGMS)

The therapeutic CGMS were added to the TRICARE pharmacy benefit at the November 2021 P&T Committee meeting, with implementation in February 2022. A summary of the utilization trends and cost of the CGMS were presented during the February 2024 meeting. The Committee also reviewed the 2024 American Diabetes Association (ADA), 2023 DoD/VA Clinical Practice Guideline for Type 2 Diabetes, and 2021 American Association of Clinical Endocrinologists (AACE) treatment guidelines for CGMS. Based on this, several changes to the CGMS PA criteria for FreeStyle Libre and Dexcom were recommended. The changes for the manual PA criteria included removing the requirements for specialist prescribing and for multiple daily insulin injections. New automated criteria were also recommended which will look back 180 days and if there is a prescription for any insulin product, the PA will be approved without requiring the manual PA (automated look-back).

COMMITTEE ACTION: CGMS PA UPDATED CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) updates to the CGMS criteria, with an implementation of the first Wednesday 60 days after signing of the minutes at all points of service. The PA changes will increase beneficiary access under the TRICARE pharmacy benefit, reduce provider administrative time, and align DoD with clinical practice guidelines. See Appendix C for the full criteria.

VIII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR TERIPARATIDE (FORTEO) INJECTION

Teriparatide (Forteo) is designated as UF and requires PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, the branded Forteo injection will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 copay for brand Forteo is recommended.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) requiring brand Forteo over the generic in all new users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Forteo injections. The effective date will be no later than 60 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

IX. RE-EVALUATION OF NF GENERICS: ANDROGENS-ANABOLIC STEROIDS: TESTOSTERONE REPLACEMENT THERAPY

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/Tier 3 drugs that are now available in generic formulations need to be readdressed. Refer to the May 2007, November 2012, and November 2022 P&T Committee minutes for additional information regarding established procedures for returning generic NF agents to formulary status.

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30 days, for the current NF transdermal/nasal testosterone products. The class was most recently reviewed in February 2023.

Currently the step-preferred products include 2% testosterone gel multi-dose pump (MDP) (generic Fortesta), which is also designated as BCF, and 1% testosterone gel (generic Androgel) MDP and gel packets. The 1.62% testosterone gel MDP and gel packets (Androgel 1.62%) and 2% solution MDP (Axiron, generics) are currently designated as NF and non-step-preferred.

The P&T Committee noted that brand Fortesta (2% gel MDP) and cost effective generics have been discontinued. Generics for 1.62% testosterone gel (generic Androgel 1.62%) and 2% solution (Axiron) have dropped in price and are now the most cost-effective options. Several changes in formulary status and step-therapy preference were recommended for the class, which would increase access as the class has recently encountered shortages; align the benefit with product cost; and eliminate NF/Tier 3 copays for the topical/nasal testosterone agents.

COMMITTEE ACTION: TESTOSTERONE AGENTS FORMULARY STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) making the following changes to formulary status, step therapy status, and prior authorization criteria, effective the first Wednesday 30 days after signing of the minutes. (See Appendix B for the MN criteria changes, Appendix C for the PA criteria updates, and Appendix G for implementation dates).

- Remove BCF status from 2% gel MDP (Fortesta, generic; GCN 98317)
- Move 2% gel MDP (the remaining Fortesta generic, GCN 98317) to UF non-step preferred status
- Return the following generically available products to UF and step-preferred status:
    - 1.62% MDP (Androgel, generic; GCN 29905); 1.62% (25 mg, 50 mg) gel packets (Androgel, generic; GCNs 33452, 33453)
    - 2% solution (Axiron, generic: GCN 29647)
    - 1% gel MDP and gel packets (generic Androgel 1%) (GCN 23141, 47851, 47852)
- Move 1% gel unit dose tubes (Testim, Vogelxo, generics; GCN 97089) to UF step-preferred status
- Retain UF non-preferred status (no change) for:
    - brand Vogelxo 1% gel MDP (GCN 23141) and gel packet (GCN 47852)
    - Androderm 2 mg and 4 mg patch (GCNs 29171, 30796
    - Natesto nasal gel (GCN 38079)
- Modify PA language and MN criteria to require use of preferred agents prior to receiving non-preferred agents
- Retain branded testosterone topical/nasal products on the EMMPI program; remove the generic products moving from NF to UF from the EMMPI program
- Make no changes to other testosterone products
- Branded products with generic equivalents (e.g., Androgel) are subject to mandatory generic policy
- New users of all testosterone products must meet manual prior authorization criteria, based on intended use

As a result, the updated formulary status for the Androgens Anabolic Steroid: Testosterone Replacement Therapy subclass is as follows:

- UF and step-preferred: 1% and 1.62% testosterone gel MDP and gel packets (Androgel, generics); 2% solution MDP (Axiron, generics); 1% gel in unit-dose tubes (Testim, Vogelxo, generics)
- UF and non-step-preferred (requires trial of preferred agents): 2% testosterone gel multi-dose pump (MDP) (Fortesta generic); brand-only Vogelxo 1% gel MDP and gel packets; Androderm patch, Natesto nasal gel; Xyosted auto-injector
- NF and non-step-preferred (requires trial of preferred agents): oral Jatenzo, Tlando, and Kyzatrex
- UF and not subject to step therapy: testosterone cypionate IM, testosterone enanthate IM, and oral methyltestosterone

X. OVER-THE-COUNTER (OTC) DRUG BENEFIT—NALOXONE 3 mg NASAL SPRAY OTC (RIVIVE)

Background: Pursuant to 32 CFR 199.21(h)(5)(i), an OTC drug may be included on the UF upon the recommendation of the P&T Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. OTC drugs placed on the UF, in general, will be treated the same as generic drugs on the UF for purposes of availability in the MTF pharmacies, retail pharmacies, and the Mail Order pharmacy program and other requirements. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the requirement for the prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under 32 CFR 199.21 (i)(2)(xii) for OTC drugs specifically used in certain emergency care treatment situations.

OTC Naloxone Nasal Spray 3 mg (RiVive): The P&T Committee evaluated the clinical and cost-effectiveness for the addition of OTC nasal naloxone 3 mg/0.1 mL (RiVive) to the UF. Other prescription naloxone formulations are available on the UF (Narcan 4 mg/0.1 mL, Kloxxado, Zimhi), with prescription Narcan nasal designated with BCF status.

Multiple references, including guidance from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, and the 2022 DoD/VA Guideline for the Use of Opioids in Management of Chronic Pain, as well as input from DoD pain management specialists, support the use of intranasal naloxone for the emergency treatment of known or suspected opioid overdose. Based on clinical effectiveness and ease of access, OTC naloxone nasal 3 mg/0.1 mL (RiVive) was recommended for addition to the UF. QLs currently exist for the class and were recommended for the OTC product.

COMMITTEE ACTION: UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT, QUANTITY LIMITS, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (15 for, 0 opposed, 0 abstained, 1 absent) the following:

- adding OTC naloxone 3 mg/0.1 mL (RiVive) nasal spray to the UF
- waiving the copay requirement
- waiving the prescription requirement
- applying the current quantity limit of 2 cartons per fill at all POS (Retail/MTF/Mail) (note each carton contains 2 devices)
- implementation plan of two weeks after signing of the minutes all points of service

The P&T Committee voted to waive the prescription and copay requirements. While the P&T Committee voted to waive the requirement for a prescription at all points of service, there may be state or operational limitations that require some provider input for processing. As an example, some states allow pharmacists who have National Provider Identifier (NPI) numbers to prescribe but the pharmacy claims adjudication systems may require a valid prescription. According to National Council for Prescription Drug Programs (NCPDP) rules, a provider NPI is required for claims to process.

Regarding copay, 32 CFR 199.21(i)(2)(xii) states as a general rule, OTC drugs placed on the UF will have copayments equal to those for generic drugs on the UF. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the copayment may be established at $0.00 for any particular OTC drug in the retail pharmacy network. The P&T Committee recommended the copay for OTC naloxone be zero at retail and the Tier 1 generic copay at mail.

Note that additional considerations of dispensing OTC naloxone (e.g., distribution to first responders, availability in exchanges/commissaries), while encouraged, fall outside the scope of P&T Committee.

XI. SELECT MAINTENANCE DRUG LIST UPDATES

Nonformulary medications are generally restricted to the Mail Order program pursuant to 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), added by Section 702(c)(2) of the NDAA for FY 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the ESI-managed TRICARE mail order program. Medications subject to either the nonformulary requirement or added to the EMMPI program are combined as the Select Maintenance Drug List.

As a follow-on to the review of medications at the November 2023 meeting, the P&T Committee reviewed two additional oral oncology agents for potential addition to the Select Maintenance Drug List.

COMMITTEE ACTION: SELECT MAINTENANCE DRUG LIST— The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 0 absent) addition of regorafenib (Stivarga) and vismodegib (Erivedge) to the Select Maintenance Drug List, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing at mail order). Note: Appendix F (Table 2) contains a running list of medications to be added to the Select Maintenance Drug List on a contingent basis; the table will be updated as drugs are added.

XII. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

The Committee was briefed on the following items:

1. Specialty Program Update
2. Innovator Drug 2023 Year in Review

XIII. ADJOURNMENT

The meeting adjourned at 1545 hours on February 8th. The next meeting will be in May 2024.

Appendix A—Attendance: February 2024 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 2024 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Completely Excluded Agents and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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:

[redacted]

Brian C. Lein, MD
Assistant Director,
Healthcare Administration
for Telita Crosland LTG, MC, USA
Director

22 Apr 24
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Paul Carby, MSC	DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
LTC Charles Lynn, MC	Army, Internal Medicine Physician
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Consultant
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
MAJ Courtney Clutter, MC	Air Force, Internal Medicine Physician
Capt Andrew Gaillardetz, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
Lt Col Blair DeStefano, MC	Air Force, Oncology Physician
Beth Days, RPh, BCOP	DHA, Oncology Pharmacist
CAPT Chris Janik, USCG	Coast Guard, Pharmacy Consultant

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Fakhrudin Valibhai, PharmD	Tpharm5 Clinical COR
Eugene Moore, PharmD	Tpharm5 Clinical COR
CAPT Bill Kelly, MCS, USN	Defense Logistics Agency
Pete Glassman, MD	Department of Veteran's Affairs
Guests	
CAPT Marisol Martinez	Indian Health Service
LCDR Brett Whitehead	Bureau of Prisons
CAPT Carl Olongo	Indian Health Service
CDR Josephine Zepeda	Indian Health Service
CDR Jackie Finocchio	USCG
Ms. Alison McMahon	DHA, TRICARE Health Plan
Others Present	
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
CDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Heather Johnson, PharmD, BCPS	DHA Formulary 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. Martha Hutchinson	DHA Formulary Management Branch Contractor
CAPT Tiffany Cline	DHA POD DFO

Appendix A—Attendance

CAPT Thien Nguyen	DHA POD DFO Alternate
Jessy Hull, PharmD	DHA Purchased Care Branch
Nicole Andover	University of Texas PharmD Student
Others Present	
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Juliane Canaley	DHA Contracting
Ms. Shiela Mirrielees	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Ms. Patricia Tyson	DHA Contracting
Mr. Keith Marasigan	DHA Contracting
Ms. Viktoria Reed	DHA Contracting
Mr. Dwight Bonham	DHA Contracting
Ms. Patricia Legra	DHA Contracting
Ms. Brooke Wolfe	DHA Contracting
Mr. Michael Nacht	DHA Contracting
Mr. Garret Pugh	DHA Contracting
Ms. Stephanie Baladez	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
Short-acting • somatropin (Humatrope) • somatropin (Nutropin) • somatropin (Serostim) • somatropin (Saizen, Saizen Prep) *Long-acting* • lonapegsomatropin – tcgd (Skytrofa) **Growth Hormone Stimulating Agents**	• Use of all step-preferred formulary agents is contraindicated • Patient has experienced significant adverse effects from all step-preferred formulary agents **Formulary alternatives: short-acting:** somatropin (Norditropin), somatropin (Genotropin), somatropin (Omnitrope), somatropin (Zomacton); **long-acting**: somatrogon-ghla (Ngenla); somapacitan-beco (Sogroya)
New Drugs MN Criteria	
• adalimumab-afzb (Abrilada) **TIBs: Tumor Necrosis Factor Inhibitors**	• Patient has experienced significant adverse effects from all formulary agents **Formulary alternatives:** adalimumab (Humira)
• bimekizumab-bkzx (Bimzelx) **TIBs**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** adalimumab (Humira), ustekinumab (Stelara), and secukinumab (Cosentyx)
• daprodustat (Jesduvroq) **Hematological Agents**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure **Formulary alternatives:** epoetin alfa (Retacrit, Procrit, Epogen) or darbepoetin alfa (Aranesp)
• lacosamide ER (Motpoly XR) **Anticonvulsants-Antimania Agents**	• Formulary agents resulted in therapeutic failure **Formulary alternatives:** lacosamide tablets (Vimpat, generics)

Appendix B—Table of Medical Necessity Criteria

• tenapanor (Xphozah) **Electrolyte Depleting Agents: Phosphate Binders**	• Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives:** sevelamer HCL, sevelamer carbonate, lanthanum carbonate, ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro)
• vonoprazan (Voquezna) **Proton Pump Inhibitors: Potassium-Competitive Acid Blockers**	• Use of 3 formulary agents is contraindicated • Patient has experienced significant adverse effects from 3 formulary agents • Use of 3 formulary agents resulted in therapeutic failure **Formulary alternatives:** omeprazole, pantoprazole, rabeprazole, esomeprazole, or lansoprazole
Utilization Management MN Criteria – NF Generics	
~~• **Testosterone transdermal solution pump; 30 mg/actuation; (Axiron)**~~ ~~• **Testosterone 1%; 25 mg/2.5 gm, 50 mg/5 gm transdermal gel packets, and 12.5 mg /actuation gel pump (Androgel 1%)**~~ ~~• **Testosterone 1.62% transdermal gel pump; 20.25 mg/actuation (Androgel 1.62%)**~~ • Oral testosterone undecanoate capsules (Jatenzo, Tlando, Kyzatrex) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the February 2024 meeting are in bold and strikethrough** ~~• Use of ALL **step-preferred** formulary **alternatives** is contraindicated (e.g., due to hypersensitivity), and treatment with Axiron, Androgel 1%, or Androgel 1.62% **oral testosterone undecanoate capsules (Jatenzo, Tlando, or) is not contraindicated.**~~ • Patient has experienced significant adverse effects from ALL **step-preferred** formulary **alternatives**. • ALL **step-preferred** formulary **alternatives** have resulted in therapeutic failure. **Step-preferred formulary alternatives: testosterone 1% gel (e.g., generic Androgel, generic Testim) or 1.62% gel (e.g., generic Androgel), or testosterone 2% solution (e.g., generic Axiron)**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
Step-preferred *Short-acting* • somatropin (Genotropin) • somatropin (Norditropin • somatropin (Omnitrope) • somatropin (Zomacton) *Long-acting* • somatrogon-ghla (Ngenla) • somapacitan-beco (Sogroya) **Growth Hormone-Stimulating Agents**	**February 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new users of Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla and Sogroya** ~~Norditropin FlexPro is the preferred Growth Stimulating Agent.~~ ~~All new and current users of the non-step-preferred Growth Stimulating Agents must try Norditropin FlexPro first.~~ Manual PA Criteria: Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla or Sogroya are approved if: For Pediatric patients: • The patient is younger than 18 years of age and has **one of** the following indications: ▪ Growth hormone deficiency ▪ Small for gestational age ▪ Chronic renal insufficiency associated with growth failure ▪ Prader-Willi Syndrome (in patients with a negative sleep study for obstructive sleep apnea) ▪ Turner Syndrome ▪ Noonan's Syndrome ▪ Short stature homeobox (ShoX) gene mutation • ~~For patients younger than 18 years of age who do not have one of the indications above, document the diagnosis below: _____~~ • For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment For Adult patients: • The patient is 18 years of age or older and has **one of** the following indications: ▪ Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood ▪ HIV/AIDS wasting/cachexia ▪ Short Bowel Syndrome • For patients older than 18 years of age, the prescription is written by or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist) ~~**AND**~~ ~~For Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim and Zomacton: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton:~~ • ~~The patient has a contraindication to Norditropin FlexPro OR~~ • ~~The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with the non-step-preferred product (e.g., because of different preservative)~~ ~~Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim or Zomacton.~~ For Pediatric and Adult patients:

	• Use of a Growth Hormone-Stimulating Agent is not approved for idiopathic short stature, the normal ageing process, obesity, or depression • Use of a Growth Hormone-Stimulating Agent is not approved for other non-FDA-approved uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment) • Concomitant use of multiple Growth Stimulating Agents is not approved Prior authorization expires in one year. A new PA must be submitted yearly
Non-step-preferred *Short-acting* • somatropin (Humatrope) • somatropin (Nutropin) • somatropin (Serostim) • somatropin (Saizen, Saizen Prep) *Long-acting* • lonapegsomatropin – tcgd (Skytrofa) **Growth Hormone-Stimulating Agents**	**February 2024 changes are in bold and ~~strikethrough~~** **Manual PA criteria apply to all new and current users of Humatrope, Nutropin, Serostim, Saizen, Saizen Prep, or Skytrofa** ~~Norditropin FlexPro is the preferred Growth Stimulating Agent.~~ ~~All new and current users of the non-step-preferred Growth Stimulating Agents must try Norditropin FlexPro first.~~ Manual PA Criteria: Humatrope, Nutropin Serostim, Saizen, Saizen-Prep, or Skytrofa are approved if: For Pediatric patients: • **The provider acknowledges that Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla and Sogroya are DoD's preferred growth hormone-stimulating agents** • The patient is younger than 18 years of age and has **one of** the following indications: ▪ Growth hormone deficiency ▪ Small for gestational age ▪ Chronic renal insufficiency associated with growth failure ▪ Prader-Willi Syndrome (in patients with a negative sleep study for obstructive sleep apnea) ▪ Turner Syndrome ▪ Noonan's Syndrome ▪ Short stature homeobox (ShoX) gene mutation • ~~For patients younger than 18 years of age who do not have one of the indications above, document the diagnosis below: _____~~ • For patients younger than 18 years of age, the prescription is written by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment For Adult patients: • **The provider acknowledges that Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla and Sogroya are DoD's preferred growth hormone-stimulating agents** • The patient is 18 years of age or older and has **one of** the following indications: ▪ Growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy, acquired as an adult or diagnosed during childhood ▪ HIV/AIDS wasting/cachexia ▪ Short Bowel Syndrome • For patients older than 18 years of age, the prescription is written by or in consultation with an appropriate specialist (endocrinologist, infectious disease specialist, general surgeon, or gastroenterologist) ~~**AND**~~ ~~For Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim and Zomacton: In addition to the above criteria, the following criteria applies to new and current users of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim, and Zomacton:~~

	~~• The patient has a contraindication to Norditropin FlexPro OR~~ ~~• The patient has experienced an adverse reaction to Norditropin FlexPro that is not expected with the non-step-preferred product (e.g., because of different preservative)~~ ~~Note that patient preference for a particular device is insufficient grounds for approval of Genotropin, Humatrope, Nutropin AQ Nuspin, Omnitrope, Saizen, Serostim or Zomacton.~~ For Pediatric and Adult patients: • **Patient has a contraindication (e.g., due to hypersensitivity to a preservative or other inactive ingredient) to the following:** ▪ **two short acting agents including Norditropin, Genotropin, Omnitrope, or Zomacton AND** ▪ **two long-acting agents including Sogroya and Ngenla** • **Patient has experienced an adverse event (e.g., due to a preservative or other inactive ingredient) to the following:** ▪ **two short acting agents including Norditropin, Genotropin, Omnitrope, or Zomacton AND** ▪ **two long-acting agents including Sogroya and Ngenla** • **Note that patient preference for a particular device is insufficient grounds for approval of Humatrope, Nutropin, Serostim, Saizen, Saizen Prep, or Skytrofa** • **Serostim is only approved for HIV cachexia and is not allowed for other indications** • Use of a Growth Hormone-Stimulating Agent is not approved for idiopathic short stature, the normal ageing process, obesity, or depression • Use of a Growth Hormone-Stimulating Agent is not approved for other non-FDA-approved uses (e.g., non-alcoholic fatty liver disease, cirrhosis, mild cognitive impairment) • Concomitant use of multiple Growth Stimulating Agents is not approved Prior authorization expires in one year. A new PA must be submitted yearly
Newly Approved Drug PAs	

Appendix C—Table of Prior Authorization (PA) Criteria

• adalimumab-afzb (Abrilada)
 	
TIBS: Tumor Necrosis Factor Inhibitors
	Manual PA criteria apply to all new and current users of the Humira biosimilar
	
	<u>Manual PA criteria</u>: Coverage is approved if all criteria are met:
	
	• Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations
	• Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient
	  ▪ Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Humira biosimilar
	• If patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease
	  ▪ If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older
	  ▪ If indication is moderate to severe Crohn's disease patient must be 6 years of age or older AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease
	• If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa
	  ▪ If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease
	  ▪ If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months
	• Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira
	• Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed)
	• Patient is not receiving other targeted immunomodulatory biologics with Humira, 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)
	
	Non-FDA approved uses are NOT approved, except if indication is approved for Humira, it is approved for a biosimilar
	PA does not expire

• bimekizumab-bkzx (Bimzelx) **TIBS: Non-Tumor Necrosis Factor Inhibitors**	Manual PA criteria apply to all new users of bimekizumab-bkzx (Bimzelx) <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Humira is the Department of Defense's preferred targeted biologic agent where patient must try Humira • Patient had inadequate response to Humira OR

	• Patient had adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND • Patient had inadequate response to Stelara OR • Patient had adverse reaction to Stelara that is not expected to occur with the requested agent OR • Patient has a contraindication to Stelara AND • Patient had inadequate response to Cosentyx OR • Patient had adverse reaction to Cosentyx that is not expected to occur with the requested agent OR • Patient has a contraindication to Cosentyx AND • Patient is 18 years of age or older • Patient has moderate to severe plaque psoriasis • Patient is a candidate for systemic therapy or phototherapy • Patient had inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) • Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed) • Patient will not be receiving any other targeted immunomodulatory biologics with bimekizumab, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Otezla, Remicade, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR Non-FDA approved uses are NOT approved PA does not expire
• capivasertib (Truqap) **Oncological Agents**	Manual PA criteria apply to all new users of capivasertib (Truqap) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with hematologist or oncologist • Patient has advanced or metastatic HR-positive, HER2-negative breast cancer • Patient has PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test • Patient has tried and failed, or is not a candidate for, adjuvant or neoadjuvant chemotherapy • Patient had disease progression while on or after endocrine therapy • Patient will be receiving fulvestrant injection (Faslodex) therapy along with capivasertib (Truqap) • 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. The diagnosis must be listed. • Provider is aware of all monitoring requirements and screening precautions Other non-FDA approved uses are NOT approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• crizotinib (Xalkori) oral pellets **Oncological Agents**	Manual PA criteria apply to all new users of crizotinib oral pellets (Xalkori) Age edit: PA does not apply to children 12 year of age and younger <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • Patient has metastatic non-small cell lung cancer (NSCLC) AND ▪ The NSCLC tumor is anaplastic lymphoma kinase (ALK) positive or ROS1-positive (as detected by an FDA-approved test) OR • Patient has relapsed or refractory systemic anaplastic large cell lymphoma (ALK positive) AND ▪ 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 refractory or refractory systemic ALK-positive anaplastic large cell lymphoma) OR • Patient has unresectable, recurrent, or refractory inflammatory myofibroblastic tumor ▪ Patient is 1 year of age or older ▪ Tumor is anaplastic lymphoma kinase (ALK) positive • 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. The diagnosis must be listed. • Provider must explain why the patient cannot take Xalkori tablets. ▪ Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience Other non-FDA approved uses are NOT approved except as noted above PA does not expire
• daprodustat (Jesduvroq) **Hematological Agents**	Manual PA criteria apply to all new users of daprodustat (Jesduvroq) <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Provider acknowledges that epoetin alfa-epbx (Retacrit) is the preferred erythropoietin stimulating agent (ESA) for TRICARE and is available without prior authorization • Patient has experienced an inadequate response or adverse reaction to Retacrit • Patient is 18 years of age or older • Prescribed by or in consultation with a nephrologist • Patient has diagnosis of anemia due to chronic kidney disease • Patient has been receiving dialysis for at least 4 months • Provider is aware of the warnings, screening, and monitoring precautions for Jesduvroq Non-FDA approved uses are not approved PA expires in 6 months Renewal Criteria: Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. Continued use of Jesduvroq will be approved indefinitely for the following: • The patient has had a positive response to therapy as shown by an increase or stabilization in hemoglobin levels or a reduction or absence in red blood cell transfusions.

Appendix C—Table of Prior Authorization (PA) Criteria

• etrasimod (Velsipity) **Sphingosine-1 Phosphate (S1p) Receptor Modulators**	Manual PA criteria apply to all new users of Velsipity Manual PA criteria: Velsipity is approved if all criteria are met: • Patient has a diagnosis of moderately to severely 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: ▪ Had an inadequate response to Humira OR ▪ Experienced an adverse reaction to Humira that is not expected to occur with Velsipity OR ▪ Has a contraindication to Humira • Provider is aware of all assessments, warnings, screening, and monitoring precautions for Velsipity. • 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.) Non-FDA-approved uses are not approved Prior authorization does not expire
• fruquintinib (Fruzaqla) **Oncological Agents**	Manual PA criteria apply to all new users of fruquintinib (Fruzaqla) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with hematologist or oncologist • Patient has a diagnosis of metastatic colorectal cancer • Patient has had progression following treatment with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy • Patient must have had progression following anti-VEGF therapy (e.g., bevacizumab, Zaltrap, Cyramza) • If RAS wild-type, patient must have had progression following treatment with anti-EGFR therapy (e.g., cetuximab, panitumumab) • 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. The diagnosis must be listed. • Provider is aware of all monitoring requirements and screening precautions Other non-FDA approved uses are NOT approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• lacosamide ER (Motpoly XR) **Anticonvulsants-Antimania Agents**	Manual PA criteria apply to all new users of lacosamide ER capsule (Motpoly XR) Manual PA criteria: Coverage is approved if all criteria are met: • Patient has a diagnosis of partial-onset seizures • Patient weighs at least 50 kg • The drug is prescribed by a neurologist • Provider is aware of the warnings, screening, and monitoring precautions for Motpoly XR • The provider must explain why the patient requires Motpoly XR and cannot take the generic formulary alternative, lacosamide tablet (fill-in blank) ▪ Acceptable responses include: the patient is having adherence problem with twice daily lacosamide tablet dosing or that the patient has had an adverse reaction to an excipient in lacosamide tablets that would not be likely to occur with Motpoly XR capsules. Non-FDA approved uses are NOT approved PA does not expire
• methotrexate (Jylamvo) oral solution **Antirheumatics**	Manual PA criteria apply to all new users of methotrexate oral solution (Jylamvo) Age edit: PA criteria does not apply to children 12 years of age and younger Manual PA criteria: Coverage is approved if all criteria are met: • Patient has acute lymphoblastic leukemia (ALL), mycosis fungoides, relapsed or refractory non-Hodgkin lymphoma, rheumatoid arthritis, severe psoriasis, or active polyarticular juvenile idiopathic arthritis • Patient has a history of difficulty swallowing tablets or has a medical condition that is characterized by difficulty swallowing or inability to swallow • 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. The diagnosis must be listed. Other non-FDA approved uses are NOT approved except as noted above PA does not expire
• metronidazole (Likmez) oral suspension **Gastrointestinal-2 Agents: Miscellaneous**	Manual PA criteria apply to all new users of metronidazole oral suspension (Likmez) Age edit: PA criteria does not apply to children 12 years of age and younger Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that metronidazole tablets are available without a PA • Patient requires metronidazole and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience PA expires after 6 months New PA required

Appendix C—Table of Prior Authorization (PA) Criteria

• mirikizumab-mrkz (Omvoh) **TIBs**	Manual PA criteria apply to all new users of mirikizumab-mrkz Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has moderately to severely active ulcerative colitis • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis • Patient had inadequate response to Humira • Patient had adverse reaction to Humira that is not expected to occur with the requested agent • Patient has a contraindication to Humira • Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc. • Patient has negative TB test result in past 12 months (or TB is adequately managed) • Patient will not be receiving any other targeted immunomodulatory biologics with mirikizumab 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), upadacitinib (Rinvoq ER), or vedolizumab (Entyvio) Non-FDA approved uses are NOT approved PA does not expire
• momelotinib (Ojjaara) **Oncological Agents**	Manual PA criteria apply to all new users of momelotinib (Ojjaara) <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with hematologist/oncologist • Patient has diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with anemia • If the patient is female, she is not pregnant or planning to become pregnant • Females of reproductive potential will use effective contraception during treatment and for 1 week after the last dose • Female patients will not breastfeed during treatment and for at least 1 week after discontinuation • Provider is aware of the warnings, screening and monitoring precautions for Ojjaara • 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. The diagnosis must be listed. Other non-FDA approved uses are NOT approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• nirogacestat (Ogsiveo) **Oncological Agents**	Manual PA criteria apply to all new users of nirogacestat (Ogsiveo) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with hematologist or oncologist • Patient has a diagnosis of progressing desmoid tumor or aggressive fibromatosis which requires systemic 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. The diagnosis must be listed. • Provider is aware of the warnings, screening and monitoring precautions for Ogsiveo Other non-FDA approved uses are NOT approved except as noted above PA does not expire
• repotrectinib (Augtyro) **Oncological Agents**	Manual PA criteria apply to all new users of repotrectinib (Augtyro) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with hematologist or oncologist • Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC) • Patient has NSCLC that is ROS1-positive • 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. The diagnosis must be listed. • Provider is aware of all warnings, screening and monitoring precautions for Augtyro Other non-FDA approved uses are NOT approved except as noted above PA does not expire
• tenapanor (Xphozah) **Electrolyte Depleting Agents**	Manual PA criteria apply to all new and current users of tenapanor tablets (Xphozah) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with a nephrologist • Patient has a diagnosis of hyperphosphatemia in chronic kidney disease (CKD) • Patient has been receiving maintenance dialysis for at least 3 months • Serum phosphate level is >5.5. mg/dL and <10 mg/dL • Patient has tried and had an inadequate response to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenol), ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate) OR • Patient has tried and been unable to tolerate at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenol), ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate) OR • Patient has a contraindication to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenol), ferric citrate (Auryxia), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate). Contraindications to phosphate binders includes bowel obstruction, iron overload, or hypercalcemia OR • Patient has had intolerance to any dose of phosphate binder therapy. Non-FDA approved uses are NOT approved, including constipation-predominant irritable bowel syndrome (IBS-C) PA does not expire
• tirzepatide (Zepbound)	Manual PA criteria apply to all new users of tirzepatide (Zepbound)

Appendix C—Table of Prior Authorization (PA) Criteria

Weight Loss Agents	Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age of age or older • Patient has a BMI greater than or equal to 30 OR BMI greater than or equal to 27 with risk factors in addition to obesity (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease) • Patient has tried and failed or has a contraindication to all of the following agents: generic phentermine, Qsymia (or its generic components) and Contrave (or its generic components) ▪ Date and duration of use or contraindication for each medication must be provided • If patient has type 2 diabetes, they must they tried and failed metformin and the preferred glucagon-like peptide-1 (GLP-1) receptor agonist (Trulicity) • Medication will not be used with another GLP1RA (for example, Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • Patient must not have a history or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient was engaged in a trial of behavioral modification and dietary restriction or at least 6 months and failed to achieve desired weight loss and will remain engaged throughout the course of therapy • Patient must not be pregnant Non-FDA approved uses are not approved PA expires in 6 months and then annually Renewal Criteria: Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. PA will be approved for 12 months if the following: • Patient is currently engaged in behavioral modification and on a reduced calorie diet • Patient lost greater than or equal to 5 percent of baseline body weight since starting medication
• vedolizumab (Entyvio) **TIBs**	Manual PA criteria apply to all new users of vedolizumab Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has moderate to severely active ulcerative colitis • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis • Patient had an inadequate response to Humira OR • Patient had an adverse reaction to Humira that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira OR • Patient tried and failed or had an inadequate response to infliximab (Remicade) • Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc. • Patient has received induction dosing with two intravenous doses of vedolizumab (Entyvio) OR patient has been receiving intravenous vedolizumab (Entyvio) and achieved clinical response or remission beyond week 6 • Patient will not be receiving any other targeted immunomodulatory biologics with vedolizumab 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)

	Non-FDA approved uses are NOT approved PA does not expire
• vonoprazan (Voquezna) **Proton Pump Inhibitors: Potassium-Competitive Acid Blockers**	Manual PA criteria apply to all new users of vonoprazan (Voquezna) <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Prescriber acknowledges that omeprazole capsules and pantoprazole tablets are the Department of Defense's preferred Proton Pump Inhibitors (PPIs) and are available without a prior authorization • Patient is 18 years of age or older • Prescription is written by or in consultation with a gastroenterologist or infectious disease specialist • Patient has a diagnosis of erosive esophagitis or *Helicobacter pylori (H. pylori)* infection • Voquezna will not be used concomitantly with a PPI • For erosive esophagitis: ▪ Patient has Los Angeles Grade C or D esophagitis ▪ Patient has had an inadequate response after an adequate 8-week trial (high-dose, twice daily dosing, administered 30-60 minutes before meals) or adverse reaction to at least TWO of the following formulary PPIs: ONE must be omeprazole, pantoprazole, esomeprazole, or lansoprazole and the OTHER must be rabeprazole ▪ Please write in date, drug name, strength, and frequency of PPI trials below: ▪ Date ____ Drug name _____ Strength _____ Frequency _____ ▪ Date ____ Drug name _____ Strength _____ Frequency _____ ▪ OR patient has a contraindication to ALL of the following: omeprazole, pantoprazole, rabeprazole, esomeprazole, and lansoprazole • For *H. pylori:* ▪ Patient has tried and failed two 14-day trials with a guideline-recommended first-line treatment regimen. Appropriate treatment combinations for *H. pylori* include PPIs, amoxicillin, rifabutin, clarithromycin, bismuth subsalicylate, metronidazole, tetracycline, and levofloxacin Non-FDA approved uses are NOT approved PA expires in 6 months for initial approval, then annually <u>Renewal Criteria:</u> Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. PA will be approved for 12 months if the following: • Provider acknowledges that current FDA labeling recommends up to 6-months of maintenance therapy with Voquezna • Patient has not had serious adverse events with Voquezna • Provider has considered step-down therapy

Appendix C—Table of Prior Authorization (PA) Criteria

• zuranolone (Zurzuvae) **Antidepressants and Non-Opioid Pain Syndrome Agents**	Manual PA criteria apply to all new users of zuranolone (Zurzuvae) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age of older • Patient has postpartum depression (PPD) • Patient is 12 months or less postpartum • Patient has a contraindication to, intolerability to, or has failed a trial of ONE formulary antidepressant medication (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose) OR • Patient is currently stable on an antidepressant medication and is experiencing break through symptoms OR • Patient is classified as having severe postpartum depression and/or is at significant risk for harm to self or others as determined by their provider and requires prompt symptom control OR • Patient is continuing therapy that was initiated during an inpatient hospital stay • The patient has not had previous treatment course with zuranolone during the current postpartum period • Females of reproductive potential will use effective contraception during treatment and for one week after the final dose • Provider acknowledges the risk of fetal harm associated with zuranolone exposure in pregnancy and has counseled patient to avoid conception for the duration of use and one week after final dose Non-FDA approved uses are NOT approved PA expires after 9 months. Provider must fill out a new PA
Newly Approved Drug Interim PAs for Completely Excluded Drugs	
• clindamycin 1.2%, adapalene 0.15%, benzoyl peroxide 3.1% topical gel (Cabtreo) **Acne Agents**	Interim Manual PA criteria apply to all new users of clindamycin phosphate, adapalene, and benzoyl peroxide topical gel (Cabtreo) Manual PA criteria: Coverage is approved if all criteria are met: • This agent has been identified as having cost-effective alternatives including adapalene (cream, gel, and lotion), clindamycin (cream, gel, lotion, and solution), clindamycin/benzoyl peroxide (combination) gel, and tretinoin (cream, and gel). These agents are available without a PA. Please consider changing the prescription to one of these agents • Patient has Acne Vulgaris • Please explain why this agent is required and patient cannot take formulary alternatives ▪ Acceptable responses include the following: the patient has tried and failed at least three step-preferred (e.g., generic formulations of clindamycin, clindamycin/benzoyl peroxide, tretinoin, tazarotene cream, or adapalene) topical acne products, including different retinoids (e.g., adapalene, tazarotene cream, and tretinoin) or other topical agents, OR ▪ The patient has experienced an adverse reaction with formulary, step-preferred topical tretinoin and adapalene agents that is not expected to occur with Cabtreo Non-FDA approved uses are NOT approved PA does not expire (until complete exclusion implementation)

• oxaprozin 300 mg capsules (Coxanto) **Pain Agents**	Interim Manual PA criteria apply to all new users of oxaprozin capsules (Coxanto) Manual PA criteria: Coverage is approved if all criteria are met: • Multiple formulary NSAIDs are available for DoD beneficiaries without a prior authorization including celecoxib, diclofenac potassium, diclofenac sodium, ibuprofen, indomethacin, meloxicam, naproxen, and oxaprozin. Please consider changing the prescription to one of these formulary NSAIDs. • Please provide the clinical rationale as to why this agent is required and the patient cannot take any of the formulary NSAIDs. ▪ Acceptable responses include the following: patient has an allergy to an excipient in oxaprozin tablets AND has tried and failed at least 3 other formulary NSAIDs Non-FDA approved uses are NOT approved PA does not expire (until complete exclusion implementation)
Utilization Management New PAs	
• potassium chloride 10 mEq packet (Pokonza) **Electrolyte-Mineral-Trace Element Replacement**	Manual PA criteria apply to all new and current users of potassium chloride 10 mEq packet (Pokonza). Manual PA criteria: Potassium chloride 10 mEq packet (Pokonza) is approved if all criteria are met: • Provider acknowledges other strengths and formulations of potassium chloride are available without prior authorization. • Provider must explain why the patient requires Pokonza and cannot take the cost-effective generic potassium chloride formulations. ▪ Acceptable responses include the following: o The patient has failed a trial of preferred potassium chloride capsules or tablets OR has documented swallowing difficulties (not due to convenience) o AND the patient has failed a trial of potassium chloride liquid AND potassium chloride 20 mEq packets, examples of failure include a documented allergy to an inactive ingredient Non-FDA-approved uses are not approved Prior authorization does not expire
• lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III) **Pain Agents: Pain Topical**	Manual PA criteria apply to all new and current users of lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III). Manual PA criteria: lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III) is approved if all criteria are met: • Provider acknowledges other formulations of lidocaine 5% patch are available without prior authorization. • Provider must explain why the patient requires DermacinRx Lidocan, Lidocan II, or Lidocan III and cannot take the cost-effective generic lidocaine 5% formulations. ▪ Acceptable responses include that the patient has failed a trial of at least 3 other preferred generic lidocaine 5% patches; examples of failure include a documented allergy to an inactive ingredient or the patch not adhering to skin. Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• glipizide 2.5 mg IR tablet **Diabetes Non-Insulin: Sulfonylureas**	Manual PA criteria apply to all new and current users of glipizide 2.5 mg IR tablets. Manual PA criteria: glipizide 2.5 mg IR tablets are approved if all criteria are met: • Provider acknowledges other formulations of glipizide are available without prior authorization. • Provider must explain why the patient requires glipizide 2.5 mg IR tablets and cannot take the cost-effective generic glipizide formulations. ▪ Acceptable responses include that the patient has failed a trial of preferred glipizide 5 mg split in half AND glipizide ER 2.5 mg Non-FDA-approved uses are not approved Prior authorization does not expire
• amcinonide 0.1% ointment **Corticosteroids-Immune Modulators: Medium Potency**	Manual PA criteria apply to all new and current users of amcinonide 0.1% ointment. Manual PA criteria: amcinonide 0.1% ointment is approved if all criteria are met: • Provider acknowledges this drug has been identified as having cost-effective alternatives including clobetasol 0.05% and fluocinonide 0.05% ointments. These agents do not require a PA. • Patient has tried for at least 2 weeks and failed, has a contraindication to, or has had an adverse reaction to fluocinonide 0.05%, desoximetasone 0.25% AND betamethasone dipropionate 0.05% ointments. • Provider must explain why the patient requires this agent and cannot take one of the cost effective alternatives. ▪ Acceptable responses include that the patient has had a past hypersensitivity to both desoximetasone AND betamethasone dipropionate (in any forms/concentrations) AND intolerance to carrier/vehicle of fluocinonide 0.05% ointment (specifically). Non-FDA-approved uses are not approved. Prior authorization does not expire.
• trientine 500 mg capsule **Binders-Chelators-Antidotes-Overdose Agents**	Manual PA criteria apply to all new and current users of trientine 500 mg capsules. Manual PA criteria: trientine 500 mg capsules are approved if all criteria are met: • Provider acknowledges other strengths of trientine capsules are available without prior authorization. • Provider must explain why the patient requires trientine 500 mg capsules and cannot take the cost-effective generic trientine formulations. ▪ Acceptable responses include if the patient has failed a trial of the preferred trientine 250 mg capsules (taking 2 capsules of the 250 mg to get to 500 mg) Non-FDA-approved uses are not approved Prior authorization does not expire
Utilization Management Updated PAs	
• olaparib (Lynparza) **Oncological Agents: Ovarian Cancer**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Lynparza. Manual PA Criteria: Lynparza is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist or urologist • Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test *see prostate diagnosis below for exception* • Lynparza will be prescribed as treatment for one of the following diagnoses: ▪ Recurrent or Stage IV Triple negative breast cancer

	▪ Recurrent or Stage IV hormone receptor (+) (ER, PR, or both) HER2(-) breast cancer AND was either: – Previously treated with prior endocrine therapy OR – Was not an appropriate candidate for endocrine therapy ▪ Recurrent advanced ovarian cancers (platinum-sensitive or platinum resistant), fallopian tube or primary peritoneal cancers AND – Patient has received at least 3 prior lines of therapy AND – Lynparza will not be used as a single agent ▪ Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene (e.g. BRCA, ATM)-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior androgen receptor-directed therapy – Of note, a patient does not require both a BRCA mutation and another separate HRR mutation; any HRR mutation satisfies requirement – this is an exception to the initial requirement that a patient have a BRCA mutation specifically ▪ Deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) in combination with abiraterone and prednisone or prednisolone ▪ Deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy • OR Lynparza will be prescribed as maintenance therapy for one of the following diagnoses: ▪ ~~**Platinum-sensitive, relapsed, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND**~~ **patients with deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or peritoneal cancer** – Patient has received 2 or more lines of platinum-based chemotherapy – Patient was in objective response (either complete or partial) to most recent treatment regimen – Lynparza will not be combined with bevacizumab (Avastin) ▪ Newly diagnosed, advanced, high-grade, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND – Patient has had a complete or partial response to primary therapy with a platinum-based therapy ▪ Metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis: _____. • Female patients are not pregnant or planning to become pregnant and will use highly effective contraception while taking Lynparza and for 6 months after the last dose • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Male patients will use effective contraception while taking Lynparza and for at least 3 months after cessation of therapy Other non-FDA-approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• encorafenib (Braftovi) **Oncological Agents**	**Updates from the February 2024 meeting are in bold.** Manual PA criteria apply to all new users of Braftovi. Manual PA criteria: Braftovi is approved if all criteria are met: • Age ≥ 18 years • Prescribed by or in consultation with an oncologist • Patient has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test • Patient has a diagnosis of: ▪ Unresectable or metastatic melanoma ▪ Unresectable or metastatic colorectal cancer ▪ **Metastatic non-small cell lung cancer** • Braftovi is being taken in combination with Mektovi, Vectibix, or Erbitux • Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis:_____ • Patient is not pregnant • Female patients of childbearing age will take highly effective contraception while taking the requested medication and for 2 weeks after the last dose • Patient will not breastfeed during treatment or within two weeks after the cessation of treatment • Male patients are aware that there is an increased chance of male infertility if the requested medication becomes supratherapeutic Other non-FDA-approved uses are not approved PA does not expire
• binimetinib (Mektovi) **Oncological Agents**	**Updates from the February 2024 meeting are in bold.** Manual PA criteria apply to all new users of Mektovi. Manual PA criteria: Mektovi is approved if all criteria are met: • Age ≥ 18 years • Prescribed by or in consultation with an oncologist • Has unresectable or metastatic melanoma or **metastatic non-small cell lung cancer** • Has confirmed BRAF V600E or BRAF V600K mutation by an FDA-approved test • Mektovi is being taken in combination with Braftovi • Patient is not on concurrent dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: Other non-FDA-approved uses are not approved

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	PA does not expire
• entrectinib (Rozlytrek) **Oncological Agents: Lung Cancer**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Rozlytrek. Manual PA Criteria: Rozlytrek will be approved if all criteria are met: • ~~**Patient is ≥ 12 years**~~ • Drug is prescribed by or in consultation with an oncologist • Patient has a diagnosis of either: ▪ ROS1(+) Metastatic NSCLC or ▪ The patient has a solid tumor that meets all three of the following criteria: – Has a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, and – Is metastatic OR where surgical resection is likely to result in severe morbidity, and – Has no satisfactory alternative treatments OR that has progressed following such treatment(s). • The patient has had a recent evaluation of his/her left ventricle including ejection fraction • The patient does not have decompensated congestive heart failure (CHF) • The patient has had a recent uric acid level evaluated • The provider is aware and has informed the patient of the risk of CHF development and exacerbation, myocarditis, neurotoxicity, fracture risk, hepatotoxicity, hyperuricemia, QT-prolongation, permanent visual impairment, and embryo-fetal toxicity • Female patients will not breastfeed during treatment and for 1 week after cessation of treatment • All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for at least 5 weeks or 3 months after cessation of treatment for females and males, respectively. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: Other non-FDA-approved uses are not approved PA does not expire
• enzalutamide (Xtandi) **Oncological Agents: 2nd Generation Antiandrogens**	**Updates from the February 2024 meeting are in bold.** Manual PA criteria apply to new users of Xtandi. Manual PA Criteria: Xtandi is approved if all criteria are met: • Patient is greater than or equal to 18 years of age • Medication is prescribed by or in consultation with an oncologist or urologist • Patient has documented diagnosis of: ▪ metastatic OR non-metastatic castration-resistant prostate cancer (CRPC) – If used in non-metastatic castration-resistant prostate cancer (nmCRPC) patient must have: PSADT ≤ 10 months ▪ OR metastatic castration-sensitive prostate cancer (mCSPC) ▪ **OR non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis**

	▪ 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: _____. • Patients **with CRPC or mCSPC** must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non-FDA-approved uses are NOT approved Prior authorization does not expire
• pirtobrutinib (Jaypirca) **Oncological Agents**	**Updates from the February 2024 meeting are in bold.** Manual PA criteria apply to all new users of pirtobrutinib (Jaypirca) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a hematologist or oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) • **OR patient has chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) and has received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor** • 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 1 week 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:_____ Other non-FDA approved uses are not approved, except as noted above PA does not expire
• ivosidenib (Tibsovo) **Oncological Agents: AML**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of ivosidenib (Tibsovo). <u>Manual PA Criteria</u>: Tibsovo is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • **Patient with a susceptible IDH1 mutation as detected by an FDA-approved test** • Patient has a diagnosis of 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 using Tibsovo as monotherapy OR in combination with azacitidine (Vidaza) 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

Appendix C—Table of Prior Authorization (PA) Criteria

	• **Patient has relapsed or refractory myelodysplastic syndrome (MDS) 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 Other non-FDA-approved uses are not approved Prior Authorization does not expire
• belzutifan (Welireg) **Oncological Agents**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Welireg Manual PA criteria: Welireg is approved if all criteria are met: • 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 OR • **The patient has advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)** • ~~**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 nonhormonal contraception during treatment and for at least 1 week 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 Non-FDA-approved uses are not approved, other than noted above Prior authorization does not expire
• venetoclax (Venclexta) **Oncological Agents: Non-BTKI for CLL**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to new users of Venclexta. Manual PA Criteria: Coverage for Venclexta is approved if all criteria are met: • Age ≥ 18 years • Drug is prescribed by or in consultation with a hematologist or oncologist • Venclexta will be used in one of the following contexts: ▪ Frontline therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation – Patient fits one of the following categories: • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patient < 65 years old – Will be combined with obinutuzumab (Gazyva) infusion ▪ Relapsed/refractory therapy for CLL/SLL without del(17p)/TP53 mutation

	– Patient fits one of the following categories: • Frail patient with significant comorbidity (not able to tolerate purine analogues) • Patient ≥ 65 years old with significant comorbidity • Patient < 65 years old ▪ Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation ▪ Patient has newly diagnosed acute myeloid leukemia (AML) and is a candidate for intensive remission induction therapy and meets the following criteria: – Age ≥ 60 years old – Unfavorable-risk cytogenetics (exclusive of AML with myelodysplasia-related changes) ▪ Patient is ≥ 60 years old and has newly diagnosed AML and is not a candidate for intensive remission induction therapy ▪ Patient is ≥ 60 years old and completed lower-intensity induction therapy for AML with a response ▪ Patient has relapsed refractory AML • Will titrate to therapeutic dose in consideration of tumor lysis syndrome (TLS) • ~~**Will not be concomitantly used at initiation or during ramp-up with a strong CYP3A inhibitor**~~ • **Provider is aware of the drug interactions and dose modifications recommended in the package insert** • Will prophylax and monitor for tumor lysis syndrome (TLS) (based on tumor burden-defined risk) • Will monitor for neutropenia • Will monitor for signs and symptoms of infection • Will not administer live attenuated vaccines prior to, during, or after treatment with Venclexta until B-cell recovery occurs. • If the patient is female, she is not pregnant or planning to become pregnant • Female patients will not breastfeed • Male patients have been informed of risk of infertility • Female patients of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Non-FDA approved uses are NOT approved Prior Authorization does not expire
• vosoritide (Voxzogo)	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Voxzogo. <u>Manual PA criteria</u>: Voxzogo is approved if all criteria are met:

Growth Stimulating Agents: Miscellaneous	~~• Patient is 5 years of age or older~~ • Drug is prescribed by or in consultation with a pediatric endocrinologist • Patient has a documented diagnosis of achondroplasia with open epiphyses • ~~**Patient/Caregiver and**~~ Provider acknowledges that Voxzogo was FDA approved in an accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials • ~~**Patient/Caregiver and**~~ Provider acknowledges that a clinical benefit with Voxzogo has not been proven • Patient/Caregiver have been instructed on how to properly use, store, and administer Voxzogo • Provider agrees to monitor growth and adjust dose according to body weight • Provider agrees to permanently discontinue Voxzogo upon closure of epiphyses Non-FDA-approved uses are not approved Prior Authorization expires after 1 year; provider must fill out a new PA
• roflumilast 0.3% cream (Zoryve) **Psoriasis Agents**	**Updates from the February 2024 meeting are in bold** Manual PA criteria apply to all new users of Zoryve **0.3% cream** Manual PA criteria: Coverage is approved if all criteria are met: • Patient is ~~12~~ **6** years of age or older • The medication is being prescribed by, or in consultation with, a dermatologist • The patient has a diagnosis of plaque psoriasis • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following: ▪ A topical corticosteroid – 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) OR – For patients ~~12~~ **6** to 17 year of age: any topical corticosteroid ▪ A topical calcineurin inhibitor (i.e., tacrolimus, pimecrolimus) Non-FDA approved uses are not approved PA does not expire
• tralokinumab-ldrm (Adbry) **Atopy**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Adbry. Manual PA criteria: Adbry is approved if all criteria are met: • Patient is ~~18~~ **12** years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – **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.**

	▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy Non-FDA-approved uses are not approved PA expires in 1 year Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies: • The patient's disease severity has improved and stabilized to warrant continued therapy.
• etanercept (Enbrel) **Targeted Immunomodulatory Biologics: TNF Inhibitors**	**Updates from the February 2024 meeting are in bold and strikethrough.** Step therapy and manual PA criteria apply to all new users. Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved for Enbrel if: contraindications exist to Humira OR inadequate response to Humira (need for different anti-TNF or non-TNF) OR adverse reactions to Humira not expected with requested non-step preferred TIB AND • Coverage approved for patients ≥ 18 years with: ▪ Moderate to severe active rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis ▪ Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy • Coverage approved for pediatric patients (age 2-17) with: ▪ Moderate to severe active polyarticular Juvenile Idiopathic Arthritis ▪ **Juvenile Psoriatic Arthritis. Note that a trial of non-biologic systemic therapy and Humira is required** • Coverage approved for pediatric patients ≥ 4 years (age 4-17) with: ▪ Plaque psoriasis. Note that a trial of Stelara is required for pediatric patients 6 years and older, however for patients ages 4 to 5 years old a trial of Stelara is not required for this age group. • Provider is aware that worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including ENBREL • 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 adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz), ustekinumab (Stelara), apremilast (Otezla), or rituximab (Rituxan) Non-FDA-approved uses are not approved Prior Authorization does not expire
• abatacept (Orencia) **Targeted Immunomodulatory**	**Updates from the February 2024 meeting are in bold.** Manual PA criteria apply to all new users of abatacept (Orencia).

Biologics: Non-TNF Inhibitors	Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, Orencia is approved if all criteria are met. • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira • Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication: • Moderate to severe active rheumatoid arthritis • Active psoriatic arthritis • 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.) • Coverage approved for patients 2 to 17 years of age with one of the following diagnosis/indication: ▪ Moderately to severely active polyarticular juvenile idiopathic arthritis ▪ **Active psoriatic arthritis. Note that a trial of non-biologic systemic therapy and Humira is required** • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) • May not be used concomitantly with other TIBs agents Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• secukinumab (Cosentyx) **Targeted Immunomodulatory Biologics: Non-TNF Inhibitors**	**Updates from the February 2024 meeting are in bold.** Manual PA criteria apply to all new users of secukinumab (Cosentyx). Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA Criteria: If automated criteria are not met, Cosentyx is approved if all criteria are met. • Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication: • Active psoriatic arthritis (PsA) • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy • 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 sacroilitis and ASDAS ≥ 2.1 • **Moderate to severe hidradenitis suppurativa (HS)**

Appendix C—Table of Prior Authorization (PA) Criteria

	OR Coverage approved for pediatric patients 6-17 years of age with diagnosis of: • Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy OR Coverage approved for pediatric patients 4-17 years of age with diagnosis of: • Active enthesitis-related arthritis (ERA) OR Coverage approved for pediatric patients 2-17 years of age with diagnosis of: • Active PsA Below criteria applies to all patients unless noted: • 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.) (Note: AS, ERA, **and HS** indications do not apply) • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS indication 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 Non-FDA-approved uses are not approved Prior Authorization does not expire
• beclomethasone (QVAR, QVAR Redihaler)) • budesonide (Pulmicort Flexhaler) • fluticasone furoate (Arnuity Ellipta) • ciclesonide (Alvesco) • flunisolide (Aerospan) • mometasone (Asmanex HFA, Asmanex Twisthaler) **Pulmonary 1-Agents: Inhaled Corticosteroids**	**Updates from the February 2024 meeting are in bold and strikethrough.** PA criteria apply to all new users of Alvesco, Arnuity Ellipta, Asmanex HFA, Asmanex Twisthaler, Pulmicort Flexhaler, Qvar, Qvar Redihaler who are older than 12 years of age. Automated PA criteria: The patient has filled a prescription for ~~**Flovent Diskus or Flovent HFA**~~ **fluticasone propionate** at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND Manual PA criteria: Alvesco, Arnuity Ellipta, Asmanex HFA, Asmanex Twisthaler, Pulmicort Flexhaler, Qvar, Qvar Redihaler are approved ~~**(e.g., trial of Flovent Diskus or Flovent HFA is NOT required)**~~ if: • Patient has experienced any of the following issues with **fluticasone propionate**, which is not expected to occur with the non-preferred ICS: ▪ inadequate response to the step preferred drugs ▪ Contraindication ▪ patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk Non-FDA approved uses are NOT approved Prior Authorization does not expire
• darolutamide (Nubeqa) **Oncological Agents: 2nd Generation Antiandrogens**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA is required for all new users of Nubeqa. Manual PA Criteria: Nubeqa is approved if all criteria are met: • Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent.

	• The patient is required to try Xtandi first. OR. Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Nubeqa AND • Patient is 18 years of age or older AND • Drug is prescribed by or in consultation with an oncologist or urologist AND • Patient has diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) AND • The patient has had a negative CT scan of abdomen/pelvis and/or negative bone scan AND • Prostate-specific antigen doubling time (PSADT) is 10 months OR • Patient has a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non-FDA-approved uses are not approved. PA expires in 1 year. ~~**Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Nubeqa is approved for 1 year for continuation therapy if all criteria are met:**~~ ~~• **The patient continues to be metastases-free**~~ ~~**The patient has not progressed onto subsequent therapy (such as abiraterone)**~~
• abiraterone (Zytiga) **Oncological Agents: CYP17 Inhibitors**	**Updates from the February 2024 meeting are in bold and strikethrough.** ~~***DoD will allow clinical PA to provide information for the 500mg tablets. Currently, the 250mg tablets are the preferred agent, so if the provider is willing to write for the 250mg tablets, then a new prescription will need to be written – but the PA will not need to be filled out more than once.***~~ Manual PA applies to all new users of Zytiga Coverage approved if <u>all</u> criteria are met: ~~• **Yonsa is the Department of Defense's preferred CYP17 Inhibitor Agent. Has the patient tried Yonsa? OR**~~ ~~• **Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Yonsa that is not expected to occur with requested agent**~~ • Patient is age 18 years or older • Drug is prescribed by or in consultation with an oncologist or urologist • Patient has documented diagnosis of non-localized disease including: ▪ metastatic castration-resistant prostate cancer (mCRPC), OR ▪ metastatic castration-sensitive prostate cancer (mCSPC), OR ▪ regional disease (TxN1M0) • OR the diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ • Patient must receive concomitant therapy with prednisone

	• Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog for example: Eligard, Lupron, Orgovyx, Trelstar, or Zoladex concomitantly OR have had a bilateral orchiectomy • ~~**Abiraterone acetate 250mg is the DoD's preferred strength. Is the prescription for Abiraterone acetate 250mg OR will the prescription be changed to the 250mg**~~ ▪ ~~**Note: If the prescription is being changed to the 250mg strength, please submit a new prescription with this PA form.**~~ ▪ ~~**Please state why the patient cannot take multiple 250mg tablets to achieve** the patient's daily dose (fill-in blank)_____~~ Other non-FDA-approved uses are NOT approved PA does not expire
• ropeginterferon alfa-2b-njft (Besremi) **Hematological Agents**	**Updates from the February 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Besremi. Manual PA criteria: Besremi is approved for 1 year if all criteria are met: • Provider acknowledges that another pegylated interferon (Pegasys) is available at the formulary copay and without requiring prior authorization • Patient is 18 years of age or older • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient has a confirmed diagnosis of polycythemia vera (PV) • ~~**Patient is high-risk (age >60 years and/or prior history of thrombosis)**~~ • Patient is currently taking aspirin 81 -100mg daily and is undergoing regular phlebotomy (to maintain hematocrit < 45%) **unless relatively contraindicated** • **If the patient has low-risk PV:** ▪ **Patient is symptomatic with potential indications for cytoreductive therapy (new thrombosis or disease-related major bleeding; frequent phlebotomy or intolerant of phlebotomy; splenomegaly; progressive thrombocytosis and/or leukocytosis; disease-related symptoms (eg, pruritus, night sweats fatigue)** • ~~**If the patient has high-risk PV:**~~ ▪ ~~**Patient must try and fail or be intolerant or resistant to (showing phlebotomy dependence and/or progressive splenomegaly) hydroxyurea OR**~~ ▪ ~~**The patient has a contraindication to hydroxyurea (e.g., pregnancy)**~~ • **Female patients of childbearing age are not pregnant confirmed by (-) HCG** • **Female patients will not breastfeed during treatment and for at least 8 weeks after the cessation of treatment** • **Female patients of childbearing potential agree to use effective contraception during treatment and for at least 8 weeks after the 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: _** Other non-FDA-approved uses are NOT approved including myeloproliferative neoplasms, essential thrombocythemia (ET), or adult T-cell leukemia (ATL). Prior Authorization expires after 1 year.

Appendix C—Table of Prior Authorization (PA) Criteria

	Renewal criteria: (Initial TRICARE PA approval is required for renewal) Coverage is approved for an additional year if the following criteria are met: • Patient has a documented improvement in symptoms
• ozanimod (Zeposia) **S1P Receptor Modulators**	**Updates from the February 2024 meeting are in bold. Note that there were not changes to the multiple sclerosis section.** Manual PA criteria apply to all new users of Zeposia. For Ulcerative Colitis Manual PA criteria: Zeposia is approved if all criteria are met: • Patient has a diagnosis of moderate to severely active Ulcerative Colitis • The patient is 18 years of age or older • Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis. • The patient must have tried Humira AND: ▪ 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 must have tried Velsipity AND:** ▪ **Had an inadequate response to Velsipity OR** ▪ **Experienced an adverse reaction to Velsipity that is not expected to occur with Zeposia.** ▪ **Has a contraindication to Velsipity OR** • 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.) Non-FDA-approved uses are NOT approved Prior Authorization does not expire
• tenapanor (Ibsrela) **Gastrointestinal 2: Chronic Idiopathic Constipation and Constipation-predominant Irritable Bowel Syndrome Agents**	**Updates from the February 2024 meeting are in bold and strikethrough. Note that there were not changes to the criteria for IBS-C** **Manual PA criteria apply to all new users of Ibsrela.** **For Hyperphosphatemia in CKD** **Manual PA criteria: Ibsrela is approved if all criteria are met:** • **The patient is 18 years of age or older** • **The drug is prescribed by or in consultation with a nephrologist** • **Patient has a diagnosis of hyperphosphatemia in chronic kidney disease (CKD)** • **Patient has been receiving maintenance dialysis for at least 3 months** • **Serum phosphate level is >5.5. mg/dL and <10 mg/dL** • **Patient has tried and had an inadequate response to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenal), ferric citrate (Auryxiz), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate) OR** • **Patient has tried and been unable to tolerate at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenal), ferric citrate (Auryxiz), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate) OR**

	• **Patient has a contraindication to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenal), ferric citrate (Auryxiz), sucroferric oxyhydroxide (Velphoro), calcium carbonate, calcium acetate intolerance to any dose of phosphate binder therapy. Contraindications to phosphate binders includes bowel obstruction, iron overload, or hypercalcemia** Non-FDA approved uses are NOT approved, including **PA does not expire for the indication of hyperphosphatemia in CKD patients receiving dialysis.**
• FreeStyle Libre 2 and 3 • Dexcom G6 and G7 **CGMs**	**Updates from the February 2024 meeting are in bold and ~~strikethrough~~** **Automated and** manual PA criteria apply to all new users of Abbott FreeStyle Libre 2 and 3 and Dexcom G6 and G7. **Automated PA criteria: The patient has filled a prescription for insulin (including basal or rapid acting insulin) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND** Manual PA criteria: **If automated criteria are not met, coverage is approved coverage is approved for FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6 and Dexcom G7** if all criteria are met: • *Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria* • Patient has a diagnosis of diabetes • **Patient is currently being treated with insulin. Please document the following:** ▪ **Insulin product: _____** ▪ **Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days.** • ~~**Patient is using basal and prandial insulin injections; OR patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR patient is on insulin therapy with a history of severe hypoglycemia episodes requiring medical intervention (grade 2 or higher)**~~ • ~~**Device is prescribed by an endocrinologist or diabetes management expert**~~ ▪ ~~**Diabetes management expert is defined as: licensed independent practitioner experienced in the management of insulin dependent diabetics requiring basal and bolus dosing or a pump and familiar with the operation and reports necessary for proper management of continuous glucose monitoring systems. This is a self-certification.**~~ • ~~**Documentation is required of all the following:**~~ ▪ ~~**Diagnosis**~~ ▪ ~~**Medication history**~~ ▪ ~~**Completion of a comprehensive diabetes education program**~~ ▪ ~~**Patient agrees to wear CGM as directed**~~ ▪ ~~**Patient agrees to share device readings with managing healthcare professional for overall diabetes management**~~ • ~~**Patient meets the age requirement (≥ two years if Dexcom G6 and Dexcom G7, ≥ two years if FreeStyle Libre 2, or FreeStyle Libre 3)**~~ • ~~**Provider and patient will assess the usage of self monitoring of blood glucose (SMBG) test strips with the goal of minimizing/discontinuing use**~~ Initial PA Expiration: annual Renewal expiration: annual for the manual PA Annual manual PA renewal criteria: • ~~**Confirm patient has seen endocrinologist or diabetes specialist within past year**~~ • Patient has utilized CGM daily

Appendix C—Table of Prior Authorization (PA) Criteria

	• Provider and patient will assess the usage of self monitoring of blood glucose (SMBG) at every visit with the goal of minimizing/discontinuing use • Patients with T2DM continue to require basal **or ~~and~~** prandial insulin injections daily • Patient continues to share data with managing healthcare professional for the purposes of clinical decision making • **Patient continues to be treated with insulin. Please document the following:** ▪ **Insulin product: _____** ▪ **Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days.**
• teriparatide injection (Forteo) **Osteoporosis Agents: Para Thyroid Hormone Analogs**	The following criteria will be added to existing PA criteria for teriparatide injection <u>Manual PA criteria:</u> teriparatide generics are approved if all criteria are met: • The provider acknowledges that the brand Forteo formulation is the preferred product over generic teriparatide 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 Forteo is a branded product, it will be covered at the generic formulary copayment or cost share) • A patient-specific justification must be provided as to why the brand Forteo product cannot be used in this patient. ▪ Acceptable reasons include the patient has had an adverse reaction to an excipient in brand Forteo that would not be likely to occur with the generic teriparatide
Nonformulary Generics Returning to Formulary Status and Step-Therapy Changes PA criteria	
• transdermal gel 1%, 1.62% (AndroGel, generics) • transdermal 1% gel tubes (Testim, Vogelxo generic) • transdermal solution (Axiron, generics) • transdermal 2% gel pump (Fortesta, generic) • transdermal 1% gel (Vogelxo) • transdermal patch (Androderm) • nasal gel (Natesto) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the February 2024 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Androderm, Androgel, Fortesta, Natesto, Testim, Vogelxo, and Axiron. <u>Manual PA Criteria</u>: **Androderm, Androgel, Fortesta, Natesto, Testim, Testosterone 1.62% gel, Vogelxo, and Axiron** approved if ALL criteria are met: Coverage approved for Hypogonadism if: • Patient is a male 18 years of age or older • Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions OR testosterone is prescribed by an endocrinologist or urologist who has made the diagnosis of hypogonadism based on unequivocally and consistently low serum total testosterone or free testosterone levels • Patient is experiencing signs and symptoms associated with hypogonadism • Provider has investigated the etiology of the low testosterone levels and has assessed the risks versus benefits of initiating testosterone therapy in this patient. Provider acknowledges that testosterone therapy is clinically appropriate and needed. OR Coverage approved for female-to-male gender-affirming hormone therapy in a natal female patient (assigned female at birth) if: • Patient is 14 years of age or older • Patient has diagnosis of Gender Dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) • Prescription if prescribed by an endocrinologist or a physician who specializes in the treatment of transgender patients • Patient is an adult, or is an adolescent with sufficient mental capacity to give informed consent for this partially irreversible treatment

	• Patient has experienced puberty to at least Tanner stage 2 • For gender dysphoria, biologically female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) OR If indication is not listed above, please write in requested indication and rationale for use: _____ (blank write-in) AND • Is the requested prescription for ~~2% gel (Fortesta) or generic testosterone 1% gel (Androgel)~~ **testosterone 1% gel (e.g., generic Androgel, generic Testim), 1.62% gel (generic Androgel), or 2% solution (generic Axiron)** – Yes, approve. No, answer below questions • Patient has tried and failed a 3-month trial, experienced a clinically significant adverse reaction, or had a contraindication or relative contraindication to one of the following: – **testosterone 1% gel (e.g., generic Androgel, generic Testim), 1.62% gel (generic Androgel), or 2% solution (generic Axiron)** OR does the patient require a testosterone replacement therapy that has a low risk of skin-to-skin transfer (option only for Androderm and Natesto) • Not approved for concomitant use with other testosterone products Testosterone will not be approved to enhance athletic performance. PA expires in 1 year Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply: • The patient has had a positive response to therapy • The risks of continued therapy do not outweigh the benefits
• testosterone cypionate IM injection • testosterone enanthate IM injection • testosterone enanthate SC injection (Xyosted) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the February 2024 meeting are in bold and strikethrough** PA does not apply to patients less than 1 year of age (age edit for testosterone cypionate or enanthate IM only) Manual PA criteria applies to new users of testosterone cypionate IM, testosterone enanthate IM, and testosterone enanthate (Xyosted) injections <u>Manual PA Criteria</u>: testosterone cypionate IM, testosterone enanthate IM, and testosterone enanthate (Xyosted) injections are approved if all criteria are met: • Coverage approved for male patients (patients male at birth) if: • Patient is younger than 18 years of age AND • Prescription is for testosterone cypionate IM or testosterone enanthate IM • Prescription is written by or in consultation with a pediatric endocrinologist or pediatric urologist OR • Patient is 18 years of age or older AND • Patient has a confirmed diagnosis of hypogonadism as evidenced by two or more morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions OR testosterone is prescribed by an endocrinologist or urologist who has made the diagnosis of hypogonadism based on unequivocally and consistently low serum total testosterone or free testosterone levels • Patient is experiencing signs and symptoms associated with hypogonadism • Provider has investigated the etiology of the low testosterone levels and has assessed the risks versus benefits of initiating testosterone therapy in this patient. Provider acknowledges that testosterone therapy is clinically appropriate and needed. OR

	Coverage approved for female-to-male gender-affirming hormone therapy in a natal female patient (assigned female at birth) if: • Patient is 14 years of age or older • Patient has diagnosis of Gender Dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) • Prescription if prescribed by an endocrinologist or a physician who specializes in the treatment of transgender patients • Patient is an adult, or is an adolescent with sufficient mental capacity to give informed consent for this partially irreversible treatment • Patient has experienced puberty to at least Tanner stage 2 • For gender dysphoria, biologically female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) OR Coverage approved for females if: • Patient has diagnosis of breast cancer • Prescription is written by or in consultation with an oncologist OR If indication is not listed above, please write in requested indication and rationale for use: _____ (blank write-in) AND • Is the requested prescription for testosterone cypionate IM or testosterone enanthate IM? o Yes, approve. No need to answer below questions • If requested prescription is for Xyosted, has the patient tried and failed a 3-month trial, experienced a clinically significant adverse reaction, or had a contraindication or relative contraindication to one drug from each of the following two categories? o testosterone cypionate IM injection or testosterone enanthate IM injection o ~~testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel)~~ **testosterone 1% gel (e.g., generic Androgel, generic Testim), 1.62% gel (generic Androgel), or 2% solution (generic Axiron)** • Not approved for concomitant use with other testosterone products. Testosterone will not be approved to enhance athletic performance. Prior Authorization expires in 1 year Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved in: • Children for one additional year if one of the following apply – The patient has had a positive response to therapy – The risks of continued therapy do not outweigh the benefits OR • Adults will be approved indefinitely for continuation of therapy if both of the following apply – The patient has had a positive response to therapy – The risks of continued therapy do not outweigh the benefits

Appendix C—Table of Prior Authorization (PA) Criteria

• testosterone undecanoate oral capsule (Jatenzo) • testosterone undecanoate oral capsule (Tlando) • testosterone undecanoate oral capsule (Kyzatrex) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the February 2024 meeting are in bold and strikethrough** Manual PA criteria applies to new users of Jatenzo, Tlando, and Kyzatrex Manual PA Criteria: Jatenzo, Tlando, or Kyzatrex is approved if all criteria are met: Coverage approved for hypogonadism if: • Patient is a male age 18 years of age or older • Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions OR testosterone is prescribed by an endocrinologist or urologist who has made the diagnosis of hypogonadism based on unequivocally and consistently low serum total testosterone or free testosterone levels • Patient is experiencing signs and symptoms associated with hypogonadism • Provider has investigated the etiology of the low testosterone levels and has assessed the risks versus benefits of initiating testosterone therapy in this patient. Provider acknowledges that testosterone therapy is clinically appropriate and needed. OR Coverage approved for female-to-male gender-affirming hormone therapy in a natal female patient (assigned female at birth) if: • Patient is 14 years of age or older • Patient has diagnosis of Gender Dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) • Prescription if prescribed by an endocrinologist or a physician who specializes in the treatment of transgender patients • Patient is an adult, or is an adolescent with sufficient mental capacity to give informed consent for this partially irreversible treatment • Patient has experienced puberty to at least Tanner stage 2 • For gender dysphori~~a~~, biologically female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) OR If indication is not listed above, please write in requested indication and rationale for use: _____ (blank write-in) AND • Patient has tried and failed a 3-month trial, experienced a clinically significant adverse reaction, or had a contraindication or relative contraindication to one drug from each of the following two categories: 1. testosterone cypionate IM injection or testosterone enanthate IM injection 2. ~~testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel)~~ **testosterone 1% gel (e.g., generic Androgel, generic Testim), 1.62% gel (generic Androgel), or 2% solution (generic Axiron) ~~testosterone 1% gel, 1.62% gel, or 2% solution~~** • Not approved for concomitant use with other testosterone products Testosterone will not be approved to enhance athletic performance. PA expires in 1 year Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply: • The patient has had a positive response to therapy • The risks of continued therapy do not outweigh the benefit

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• adalimumab-afzb (Abrilada) **TIBs**	▪ Retail/MTF/Mail: 60-day supply
• bimekizumab-bkzx (Bimzelx) **TIBs**	▪ Retail/MTF/Mail: 60-day supply
• capivasertib (Truqap) **Oncological**	▪ Retail/MTF/Mail: 60-day supply
• crizotinib (Xalkori) oral pellets **Oncological**	▪ Retail/MTF/Mail: 30-day supply
• fruquintinib (Fruzaqla) **Oncological**	▪ Retail/MTF/Mail: 60-day supply
• mirikizumab-mrkz (Omvoh) **TIBs**	▪ Retail/MTF/Mail: 60-day supply
• momelotinib (Ojjaara) **Oncological**	▪ Retail/MTF/Mail: 60-day supply
• nirogacestat (Ogsiveo) **Oncological**	▪ Retail/MTF/Mail: 60-day supply
• repotrectinib (Augtyro) **Oncological**	▪ Retail/MTF/Mail: 60-day supply

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

Drug / Drug Class	Quantity Limits
• vedolizumab (Entyvio) **TIBs**	▪ Retail/MTF/Mail: 60-day supply
• vonoprazan (Voquezna) **Proton Pump Inhibitors: Potassium-Competitive Acid Blockers**	▪ Retail: 30 days per fill ▪ MTF and Mail Order: 90 days per fill
• etrasimod (Velsipity) **SP-1 Phosphate Receptors**	▪ Retail/MTF/Mail: 60-day supply
• perfluorohexyloctane ophthalmic (Miebo) **Ophthalmic: Dry Eye Agents**	▪ Retail: 1 bottle/30 days ▪ MTF and Mail Order: 3 bottles/90 days

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• adalimumab-afzb (Abrilada) TIBS: Tumor Necrosis Factor Inhibitors	• Humira and its biosimilars	• Prefilled pen: 40 mg/0.8 mL • Prefilled syringe: 10 mg/0.2mL, 20 mg/0.4mL, 40 mg/0.8 mL • Dosing: varies based on indication	• Rheumatoid Arthritis • Juvenile Idiopathic Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Adult Crohn's Disease • Pediatric Crohn's Disease • Ulcerative Colitis • Plaque Psoriasis • Hidradenitis Suppurativa • Uveitis	ADRs (>10%): • infections • injection site reactions • headache • rash	• Ninth Humira biosimilar to launch out of nine FDA approved Humira biosimilars • Abrilada only comes in a low concentration formulation • This formulation is citrate free and latex free • Abrilada is interchangeable with the reference product • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • MN • QL • EMMPI
• bimekizumab-bkzx (Bimzelx) TIBS: Non-Tumor Necrosis Factor Inhibitors	• Humira • Otezla • Cosentyx • Taltz • Tremfya • Cimzia • Sotyktu	• Prefilled syringe: 160mg/ml • Autoinjectors: 160mg/ml • Dosing: 320 mg SC at weeks 0, 4, 8, 12, 16 then Q8W thereafter	• Moderate to Severe Plaque Psoriasis in adults who are not candidates for systemic therapy or phototherapy	ADRs (>1%): • upper respiratory track infections • oral candidiasis • injection site reactions • tinea infections • gastroenteritis • herpes simplex infections • acne • folliculitis • other candida infections • fatigue	• Interleukin 17A/17F blocker • First phase 3 study demonstrated a higher proportion of patients on Bimzelx achieved a PASI 90 at Week 16 (85% vs. 50% vs Stelara and 5% for placebo) • Second phase 3 study demonstrated a higher proportion of patients on Bimzelx achieved a PASI 90 at Week 16 (86% vs. 47% with adalimumab) • Third phase 3 study demonstrated a PASI 90 response at Week 16 which higher with Bimzelx (91%) compared with placebo (1%) • Bimzelx can only be used in adults while Cosentyx can be used in pediatric patients as young as 6 years old • Bimzelx has unique warnings for suicidal ideation/behavior and liver biochemical abnormalities • Bimzelx does have a unique adverse effect of oral candidiasis, which is mostly mild to moderate in nature • Provides a therapeutic alternative to other IL-17 blockers, IL-23 blockers and other biologics	• NF non-step-preferred • PA • MN • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• capivasertib (Truqap) Oncological Agents	• Pikray • Verzenio • Ibrance • Kisqali	• Oral Tablet: 160 mg 200 mg • Dosing: 400 mg BID x 4 days followed by 3 days off	• HR-positive, HER2-negative locally advanced or metastatic breast cancer	ADRs (>20%): • diarrhea, • cutaneous adverse reactions • increased random & fasting glucose • decreased lymphocytes, hemoglobin, leukocytes, neutrophils • decreased hemoglobin • nausea/vomiting • stomatitis • fatigue • increased triglycerides • increased creatinine	• First-in-class inhibitor of all three AKT isoforms (AKT1/2/3) for the treatment of HR-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations after progression or recurrence on previous therapy • Phase 3 study demonstrated Truqap + fulvestrant reduced the risk of disease progression or death by 50% compared with placebo + fulvestrant in the AKT pathway-altered population • NCCN guidelines cite Truqap plus fulvestrant as a category 1 “Preferred Regimen” for PIK3CA/AKT1/PTEN-activating mutations as second or subsequent-line therapy • Pikray is indicated for patients with a PIK3CA mutation as second or subsequent-line therapy • Provides an option in the second line setting for patients with one of the PIK3CA/AKT1/PTEN pathways	• UF • PA • QL • EMMPI
• clindamycin 1.2%, adapalene 0.15%, and benzoyl peroxide 3.1% topical gel (Cabtreo) Acne Agents: Topical Acne and Rosacea Agents	• clindamycin/ benzoyl peroxide 1.2% - 5% gel • adapalene 0.3% gel • Twyneo	Topical gel consisting of: • clindamycin phosphate 1.2% • adapalene 0.15% • benzoyl peroxide 3.1% • Dosing: Apply thin layer once daily	• Acne vulgaris in adults and pediatrics >12 years of age	ADRs (>1%) • application site reactions • pain • erythema • dryness • irritation • exfoliation • dermatitis	• Cabtreo is a combination acne product • Two phase 3 studies demonstrated higher mean absolute reductions in inflammatory and non-inflammatory lesions vs. vehicle • Adverse reactions were mostly mild to moderate and consisted mainly of local skin reactions • Despite this combination being a guideline recommended first-line treatment option for mild, moderate, and severe acne, there are multiple generic drugs on the formulary containing these agents as single or dual combos • Provides no compelling clinical advantage over existing agents	• Complete Exclusion • Interim PA until Complete Exclusion implementation

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• crizotinib oral pellets (Xalkori) Oncological Agents	• Xalkori • Lobrena • Tabrecta • Alecensa	• Oral pellets: 20 mg 50 mg 100 mg • Dosing: NSCLC: 250 mg PO BID ALCL: 280 mg/m2 PO BID Unresectable IMT: 250 mg PO BID (adults), 280 mg/m2 PO BID (pediatrics)	• Adults with metastatic Non-Small Cell Lung Cancer (NSCLC) whose tumors are Anaplastic Lymphoma Kinase (ALK) or ROS1-positive • Pts ≥1 year/young adults with relapsed or refractory, systemic Anaplastic Large Cell Lymphoma (ALCL) that is ALK-positive. • Pts ≥1 year/adults with unresectable, recurrent or refractory Inflammatory Myofibroblastic Tumor (IMT) that is ALK-positive	ADRs (>25%): • vision disorders • nausea • diarrhea • vomiting • edema • constipation • elevated transaminases • fatigue • decreased appetite • upper respiratory infection • dizziness • neuropathy	• Another oral formulation of crizotinib in oral pellets that has the same indications and dosing as the original Xalkori capsule formulation • No new clinical studies; approval based on bioavailability to the capsules • Xalkori capsules should be swallowed whole; do not chew, crush or split • Xalkori received the indication for patients as young as 1 year of age in 2021, however the only available dosage form were the capsules. Approval of the pellets in Sept 2023 now allows an alternative dosage formulation for patients with low Body Surface Area and young children • Pellets should be reserved for children or adults with low body surface area	• UF • PA • QL • EMMPI
• daprodustat (Jesduvroq) Hematological Agents	Erythropoietin stimulating agents (ESAs): • Procrit/Epogen • Retacrit • Aranesp	• Oral tablets: 1 mg 2 mg 4mg 6 mg 8 mg • Dosing: varies based on hemoglobin level, liver function, and concomitant medications	• Adults with anemia due to chronic kidney disease who have been receiving dialysis for at least 4 months	ADRs (>10%): • hypertension • thrombotic vascular events • abdominal pain	• Oral hypoxia-inducible factor prolyl hydroxylase inhibitor to treat anemia due to chronic kidney disease in adults • Phase 3 study demonstrated non-inferiority of Jesduvroq to ESA therapy in the mean change in Hgb from baseline to weeks 28 -52 and for major adverse CV events • Contains a BBW for increased risks of death, MI, stroke, venous thromboembolism and thrombosis of vascular access, similar to ESAs • As an oral therapy, is also associated with gastrointestinal adverse effects (i.e., gastric or esophageal erosions) • ESAs have an expanded role in the management of anemia due to CKD for those on dialysis and not on dialysis	• NF • PA • MN • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					• Jesduvroq can cause fetal harm and breastfeeding is not recommended until 1 week after the last dose • Not recommended in severe hepatic impairment (Child-Pugh Class C) • Provides no compelling clinical advantage over existing agents	
• etrasimod (Velsipity) S-1P receptor modulators	• Humira • Zeposia	• Oral tablet: 2 mg • Dosing: 2mg PO daily	• Treatment of moderately to severely active Ulcerative Colitis in adults	ADRs (≥5%): • headache • elevated liver tests • dizziness	• Velsipity is another oral S1P indicated for the treatment of moderate to severe ulcerative colitis • Clinical studies demonstrated statistically significant achievement of clinical remission when compared to placebo, and additional secondary endpoints were also met • A 2023 NMA comparing ozanimod and etrasimod demonstrated similar outcomes for inducing clinical remission and adverse events. • Provides no compelling clinical advantage over existing agents	• UF • PA • Do not add to EMMPI List
• fruquintinib (Fruzaqla) Oncological Agents	• Lonsurf • Xeloda • Stivarga	• Oral capsules: 1 mg 5 mg • Dosing: 5 mg PO QD for the first 21 days	• Adults with metastatic Colorectal Cancer (mCRC) previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy	ADRs (≥20%): • hypertension • palmar-plantar erythrodysesthesia • proteinuria • dysphonia • abdominal pain • diarrhea • asthenia	• VEGF inhibitor for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-based chemotherapy, anti-VEGF therapy and if RAS wild-type and medically appropriate, an anti-EGFR therapy • Two phase 3 studies demonstrated a higher overall survival rate vs. placebo (7.4 months vs. 4.8 months and 9.3 months vs. 6.6 months, respectively) • Fruzaqla has a high incidence of hypertension which must be addressed prior to therapy and monitored while on therapy • Provides an alternative third line option for patients with metastatic colorectal cancer	• UF • PA • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• lacosamide extended release (Motpoly XR) Anticonvulsants Antimania Agents	• lacosamide tablet • lacosamide solution	• Extended Release Capsule: 100 mg 150 mg 200 mg • Dosing: 100 mg to 400 mg PO Daily	• Treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg	ADRs (≥10%) • dipolopia • headache • dizziness • nausea • somnolence	• Extended-release lacosamide formulation for partial-onset seizures in adults and in pediatric patients weighing at least 50 kg • No new clinical studies are available as it was approved via the 505(b)(2) pathway using data from the originator product Vimpat • Motpoly XR can be used in pediatric patients greater than 50 kg and is dosed once daily, while its competitor, lacosamide tablet (Vimpat), can be used in patients who are 1 month or older and is dosed twice daily • Provides no significant clinical advantage over existing agents	• NF • PA • MN • Do not add to EMMPI List
• methotrexate (Jylamvo) oral solution Antirheumatics	• methotrexate tablet • Xatmep	• Oral solution: 2 mg/mL • Dosing: varies based on indication	• Acute Lymphoblastic Leukemia • Mycosis Fungoides • Non-Hodgkin Lymphoma • Rheumatoid Arthritis • Severe Psoriasis	Common ADRs: • ulcerative stomatitis • leukopenia • nausea • abdominal distress	• Jylamvo is another formulation of methotrexate oral solution • No new clinical studies; approved via 505(b)(2) pathway • Available in a 2 mg/mL concentration with an orange flavor • Provides little to no compelling clinical advantage over existing agents	• UF • PA • Do not add to EMMPI List
• metronidazole (Likmez) oral suspension Gastrointestinal-2 Agents: Miscellaneous	• metronidazole tablets and capsules	• Oral Suspension: 500 mg/5 mL • Dosing: varies based on indication and patient age/weight	• Trichomoniasis in adults • Amebiasis in adults and pediatric patients • Anaerobic bacterial Infections in adults	Common ADRs: • nausea • headache • anorexia • vomiting • diarrhea • abdominal cramping • epigastric distress • constipation	• Likmez is an oral suspension formulation of metronidazole for the treatment of trichomoniasis, amebiasis, and anaerobic bacterial infections • No new clinical studies; approved via 505(b)(2) pathway • Alternatively, metronidazole IR tablets can be cut or crushed, but they have an unpleasant, metallic taste • Likmez offers a taste-masked, oral suspension for children and adults with swallowing difficulties	• UF • PA • 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	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• mirikizumab-mrkz (Omvoh) Targeted Immuno-modulatory Biologics (TIBs)	• Humira • Stelara • Rinvoq • Entyvio	• Prefilled pen: 100 mg/ml • Dosing: 200mg SC at week 12 then Q4W following 300 mg IV induction	• Treatment of moderately to severely active Ulcerative Colitis in adults	ADRs (≥2%) • upper respiratory tract infections • injection site reactions • arthralgia • rash • headache • herpes viral infection	• New SC IL-23 antagonist indicated for maintenance after induction with IV therapy • Phase 3 study demonstrated more patients treated with Omvoh 200 mg SC Q4W achieved clinical remission at 40 weeks compared with placebo (51% vs. 27%, respectively) • Safety similar toother options in class, URI/Infection, injection site reaction most common • Does carry risk for hepatoxicity, monitor • Provides an alternative to Humira, Stelara, Entyvio and other biologics for maintenance treatment of ulcerative colitis in adults	• UF, non-step preferred • PA • QL • Do not add to EMMPI List
• momelotinib (Ojjaara) Oncological Agents	• ruxolitinib (Jakafi) • fedratinib (Inrebic)	• Oral tablet: 100 mg 150 mg 200 mg • Dosing: 200 mg PO daily	• Treatment of intermediate or high-risk Myelofibrosis (MF), including 1° MF or 2° MF [Post-polycythemia vera (PV) and Post-essential Thrombo-cythemia (ET)], in adults with anemia	ADRs (≥20%) • thrombocytopenia • hemorrhage • bacterial infection • fatigue • dizziness • diarrhea • nausea	• Ojjaara is approved for the treatment of intermediate or high-risk myelofibrosis, including primary MF or secondary MF in adults with anemia • Efficacy was established via two clinical trials: One single phase 3 study demonstrated statistically significant reduction in spleen volume and improvement in the Myelofibrosis Symptom Assessment Form: Total Symptom Score compared to danazol. An additional phase 3 study demonstrated non-inferiority of Ojjaara when compared to Jakafi for reducing spleen volume • Common adverse events included thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, nausea • Ojjaara provides an additional treatment option for this fatal disorder	• UF • PA • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• nirogacestat (Ogsiveo) Oncological Agents	• sorafenib • imatinib	• Oral tablet: 50 mg • Dosing: 150 mg PO twice daily until disease progression or unacceptable toxicity	• Adults with progressing desmoid tumors who require systemic treatment	ADRs (≥15%) • diarrhea • ovarian toxicity • rash • nausea • fatigue • stomatitis • headache • abdominal pain • cough • alopecia • URI • dyspnea	• Ogsiveo is approved for the treatment of adults with progressive desmoid tumors who require systemic treatment. • A phase 3 study demonstrated a statistically significant 71% reduction of in the risk of disease progression or death for Ogsiveo-treated patients compared to placebo. • Common adverse events include diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, URI, and dyspnea • Ogsiveo provides an additional pharmacologic treatment option for this locally aggressive tumor	• UF • PA • QL • EMMPI
• oxaprozin 300 mg capsules (Coxanto) Pain Agents	• oxaprozin 600 mg tablet • meloxicam tablet • naproxen sodium controlled release (Naprelan, generic) • Zipsor	• Oral capsule: 300 mg • Dosing: varies based on indication and patient weight	Relief of signs and symptoms of the following: • Osteoarthritis (OA) • Rheumatoid Arthritis • Juvenile Rheumatoid Arthritis	ADRs (>3%) • constipation • diarrhea • dyspepsia • nausea • rash	• Coxanto is another oral formulation of oxaprozin • No new clinical studies; approved via 505(b)(2) pathway • Several other NSAIDs are designate UF and available as generics • Provides no compelling clinical advantage over existing agents	• Complete Exclusion • Interim PA until Complete Exclusion implementation
• repotrectinib (Augtyro) Oncological	• Xalkori	• Oral capsule: 40 mg • Dosing: 160 mg PO Daily x 14 days then increase to 160 mg PO BID	• Treatment adults with locally advanced or metastatic ROS1-positive Non-Small Cell Lung Cancer (NSCLC)	ADRs (>20%) • dizziness • dysgeusia • peripheral neuropathy • constipation • dyspnea • ataxia • fatigue • cognitive disorders • muscular weakness	• Another ROS1 inhibitor for ROS1-positive NSCLC • Phase 1/2 single arm study demonstrated 79% overall response rate (ORR) in TKI-naïve patients and 38% ORR in TKI-pretreated patients • Current NCCN guidelines recommend Rozlytrek, Xalkori, and Augtyro as preferred first-line treatment options for ROS1-positive NSCLC • Augtyro does not have warnings for QT prolongation like Xalkori and Rozlytrek • Head-to-head study versus Xalkori underway with results expected in 2031 • Provides another option for ROS1-positive NSCLC	• UF • PA • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• tenapanor (Xphozah) Electrolyte Depleting Agents	• Renagel • Renlev • Fosrenol • Auryxia • Velphoro • Ibsrela	• Oral tablets: 20 mg 30 mg • Dosing: 30 mg PO BID	• Reduce serum phosphorus in adults with Chronic Kidney Disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy	ADRs (43-53%) • diarrhea	• Phosphate absorption inhibitor approved to decrease serum phosphate (s-P) in adults with CKD on dialysis • Three phase 3 studies demonstrated a greater proportion of patients achieved modest ↓ in s-P as monotherapy and/or in combination with phosphate binders vs. placebo • Xphozah ↓ phosphate levels by 0.7 mg/dL, compared to ~1.5 to 2.2 mg/dL decrease seen with traditional phosphate binders • s-P is a surrogate outcome accepted by the FDA; there is no date to show that lowering s-P results in decreased CV events or mortality • Clinical practice guidelines do not currently mention Xphozah • Also approved under the trade name Ibsrela to treat IBS-C; accordingly, diarrhea is the main AE, occurring in approximately 50% of patients; usually is mild to moderate, but severe diarrhea reported in 5% of pts • Provides an alternative option to lower phosphate levels with a lower tablet burden than traditional phosphate binders in patients with CKD on dialysis but place in therapy remains to be determined and diarrhea is a notable adverse event	• NF • PA • MN • EMMPI
• tirzepatide (Zepbound) Weight Loss Agents	• Saxenda • Wegovy • Qsymia • Contrave	• Prefilled pen: • 2.5 mg/0.5ml, 5 mg/0.5ml, 7.5 mg/0.5ml, 10 mg/0.5ml, 12.5 mg/0.5ml, 15 mg/0.5ml, • Dosing: 2.5mg SC Weekly	• Chronic weight management in adults with an initial body mass index (BMI) ≥30 kg/m2 (obesity) or ≥27 kg/m2 (overweight) who have at least one comorbid condition (e.g., hypertension, dyslipidemia, T2DM, obstructive sleep apnea or cardiovascular disease)	ADRs (>5%) • nausea • diarrhea • vomiting • constipation • abdominal pain • dyspepsia • injection site reaction • fatigue • hypersensitivity reactions • eructation • hair loss • gastroesophageal reflux disease	• Third GLP-1 agonist approved for weight loss in adults; it is also an agonist of GIP • First phase 3 study demonstrated average weight loss, in patients with at least one weight-related comorbid condition, of -20.9% (-24.4 kg) for Zepbound 15 mg vs. -3.1% with placebo • Second phase 3 study demonstrated average weight loss in T2DM patients of -14.7% with Zepbound 15 mg vs. -3.2% with placebo • Meta-analysis demonstrated tirzepatide 15 mg followed by the tirzepatide 10 mg regimen had improved efficacy outcomes compared with all other GLP-RAs, with a comparable safety profile to the other GLP-1 RAs	• UF • PA • 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	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					• Unlike Wegovy and Saxenda, Zepbound is not labeled for use in pediatrics • Ongoing CV outcomes trial, will provide further clarity on potential long-term effects of Zepbound among patients with and without existing CV disease • Zepbound appears to provide similar safety and more potent weight reduction than Wegovy and Saxenda in adults with obesity or overweight with one or more weight-related comorbidities	
• vedolizumab (Entyvio) TIBs	• Humira • Stelera • Rinvoq • Omvoh	• Prefilled syringe: 108 mg/0.68 mL • Prefilled Pen: 108 mg/0.68 mL • Dosing: 108 mg SC Q2W at week 6 after 2 IV doses	• Moderately to severely active Ulcerative Colitis • Moderately to severely active Crohn's disease	ADRs (≥3%) • nasopharyngitis • headache • arthralgia • nausea • pyrexia • upper respiratory tract infection • fatigue • cough • bronchitis • influenza • back pain • rash • pruritis • sinusitis • oropharyngeal pain • pain in extremities	• New SC formulation of Entyvio indicated for maintenance of moderately to severely active ulcerative colitis in adults who have received induction with IV Entyvio • Phase 3 study demonstrated a greater proportion of patients treated with Entyvio SC maintenance therapy were in clinical remission at Week 52 vs. Placebo (46% vs. 14% respectively) • Clinical remission was more common in patients who had not previously received a TNFi (54%, 19%, and 53% for Entyvio SC, placebo, and Entyvio IV) vs. Those with previous TNFi exposure (33%, 5%, and 27% for respective treatment groups). • Safety findings were similar between Entyvio SC and IV where they both have a warning for progressive multifocal leukoencephalopathy (PML) • Provides and alternative to Entyvio IV for maintenance treatment of ulcerative colitis in adults	• UF non-step-preferred • PA • QL • EMMPI
• vonoprazan (Voquezna) **Proton Pump Inhibitors: Potassium-Competitive Acid Blockers**	• omeprazole • rabeprazole • dexlansoprazole • Voquezna dual and triple packs	• Oral tablets: 10 mg 20 mg • Dosing: Treatment: 20mg PO Daily x 8 weeks	Adults with the following: • Healing of all grades of Erosive Esophagitis (EE) and relief of heartburn associated with erosive esophagitis.	ADRs (≥2%) • gastritis • diarrhea • abdominal distension • abdominal pain • nausea • dyspepsia	• Voquezna provides a new mechanism (PCAB) for: • Healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis • Maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis	• NF • PA • MN • QL • EMMPI

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
		Maintenance: 10mg PO Daily x 6 months	• Maintenance of healing of EE • In combination with amoxicillin and clarithromycin for Helicobacter pylori (H. pylori) infection • In combination with amoxicillin for H. pylori infection	• hypertension • urinary tract infection	• Can be used in combination with amoxicillin and clarithromycin or in combination with amoxicillin alone for the treatment of H. pylori infection • Phase 3 study demonstrated higher rates of healing and maintenance of healing of erosive esophagitis with Voquezna than lansoprazole, largest difference seen in those with more severe esophagitis • Similar safety as seen with PPIs, but still awaiting more long-term safety data • U.S. GERD guidelines do not yet discuss Voquezna's role in therapy • Provides a therapeutic alternative to generically available proton pump inhibitors	
zuranolone (Zurzuvae) Antidepressants and Non-Opioid Pain Syndrome Agents	• citalopram • sertraline • Trintellix • Viibryd • Festzima • Pexeva	• Oral Capsules: 25 g 25 mg 30 mg • Dosing: 50 mg PO Daily x 14 days	• Treatment of Postpartum Depression (PPD) in adults	ADRs (≥5%) • somnolence • dizziness • diarrhea • fatigue, • nasopharyngitis • urinary tract infection	• First oral medication for postpartum depression; second neuroactive GABA-A receptor modulator with this indication after brexanolone (Zulresso) (medical benefit) • No head-to-head trials are available comparing Zurzuvae with alternative treatment options. • In pivotal trials, it showed clinically and statistically significant changes from baseline in HAMD-17 scores compared with placebo. • Zurzuvae demonstrates a rapid onset of symptom relief as early as day 3 with sustained symptom reduction through day 45. This rapid onset is comparable to brexanolone, with symptom reduction starting as early as 24hrs post infusion, in contrast to SSRIs and SNRIs which typically take 3-4 weeks for symptom reduction. • In terms of safety, zuranolone carries black box warnings and caution for somnolence. • ACOG recommends considering Zurzuvae for treatment of moderate to severe PPD, alone or as an adjunct to other oral antidepressant therapy (SSRIs and SNRIs). • Overall Zurzuvae offers a new oral option for treatment of postpartum depression	• UF • PA • Do not add to EMMPI

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary*

Table 1: Mail Order Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes

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 2024	**Drug Class Reviews** **Growth-Stimulating Hormone Agents (see Table 2)** **Utilization Management/Re-evaluation of NF Generics** **Androgens-Anabolic Steroids: Testosterone Replacement Therapy (Transdermal/Nasal Agents)** *Retain branded agents on EMMPI* • Androgel, Androderm, Fortesta, Natesto, Testim, Vogelxo **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated NF*** *No reason to exempt from NF-2-Mail requirement:* • daprodustat (Jesduvroq) • tenapanor (Xphozah) • vonoprazan (Voquezna)	**Drug Class Reviews** **Growth-Stimulating Hormone Agents** ***Designated UF*** *Not cost advantageous to government* • somapacitan (Sogroya) • somatrogon-ghla (Ngenla) • somatropin injection (Norditropin, Genotropin, Zomacton) ***Designated NF*** *Exempt from NF requirement (not cost advantageous to government)* • lonapegsomatropin (Skytrofa) • somatropin injection (Humatrope, Nutropin, Saizen, Serostim) **Utilization Management/Re-evaluation of NF Generics** **Androgens-Anabolic Steroids: Testosterone Replacement Therapy (Transdermal/Nasal Agents)** *Remove generic agents moving to UF status* • testosterone 1.62% gel (Androgel, generics) • testosterone 2% solution (Axiron, generics) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** *Acute or limited duration of use* • metronidazole oral suspension (Likmez) • zuranolone (Zurzuvae) *Not cost advantageous to government* • etrasimod (Velsipity) • methotrexate oral solution (Jylamvo) • mirikizumab-mrkz (Omvoh) • tirzepatide (Zepbound) ***Designated NF*** *Exempt from NF requirement (limited distribution/availability)* • lacosamide extended-release capsule (Motpoly XR)

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy. Medications subject to EMMPI program requirements are listed on the Select Maintenance Drug List.

Table 2: Mail Order Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

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 2024	**Drug Class Reviews** **Growth-Stimulating Hormone Agents (see Table 2)** ***Designated UF*** • Somatropin injection (Omnitrope) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** *Designated UF* • capivasertib (Truqap) • crizotinib oral pellets (Xalkori) • fruquintinib (Fruzaqla) • momelotinib (Ojjaara) • nirogacestat (Ogsiveo) • repotrectinib (Augtyro) • vedolizumab (Entyvio) *Designated NF* *No reason to exempt from NF-2-Mail requirement, similar agents already on list:* • adalimumab-afzb (Abrilada) • bimekizumab-bkzx (Bimzelx) **Drugs or Drug Classes Designated by the P&T Committee as Generally Suitable for Inclusion** ***Designated UF*** ***Added as Individual Agents*** • regorafenib (Stivarga) • vismodegib (Erivedge)	

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy. Medications subject to EMMPI program requirements are listed on the Select Maintenance Drug List.

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: April 22nd, 2024

Two weeks after signing: May 8th, 2024

30 days after Signing: May 29th, 2024

60 days after signing: June 26th, 2024

90 days after signing: July 31st, 2024

120 days after signing: August 28th, 2024

*** Note that implementation occurs the first Wednesday following "X" days after signing of the minutes in all points of service.**

Appendix H—Completely Excluded Agents and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Complete Excluded Products	Formulary Alternatives	Implementation
February 2024	Acne Agents: Topical Acne and Rosacea	• clindamycin 1.2%, adapalene 0.15%, and benzoyl peroxide 3.1% topical gel (Cabtreo)	• clindamycin/benzoyl peroxide gel • adapalene gel • tretinoin cream	• 120 days
February 2024	Pain Agents: NSAIDs	• oxaprozin 300 mg capsules (Coxanto)	• meloxicam • oxaprozin 600 mg tablets • naproxen ER (Naprelan ER)	• 120 days

*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. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3).

Drugs recommended for complete exclusion 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 complete exclusion agents at the Retail points of service.

For a cumulative listing of all completely excluded agents to date, refer to previous versions of the P&T Committee quarterly meeting minutes, found on the heatlh.mil website.