

**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 (Omvo) – 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 (Napreelan 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 Zurzuva.
- 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, Aerospans, 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 to 50 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.

[REDACTED]



concurs with the recommendations, except for the following:

[REDACTED]

[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. Julianne Canaley	DHA Contracting
Ms. Shiela Mirrieles	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	
<i>Short-acting</i> - somatropin (Humatrope) - somatropin (Nutropin) - somatropin (Serostim) - somatropin (Saizen, Saizen Prep) <i>Long-acting</i> - 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: somatrogen-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 (Velporo)
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 <i>Short-acting</i> - somatropin (Genotropin) - somatropin (Norditropin) - somatropin (Omnitrope) - somatropin (Zomacton) <i>Long-acting</i> - 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.~~ <u>Manual PA Criteria:</u> Genotropin, Norditropin, Omnitrope, Zomacton, Ngenla or Sogroya are approved if: <u>For Pediatric patients:</u> - 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 <u>For Adult patients:</u> - 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.~~ <u>For Pediatric and Adult patients:</u>

Appendix C—Table of Prior Authorization (PA) Criteria

	• 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 <i>Short-acting</i> • somatropin (Humatrope) • somatropin (Nutropin) • somatropin (Serostim) • somatropin (Saizen, Saizen Prep) <i>Long-acting</i> • 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.~~ <u>Manual PA Criteria:</u> Humatrope, Nutropin Serostim, Saizen, Saizen-Prep, or Skytrofa are approved if: <u>For Pediatric patients:</u> • 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 <u>For Adult patients:</u> • 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:~~

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	~~• 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.~~ <u>For Pediatric and Adult patients:</u> • 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

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	• 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, aminosaliclates, 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

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• 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.

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etrasimod (Velsipity) Sphingosine-1 Phosphate (S1p) Receptor Modulators	Manual PA criteria apply to all new users of Velsipity <u>Manual PA criteria:</u> 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) <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 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

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• lacosamide ER (Motpoly XR) Anticonvulsants- Antimania Agents	Manual PA criteria apply to all new users of lacosamide ER capsule (Motpoly XR) <u>Manual PA criteria:</u> 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 <u>Manual PA criteria:</u> 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 <u>Manual PA criteria:</u> 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

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• 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 (Olmiant), 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

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nirogacestat (Ogsiveo) Oncological Agents	Manual PA criteria apply to all new users of nirogacestat (Ogsiveo) <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 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) <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 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) <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 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)

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Weight Loss Agents	<u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years 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 <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: • 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 <u>Manual PA criteria:</u> 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)

Appendix C—Table of Prior Authorization (PA) Criteria

	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 <i>Helicobacter pylori</i> (<i>H. pylori</i>) 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 <i>H. pylori</i>: ▪ Patient has tried and failed two 14-day trials with a guideline-recommended first-line treatment regimen. Appropriate treatment combinations for <i>H. pylori</i> 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) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has postpartum depression (PPD) • Patient is 12 months or less postpartum • Patient has a contraindication to, intolerance 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) <u>Manual PA criteria:</u> 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)

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oxaprozin 300 mg capsules (Coxanto) Pain Agents	Interim Manual PA criteria apply to all new users of oxaprozin capsules (Coxanto) <u>Manual PA criteria:</u> 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). <u>Manual PA criteria:</u> 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: - The patient has failed a trial of preferred potassium chloride capsules or tablets OR has documented swallowing difficulties (not due to convenience) - 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). <u>Manual PA criteria:</u> 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

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glipizide 2.5 mg IR tablet Diabetes Non-Insulin: Sulfonyleureas	Manual PA criteria apply to all new and current users of glipizide 2.5 mg IR tablets. <u>Manual PA criteria:</u> 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. <u>Manual PA criteria:</u> 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. <u>Manual PA criteria:</u> 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

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	▪ 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
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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. <u>Manual PA Criteria:</u> Rozlytrek will be approved if <u>all</u> 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. <u>Manual PA Criteria:</u> 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

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	- 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

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	• 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 <u>Manual PA criteria:</u> 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. <u>Manual PA Criteria:</u> 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

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	- 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:

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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 <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 12-17 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 ~~4-6~~ 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. <u>Manual PA criteria:</u> Adbry is approved if all criteria are met: • Patient is ~~4-12~~ 12-17 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, intolerance 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.

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	- Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - The patient has a contraindication to, intolerance 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 <u>Renewal criteria:</u> (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. <u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved for 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).

Appendix C—Table of Prior Authorization (PA) Criteria

Biologics: Non-TNF Inhibitors	<u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated criteria are not met, 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). <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated criteria are not met, 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. <u>Automated PA criteria:</u> 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 <u>Manual PA criteria:</u> 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. <u>Manual PA Criteria:</u> Nubeqa is approved if all criteria are met: Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent.

Appendix C—Table of Prior Authorization (PA) Criteria

	• 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

Appendix C—Table of Prior Authorization (PA) Criteria

	• 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. <u>Manual PA criteria:</u> 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

	<u>Renewal criteria:</u> (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 <u>Manual PA criteria:</u> 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 <u>Manual PA criteria:</u> 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

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient has a contraindication to at least two phosphate binders (e.g., sevelamer (Renagel, Renleva), lanthanum (Fosrenal), ferric citrate (Auryxiz), sucroferric oxyhydroxide (Velporo), 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. <u>Automated PA criteria:</u> 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 <u>Manual PA criteria:</u> 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: • <i>Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria</i> • 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 <u>Annual manual PA renewal criteria:</u> • ~~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 Analogues	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

Appendix C—Table of Prior Authorization (PA) Criteria

	• 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

Appendix C—Table of Prior Authorization (PA) Criteria

	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? ○ 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? ○ testosterone cypionate IM injection or testosterone enanthate IM injection ○ ~~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
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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 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 - 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: - testosterone cypionate IM injection or testosterone enanthate IM injection ~~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
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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 - Twynéo	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 (Jesduvrog) 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 Jesduvrog 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%) - diplopia - 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 to other options in class, URI/Infection, injection site reaction most common - Does carry risk for hepatotoxicity, 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 Thrombocythemia (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 data 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 - Omvoq	- 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 an 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 (Zurzuva) Antidepressants and Non-Opioid Pain Syndrome Agents	- citalopram - sertraline - Trintellix - Viibryd - Fetzima - 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 Zurzuva with alternative treatment options. - In pivotal trials, it showed clinically and statistically significant changes from baseline in HAMD-17 scores compared with placebo. - Zurzuva 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 Zurzuva for treatment of moderate to severe PPD, alone or as an adjunct to other oral antidepressant therapy (SSRIs and SNRIs). - Overall Zurzuva 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) <i>Retain branded agents on EMMPI</i> - Androgel, Androderm, Fortesta, Natesto, Testim, Vogelxo Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated NF <i>No reason to exempt from NF-2-Mail requirement:</i> - daprodustat (Jesduvroq) - tenapanor (Xphozah) - vonoprazan (Voquezna)	Drug Class Reviews Growth-Stimulating Hormone Agents Designated UF <i>Not cost advantageous to government</i> - somapacitan (Sogroya) - somatropin-ghla (Ngenla) - somatropin injection (Norditropin, Genotropin, Zomacton) Designated NF <i>Exempt from NF requirement (not cost advantageous to government)</i> - lonapegsomatropin (Skytrofa) - somatropin injection (Humatrope, Nutropin, Saizen, Serostim) Utilization Management/Re-evaluation of NF Generics Androgens-Anabolic Steroids: Testosterone Replacement Therapy (Transdermal/Nasal Agents) <i>Remove generic agents moving to UF status</i> - testosterone 1.62% gel (Androgel, generics) - testosterone 2% solution (Axiron, generics) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Acute or limited duration of use</i> - metronidazole oral suspension (Likmez) - zuranolone (Zurzuvae) <i>Not cost advantageous to government</i> - etrasimod (Velsipity) - methotrexate oral solution (Jylamvo) - mirikizumab-mrkz (Omvoh) - tirzepatide (Zepbound) Designated NF <i>Exempt from NF requirement (limited distribution/availability)</i> - 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.

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

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) - mometinib (Ojjaara) - niraparicicab (Ogsoveo) - repotrectinib (Augtyro) - vedolizumab (Entyvio) Designated NF <i>No reason to exempt from NF-2-Mail requirement, similar agents already on list:</i> - 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 [health.mil](https://www.health.mil) website.

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

May 2024

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 1st and 2nd, 2024.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February 2024 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the February 2024 DoD P&T Committee meeting on April 22nd, 2024.

B. Clarification of previous meeting minutes

- **February 2024**
 - **Growth Hormone Stimulating Agents—Norditropin:** Patients affected by the copay change for Norditropin from the Tier 1 to the Tier 2 copay will receive letters.
 - **Continuous Glucose Monitoring Systems (CGMS)—FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6 and Dexcom G7:** The PA updates for the CGMS were originally set to implement at 60-days after signing (June 26th), however, implementation occurred early at 30-days after signing (May 29th).
 - **Oncological—crizotinib (Xalkori) pellets:** The quantity limits will be 30 days at all points of service, similar to Xalkori tablets. Additionally, an age edit will apply to children 12 years of age and younger; they will not have to go through the prior authorization PA process.
 - **Lidocaine patch (Lidocan II/III)** are designated as uniform formulary (UF) with a default PA; they are not on the basic core formulary (BCF).

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 TRICARE Mail Order Pharmacy (TMOP) 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 TMOP.

IV. UF DRUG CLASS REVIEWS

A. Insulins: Basal Insulin Analogs

Background—The Basal Insulin subclass was last reviewed at the August 2017 DoD P&T Committee meeting, and branded insulin glargine (Lantus) was designated as step-preferred. Since the last review, several biosimilars and unbranded biologics are now marketed.

There is significant biosimilar presence for the Basal Insulins. A biosimilar is defined by the Food and Drug Administration (FDA) as a biological product that is approved based on data demonstrating it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. The DoD P&T Committee at the November 2022 meeting concluded that by FDA approval and definition, biosimilars are equally safe and efficacious which provides strong competition within products for drug classes with biosimilars. Not all biosimilars are cost effective when compared to their reference product. Unbranded biologics are marketed under the same 351(a) Biologic License Application (BLA) as the reference product. These unbranded biologics can have differing formulary status compared to their reference product.

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

Products

- The branded products in the Basal Insulins subclass include insulin glargine (Lantus), insulin detemir (Levemir), insulin glargine U-300 (Toujeo), insulin degludec (Tresiba U-100, Tresiba U-200), and three other branded insulin glargine products, Basaglar, Semglee, and Rezvoglar. Several biosimilars and unbranded biologics for glargine and degludec are available.
- The products are all supplied as prefilled disposable pens. In addition, vials are available for all the products with the exception of Toujeo, Basaglar, and Rezvoglar.

- Market discontinuation will occur this year for insulin detemir (Levemir) and insulin glargine (Semglee). Market supply disruptions have also affected the subclass.

Clinical Practice Guidelines

- Professional treatment guidelines for both Type 1 diabetes mellitus (T1DM) and Type 2 diabetes mellitus (T2DM) from the American Diabetes Association (ADA) do not state a preference for one basal insulin analog over another. Similar recommendations are made by the American Association of Clinical Endocrinology (ACCE) and by the United Kingdom National Institute for Health and Care Excellence (NICE).
- For pregnancy and gestational diabetes, the ADA and American College of Obstetrics and Gynecology prefer insulin glargine, detemir, and neutral protamine Hagedorn (NPH) over other basal insulins, based on long marketing history and not due to efficacy or safety concerns.
- For children, the ADA and the International Society for Pediatric and Adolescent Diabetes recommend basal insulins over other insulins, but no preference is stated for a particular product.

Efficacy

- There was no new compelling data to change the 2017 efficacy conclusion that while basal insulins differ in pharmacokinetic properties such as duration of action and dosing frequency, this variance does not translate into improved glycemic control or hemoglobin A1C improvements compared to one another.

Safety

- For T1DM, systematic reviews and meta-analyses in pediatric and nonpregnant adult patients comparing insulin detemir to insulin glargine, insulin degludec to insulin detemir, or insulin degludec to insulin glargine did not find clinically relevant differences for outcomes, including rates of hypoglycemia.
- Similar results were found for systematic reviews and meta-analyses in nonpregnant adult patients with T2DM when comparing insulin glargine or insulin detemir to NPH insulin.

Individual Product Characteristics

- **insulin glargine (Lantus)** is the reference biologic for insulin glargine. Advantages include availability in a prefilled pen, cartridge and vial, and approval for both adult and pediatric administration without a lower age limit. Lantus is well-accepted for use in pregnant patients. It is available in 100 units per milliliter (mL) which provides 80 units as the maximum dose. Lantus has a long history as the preferred MHS basal insulin dating back to 2010.

- Unbranded insulin glargine U-100 is available.
- **insulin glargine U-300 (Toujeo)** is a concentrated insulin glargine product containing 300 units per mL in two prefilled reusable pen options. It is approved for pediatric patients down to age six. Compared to Lantus, Toujeo offers a longer half-life (19 hours vs. 12 hours) and longer duration of action (24-36 hours vs. 24 hours). Toujeo is available in a SoloStar pen which administers up to 80 units per dose, and a Max SoloStar pen which administers up to 160 units per dose.
 - Unbranded insulin glargine U-300 SoloStar and Max SoloStar are available.
- **insulin glargine (Basaglar)** is considered a “follow-on” insulin (originally approved by the 505(b)(2) pathway but through FDA administrative action is deemed a BLA ~~on~~ as of March 23, 2020) and is not a true biosimilar to Lantus, although the data to support approval included a series of clinical studies to demonstrate similarity to the insulin (Lantus). Basaglar has the same amino acid and pH as Lantus. Basaglar has the same amino acid and pH as Lantus.
 - Basaglar is also available as a TempoPen. The TempoSystem consists of a phone app, glucometer, Tempo Smart Button, and Tempo Insulin Pen. The TempoPen provides no additional benefit as compared to KwikPen formulations. The TempoSystem is not a TRICARE pharmacy benefit and is not currently covered under the TRICARE medical benefit.
- **insulin glargine (Semglee), insulin glargine-yfgn (Semglee), insulin glargine-aglr (Rezvoglar)** are biosimilars of Lantus. Semglee is available in both pens and vials. Semglee and Rezvoglar are interchangeable with Lantus. The branded insulin glargine (Semglee) formulation will be discontinued.
 - Unbranded insulin glargine-yfgn is available.
- **insulin degludec (Tresiba)** is the reference product for insulin degludec and offers a long duration of action up to 42 hours which allows for flexibility with regard to time of administration. Tresiba is available in both a U-100 and U-200 concentration. The U-100 pen administers up to 80 units per single injection and the U-200 pen administers up to 160 units per single injection.
 - Both concentrations are available as unbranded biologic products.
- **insulin detemir (Levemir)** is the reference insulin detemir product. Detemir requires twice daily dosing. Market discontinuation will occur in 2024. There are no biosimilar nor unbranded products available.

Other Factors

- The basal insulins are rated as pregnancy category C, with the exception of detemir which is rated as pregnancy category B.
- There is no compelling evidence to support use of one basal product over another in either pregnancy or pediatric patients per current guidelines.

Overall Clinical Conclusion

- There is no new meaningful clinical evidence to change the previous conclusions from 2017 formulary review.
- Per the definition of a biosimilar product, there are no clinically meaningful differences between the reference drug product and the biosimilar, allowing for a high degree of therapeutic interchangeability.
- Clinical practice guidelines do not prefer one basal product over another for safety or efficacy. Basal insulin analogs are considered equally safe and efficacious when compared to one another.
- Differences between basal products are largely based on provider experience or patient preferences.
- MHS provider feedback was overwhelmingly positive for Lantus remaining on the formulary.
- In order to meet the needs of MHS patients, one basal insulin product is needed, but additional options should be considered to protect against shortage situations.

Relative Cost Effectiveness Analysis and Conclusion—The 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 (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that insulin glargine yfgn (unbranded), Lantus, insulin glargine (unbranded) and Rezvoglar, were the most cost effective basal insulins, followed by Toujeo; Levemir, Basaglar and Tresiba were the least 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 basal insulins in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

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

- UF step-preferred

- insulin glargine (Lantus)
- UF non-step-preferred
 - insulin glargine U-300 (Toujeo SoloStar, Toujeo Max SoloStar)
 - insulin glargine U-300 (unbranded)
 - insulin glargine (Rezvoglar) (*moves from NF to UF non-step-preferred*)
 - insulin glargine-yfgn (unbranded) (*moves from NF to UF non-step-preferred*)
 - insulin glargine U-100 (unbranded by Winthrop) (*vials move from NF to UF non-step-preferred, pens remain UF non-step-preferred*)
- NF non-step-preferred
 - insulin detemir (Levemir), pens and vials (*pens move from UF to NF non-step-preferred, vials remain NF non-step-preferred*); *note market removal in 2024*)
 - insulin degludec (Tresiba)
 - insulin degludec (unbranded)
 - insulin glargine (Basaglar)
 - insulin glargine (Semglee); *note market removal in 2024*
 - insulin glargine-yfgn (Semglee)
- Completely Excluded - None
- Note that as part of this recommendation, a trial of Lantus is required in all new users for all non-step-preferred products. (See the PA criteria section for additional details.)
- Note that Lantus will remain on the Basic Core Formulary (BCF)

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA is not required for Lantus, however PA criteria have applied to the non-step-preferred products since the 2017 class review. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) changes to the PA criteria for the non-step-preferred products in all new users as outlined below. See Appendix C for the full criteria.

- For new users of Basaglar, Semglee, Semglee-yfgn, Rezvoglar, insulin glargine-yfgn (unbranded), insulin glargine (unbranded), or insulin detemir (Levemir), a trial of Lantus is required first, unless the patient has had an inadequate response to Lantus.

- New users of insulin glargine U-300 (Toujeo, unbranded) must be currently using greater than 80 units of basal insulin per day and have experienced clinically significant hypoglycemia, or they must be using greater than 100 units of basal insulin per day (regardless of whether they have experienced hypoglycemia).
 - Providers ordering insulin degludec (unbranded) for new users must explain why the patient cannot use Lantus and Toujeo.
 - For insulin degludec (Tresiba) in new users, the provider must indicate why the patient cannot use Lantus, Toujeo, and insulin degludec (unbranded).
3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for the NF, non-step-preferred products, (Levemir, Tresiba, unbranded insulin degludec, Basaglar, Semglee, Semglee-yfgn). See Appendix B for the full criteria.
 4. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the basal insulins on the EMMPI program. See Appendix F).
 5. **COMMITTEE ACTION: TIER 1 COPAY FOR LANTUS**—Lantus currently has a Tier 1 copay, implemented in 2017. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the Tier 1 copay for Lantus.
 6. **COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding the basal insulins to the program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.
 7. **COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM, TIER 1 COPAY, RAPID RESPONSE PROGRAM and IMPLEMENTATION PERIOD**—The P&T Committee recommended (17 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 receiving Levemir who will be affected by the NF recommendation and market removal. See Appendix G for the actual implementation date.

B. Weight Loss Agents

Background—Section 729 of the NDAA for FY 2017 authorized coverage under TRICARE Prime and TRICARE Select for medically necessary treatment of obesity even if it is the sole or major condition treated. The DoD P&T Committee initially reviewed the weight loss agents for formulary status in 2017.

The drugs in the class are comprised of older amphetamine derivatives (e.g., phentermine, benzphetamine), and branded products including fixed dose combinations of phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), a proprietary phentermine 8 mg formulation (Lomaira), the fat absorption inhibitor orlistat (Xenical) and the injectable glucagon-like peptide-1 receptor agonists (GLP1-RAs) liraglutide (Saxenda), semaglutide (Wegovy), and tirzepatide (Zepbound). Semaglutide, tirzepatide and liraglutide are also FDA-approved under distinct brand names for diabetes (Ozempic, Mounjaro, and Victoza, respectively). Notable changes since the last formulary review include clinical practice guideline updates and market removal of locaserin (Belviq) in 2020.

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

Clinical Practice Guidelines

- In overweight and obese individuals, particularly those with comorbidities, long-term weight loss greater than or equal to 5 percent of baseline body weight following diet, exercise, or drug treatment is associated with improvement in metabolic and cardiovascular risk factors.
- Although professional treatment guidelines differ with respect to weight loss recommendations, there is universal agreement that comprehensive lifestyle intervention is the foundation for obesity management. Pharmacotherapy may be considered for patients with a body mass index (BMI) greater than 30 and for those with a BMI greater than or equal to 27 with additional obesity-associated comorbidities (e.g., diabetes, impaired glucose tolerance, hypertension, dyslipidemia, sleep apnea).
- The 2024 ADA Standards of Care in Diabetes state obesity management can delay the development of T2DM. There is additional strong evidence that maintaining a 10% weight loss can lead to disease modifying effects and possible remission of T2DM. The guideline specifies that semaglutide and tirzepatide are very highly effective for weight loss compared to other available therapies, with dulaglutide (Trulicity) and liraglutide (Victoza), which are GLP-1RAs approved for diabetic patients listed as highly effective.
- The 2023 AACE consensus statement recommends the GLP-1RA agents (semaglutide, liraglutide, tirzepatide) or Qsymia for overweight or obese patients who are at risk of developing T2DM and who have failed lifestyle modification. Contrave, short-term phentermine, or orlistat can be used if the above medications are not tolerated or are inaccessible to patients.

- The 2022 American Gastroenterological Association (AGA) guideline recommends semaglutide over other approved anti-obesity medications for long term treatment in most patients with an inadequate response to lifestyle interventions. The AGA recommends against the use of orlistat (Xenical) for weight loss. Tirzepatide was not yet approved for weight loss at the time of the guideline publication.

Efficacy

- There are limited head-to-head comparative data for the weight loss drugs. Individual clinical trial data, package labeling and meta-analyses show greater weight loss with semaglutide and tirzepatide compared to phentermine, liraglutide, phentermine/topiramate and bupropion/naltrexone.
- A 2023 network meta-analysis comparing the efficacy of the GLP-1RAs for obesity management concluded the GLP-1RAs produce significant reductions in weight. Tirzepatide resulted in greater weight loss than semaglutide or liraglutide.
- A comparison of semaglutide with dulaglutide in the SUSTAIN-7 trial in diabetic patients showed the magnitude of weight loss achieved with semaglutide was double the amount achieved with dulaglutide.
- The SELECT trial evaluated major adverse cardiovascular events (MACE) between placebo and semaglutide in obese patients with pre-existing cardiovascular disease with no history of diabetes. After a mean follow-up of 40 months, semaglutide resulted in a 20% reduction in the risk of MACE (a composite of cardiovascular (CV) death, nonfatal myocardial infarction or non-fatal stroke), compared with placebo. The Wegovy package labeling was updated for this indication in March 2024.
 - The ongoing SURMOUNT-MMO trial is investigating cardiovascular outcomes with tirzepatide in obese patients without diabetes, with results expected in 2027.

Safety

- The products differ in their individual safety profiles, but common adverse reactions for most agents include increased heart rate, nausea, and diarrhea.
- Phentermine and the other amphetamine products are contraindicated in patients with a history of cardiovascular disease including coronary artery disease, stroke, arrhythmias, congestive heart failure, and uncontrolled hypertension.
- The GLP-1RAs share the same precautions, warnings, and adverse events. Gastrointestinal (GI) adverse events are most commonly reported and include nausea and vomiting. Patients receiving a GLP-1RA require

counseling regarding potential mental health side effects, need for contraception, and risk of GI paralysis.

- Contrave labeling includes a black box warning against use in major depression or psychiatric disorders and should be avoided in patients who have a history of seizures, uncontrolled hypertension, and in patients taking opioids.
- Qsymia requires a Risk Evaluation and Mitigation Strategy (REMS) program due to safety concerns in pregnant women and risk of congenital malformations, due to the topiramate component. Patients with hypertension, elevated heart rate, or renal dysfunction should use Qsymia with caution.
- Xenical should be avoided in patients with gallbladder disease or malabsorption syndromes.

Individual Product Characteristics

- **phentermine, phendimetrazine, benzphetamine and diethylpropion** have been approved for decades for short-term weight management. MHS provider feedback support phentermine as a first step for treating obese patients who do not have contraindications.
- **phentermine 8 mg (Lomaira)** is a low-dose phentermine formulation approved for short-term use that can be administered up to three times daily before meals. Package labeling contains the same cardiovascular warning as the other amphetamine products.
- **phentermine/topiramate (Qsymia)** is mentioned in the 2023 AACE guidelines and can produce weight loss ranging from 5% to 11% from baseline. Disadvantages include the REMS program requirement for teratogenicity, its controlled substance status (CIV), and unavailability from TMOP (due to the REMS program). Qsymia generic formulations are expected in late 2024. MHS providers mentioned they prescribe the individual generic components separately.
- **naltrexone SR/bupropion SR (Contrave)** treatment results in a weight loss average of 5% from baseline. Contrave is relegated to second-line status due to the black box warning for suicidal thoughts and reduced efficacy relative to the other drugs in the class.
- **orlistat (Xenical)** is approved for children however it results in minimal weight loss, causes significant adverse GI effects, and is no longer recommended in clinical practice guidelines.
- **liraglutide (Saxenda)** advantages include evidence for reduced major adverse cardiovascular outcomes with the Victoza branded product. It is the least effective of the injectable weight loss GLP-1RAs, resulting in an average 8% weight loss.

- **semaglutide (Wegovy)** treatment results in an average 15% weight loss from baseline. Semaglutide is mentioned in several guidelines as being highly effective for weight loss. It is the only GLP-1RA labeled to reduce the risk of adverse CV outcomes, based on the SELECT trial.
- **tirzepatide (Zepbound)** treatment can reduce baseline weight on average of 15% to 20%. MHS providers mentioned a potentially better tolerated GI side effect profile of tirzepatide over semaglutide.

Other Factors

- For adolescent patients, Wegovy, Qsymia and Xenical are approved for patients as young as 12 years, while phentermine is not recommended for those under 16 years of age.
- A comparison of DoD with other health care plans showed several commercial plans do not cover weight loss medications due to cost considerations.
- Shortages have notably affected this class as demand increases nationally and globally. Prescribers are encouraged to reserve use of GLP1-RAs specifically approved for diabetes [e.g., dulaglutide (Trulicity), liraglutide (Victoza), semaglutide (Ozempic) and tirzepatide (Mounjaro)], solely for patients with diabetes and not for treating non-diabetic obese patients.

Overall Clinical Conclusion

- There is a moderate degree of interchangeability within the weight loss class as a whole due to differences in efficacy and safety profiles. However, there is a high degree of interchangeability between Wegovy and Zepbound.
- Provider feedback showed support for a shared decision-making model for pharmacotherapy for weight management. There was strong agreement for formulary inclusion of at least one GLP-1RA.

Relative Cost Effectiveness Analysis and Conclusion—The 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 (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- The committee reviewed the CMA results for benzphetamine, diethylpropion IR and ER, liraglutide (Saxenda), naltrexone SR/bupropion SR (Contrave), orlistat (Xenical, generics), phendimetrazine, phentermine, phentermine 8 mg (Lomaira, generics), phentermine/topiramate (Qsymia), semaglutide (Wegovy), and tirzepatide (Zepbound).
- 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 weight loss 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 (16 for, 0 opposed, 0 abstained, 2 absent) the following.

- UF generics
 - phentermine (Adipex-P, generics)
 - benzphetamine (Didrex, generics)
 - diethylpropion immediate release (IR) and sustained release (SR) (Tenuate, Tandil, generics)
 - phendimetrazine IR and SR (Bontril, generics)
 - phentermine 8mg (Lomaira, generics)
- UF step-preferred brands
 - naltrexone SR/bupropion SR (Contrave) – *moves from NF to UF step-preferred*
 - phentermine/topiramate (Qsymia) – *moves from NF to UF step-preferred*
 - semaglutide (Wegovy) – *moves from UF to UF step-preferred*
 - tirzepatide (Zepbound) – *moves from UF to UF step-preferred*
- NF non-step-preferred brands
 - liraglutide (Saxenda)
 - orlistat (Xenical, generics)
- Completely Excluded – None
- Note that as part of this recommendation, a trial of generic phentermine or one of the older generic phentermine derivatives in addition to all of the step-preferred branded drugs is required first for the NF, non-step-preferred products in all new users, unless the patient has a contraindication, inadequate response, or has experienced adverse effects with the step-preferred products.

2. COMMITTEE ACTION: MANUAL PA CRITERIA—PA has been in place since the original class review in 2017, with several updates made since then. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria as discussed below in new users. PA is required to ensure appropriate use of the weight loss drugs

and due to national supply shortages. Currently a sequential trial of phentermine, Qsymia, and Contrave is required before a GLP1-RA. The PA changes will apply to new patients, due to the varying mechanisms of action for the products and national supply shortages. See Appendix C.

- Lifestyle modification remains a requirement prior to use of pharmacotherapy, based on clinical practice guidelines.
- PA is removed for phentermine, benzphetamine, diethylpropion IR/SR, phendimetrazine IR/and Lomaira.
- For Contrave, Qsymia, Wegovy and Zepbound, only a trial of generic phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR is required, rather than sequential use of all the products, unless the patient has a contraindication, inadequate response, or has experienced adverse effects to the step-preferred products.
- For Wegovy and Zepbound, the requirement for a trial of dulaglutide (Trulicity) and metformin first in patients with diabetes is removed, as Trulicity is not as effective at weight loss compared to semaglutide and tirzepatide.
- For new adult users of Saxenda and Xenical, a trial of phentermine plus all the step-preferred branded drugs (Contrave, Qsymia, Wegovy, and Zepbound) is required first, unless the patient has a contraindication, inadequate response, or has experienced adverse effects to the step-preferred products.
- The initial four- or six- month renewal period was removed, and the PAs will now expire annually (yearly renewal required).
- FDA-approved ages for pediatric patients were considered in the step-therapy requirements for adolescents.

3. COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updated MN criteria for Saxenda and Xenical. See Appendix B for the full criteria.

4. COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) excluding all the weight loss products from the EMMPI program. See Appendix F.

5. COMMITTEE ACTION: UF, PA, MN, EMMPI PROGRAM and IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date the first

Wednesday 30 days after signing of the minutes in all points of service.
See Appendix G for the actual implementation date.

C. PULMONARY II AGENTS: INHALED CORTICOSTEROIDS (ICS) SUBCLASS

Background—The P&T Committee evaluated the relative clinical effectiveness of the Inhaled Corticosteroids (ICS) subclass. The class includes a variety of dry powder inhalers and hydrofluoroalkane (HFA) oral inhalers. This class was last reviewed for formulary status in May 2014, when fluticasone propionate (Flovent Diskus and Flovent HFA) was designated as the UF step-preferred products, and all other products were non-step-preferred.

The branded Flovent HFA and Diskus 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. Additionally, the previous Tier 1 copay for brand Flovent HFA and Flovent Diskus were removed in November 2023.

Note that budesonide nebulized solution (Pulmicort Respule) remains UF but is not subject to the step-therapy structure for this subclass. All agents are FDA-approved for asthma management. The clinical review focused on available published trials, clinical practice guidelines, meta-analyses, and systematic reviews.

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

Clinical Practice Guidelines

- *Asthma*: Guidelines support monotherapy with ICS as part of a treatment plan for children and as an alternative treatment option for adolescents and adults. Preferred asthma treatment continues to support use of Maintenance and Reliever Therapy (MART) with combination formoterol and ICS. Society guidelines do not prefer one specific ICS product over another.
- *Off-label uses*:
 - *Eosinophilic Esophagitis (EoE)*: Topical corticosteroids may be used to treat EoE; however no single product is favored in guidelines.
 - *Chronic Obstructive Pulmonary Disease (COPD)*: Professional guidelines state monotherapy with ICS is not recommended.

Efficacy

- *Asthma*: There is limited head-to-head data between agents within the subclass. A network meta-analysis was reviewed for asthma treatment in children and concludes an improvement in asthma symptoms and exacerbations with ciclesonide versus budesonide and fluticasone could be neither demonstrated nor refuted. An additional network meta-analysis was reviewed which supported comparable treatment effect between

fluticasone furoate (Arnuity Ellipta) and fluticasone propionate (Flovent) in adolescents and adults with persistent asthma.

Safety

- In terms of safety, all agents carry similar warnings. Milk allergen concerns are unique to dry powder inhaler formulations. Budesonide remains the preferred ICS for use in pregnancy. MHS providers mentioned ciclesonide (Alvesco) may be preferred for use in rare cases of concern for patients with adrenal suppression.

Other Factors and Individual Product Characteristics

- **Budesonide** is the only drug in this subclass which is available in a nebulized solution (Pulmicort Respules) and dry powder inhaler (Pulmicort Flexhaler). **Mometasone** is available in a dry powder inhaler (Asmanex Twisthaler) and HFA (Asmanex HFA).
- **Fluticasone propionate** is available in multiple formulations, including dry powder inhaler (diskus) and HFA. The branded Flovent products were removed from the market by the manufacturer in late 2023, but authorized generic formulations are available for both the diskus and HFA. The completely excluded agent, fluticasone propionate digihaler (ArmonAir Digihaler), continues to offer no significant clinical benefit relative to other ICS agents and the needs of TRICARE beneficiaries are met by numerous alternative agents.
- **Fluticasone furoate (Arnuity Ellipta)** is available as a single product (dry powder inhaler) and offers no compelling clinical advantages compared to using fluticasone propionate.
- **Beclomethasone (Qvar Redihaler)** and **ciclesonide (Alvesco)** are only available in HFA formulations.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, at least two ICS products are required on the formulary.

Relative Cost Effectiveness Analysis and Conclusion—The 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 (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results of the ICSs showed the following, ranked from most cost effective to least cost effective: ciclesonide (Alvesco HFA), mometasone furoate (Asmanex Twisthaler), fluticasone propionate diskus authorized generic, mometasone furoate (Asmanex HFA), fluticasone propionate HFA authorized generic, fluticasone propionate (Flovent Diskus brand - discontinued), fluticasone furoate (Arnuity Ellipta), budesonide (Pulmicort Flexhaler), beclomethasone (Qvar Redihaler), fluticasone propionate (Flovent

HFA brand - discontinued), budesonide (Pulmicort Respule) and fluticasone propionate digihaler (Armonair Digihaler).

- 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 ICS 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 (17 for, 0 opposed, 0 abstained, 1 absent) the following.
 - UF
 - ciclesonide (Alvesco) – *moves from NF to UF status*
 - fluticasone propionate diskus authorized generic
 - fluticasone propionate HFA authorized generic
 - mometasone (Asmanex Twisthaler) – *moves from NF to UF status*
 - mometasone (Asmanex HFA)
 - NF
 - beclomethasone (QVAR Redihaler)
 - budesonide (Pulmicort Flexhaler)
 - fluticasone furoate (Arnuity Ellipta) – *moves from UF to NF status*
 - Completed Excluded
 - fluticasone propionate digihaler (Armonair Digihaler)
 - Note that budesonide nebulized solution (Pulmicort Respules) remains UF
 - Note the brand fluticasone diskus and HFA (Flovent Diskus, Flovent HFA) are no longer marketed e
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA and step therapy have been required since the original class review in 2014. The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria and step therapy for all the products in the class.
 3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1

absent) updates for the MN criteria for Arnuity Ellipta, Pulmicort Flexhaler, and Qvar Redihaler. See Appendix B for the full criteria.

4. **COMMITTEE ACTION: QUANTITY LIMITS**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent), maintaining the current QL for all the ICS products at all points of service. See Appendix D.
5. **COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the ICS products on the EMMPI program. See Appendix F).
6. **COMMITTEE ACTION: UF, MN, PA REMOVAL, QLs, EMMPI PROGRAM, and IMPLEMENTATION PERIOD**—The P&T Committee recommended (17 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) DHA mail letters to patients affected by the copay change for Arnuity Ellipta. See Appendix G for the actual implementation date.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 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 TMOP.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:
 - UF
 - birch triterpenes 10% (w/w) topical gel (Filsuvez) – Skin Preps for epidermolysis bullosa
 - budesonide 2 mg/10 mL oral suspension (Eohilia) – Gastrointestinal-1 Agent for eosinophilic esophagitis (EoE)
 - eflornithine tablets (Iwilfin) – Oncological Agent for neuroblastoma

- eltrombopag 9 mg, 18 mg, 35 mg, 54 mg tablets (Alvaiz) – Hematological Agents: platelets, for chronic immune thrombocytopenia (ITP)
- eplontersen injection (Wainua) – Miscellaneous Neurological Agent for hereditary transthyretin-mediated amyloidosis
- infliximab-dyyb injection (Zymfentra) – Targeted Immunomodulatory Biologics (TIBs): tumor necrosis factor (TNF) inhibitor for ulcerative colitis and Crohn’s disease.
- nedosiran injection (Rivfloza) – Nephrology Agent for hyperoxaluria type 1 (PH1)
- omalizumab autoinjector (Xolair) – Atopy Agents; new formulation and indication for reduction of allergic reactions (Type I) in patients with IgE-mediated food allergy
- vamorolone oral suspension (Agamree) – Corticosteroids – Immune Modulator for Duchenne Muscular Dystrophy
- zilucoplan injection (Zilbrysq) – Miscellaneous Neurological Agent for myasthenia gravis
- NF
 - bosutinib capsules (Bosulif) – Oncological Agents for chronic myelogenous leukemia (CML)
 - cyclosporine 0.1% ophthalmic solution (Vevye) – Ophthalmic agent for dry eye disease
 - iptacopan (Fabhalta) – Hematological Agent for paroxysmal nocturnal hemoglobinuria (PNH)
 - roflumilast 0.3% topical foam (Zoryve) – Psoriasis Agent
 - sitagliptin free base (Zituvio) – Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitor for diabetes
 - sitagliptin free base (Zituvio authorized generic) – Diabetes Non-Insulin: (DPP-4) Inhibitor for diabetes
- Completely Excluded – None

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Bosulif capsules, Vevye, Fabhalta, Zoryve foam, Zituvio and Zituvio authorized generic. See Appendix B for the full criteria.

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

- Applying manual PA criteria to new users of the oncology drugs Bosulif capsules and Iwifin; and for new users of Filsuvez, Eohilia, Wainua, Fabhalta, Rivfloza, Agamree, Xolair and Zilbrysq.
 - Applying manual PA criteria to new users of Zymfentra requiring a trial of Humira or intravenous infliximab, similar to what is in place for the other non-step-preferred TIBs approved for treating ulcerative colitis.
 - Applying manual PA criteria to new users of Vevye, requiring a three-month trial of generic Restasis unit dose, Cequa, and Xiidra first, similar to the requirements for the other NF ophthalmic cyclosporine products.
 - Applying manual PA criteria to new users of Zituvio and Zituvio authorized generic, requiring a trial of Januvia, similar to other NF, non-step-preferred DPP-4 inhibitor in the class.
4. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) QLs for Filsuvez, Bosulif, Vevye, Iwifin, Wainua, Zymfentra, Fabhalta, Rivfloza, Xolair, Zoryve, Agamree, and Zilbrysq. See Appendix D for the QLs.
5. **COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding or exempting the drugs listed in Appendix F to/from the 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 TMOP requirement.
6. **COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD**—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.
- **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.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

- a) **Anticonvulsants-Antimania Agents—brivaracetam (Briviact)**—Briviact was reviewed as an innovator at the August 2016 P&T meeting and designated as NF. Briviact is an analog related to levetiracetam

(Keppra). Indirect comparison suggests there are no statistically significant differences between Briviact and Keppra with regard to efficacy and adverse effects.

Specialist feedback supported use of other anticonvulsants, including levetiracetam, before prescribing Briviact. MHS utilization data showed 50% of Briviact prescriptions were initiated by a neurologist, and nearly 50% of patients did not have a trial of levetiracetam first. Many commercial health plans require PA criteria for Briviact. PA criteria were recommended for Briviact tablets and oral solution in new patients requiring neurologist prescribing, limiting use to FDA-approved indications, and requiring a trial of levetiracetam first. An automated look back will apply, allowing coverage if the patient has received any formulation of levetiracetam in the past 180 days.

COMMITTEE ACTION: BRIVARACETAM (BRIVIACT) PA CRITERIA, RAPID RESPONSE PROGRAM ADDITION AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) PA criteria in new users of Briviact tablets and oral solution. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. Additionally, Briviact will be added to the rapid response (“safety net”) program managed by the TRICARE pharmacy contractor. See Appendix C for the full PA criteria.

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

Manual PA criteria was recommended for one recently marketed drug produced by a sole manufacturer which contains an active ingredient that is widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, the product does not meet the criteria for innovators and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

- a) Narcotic Analgesics and Combinations—tramadol 25 mg tablets—** Numerous other tramadol formulations are available, including scored tramadol 50 mg tablets, that are more cost-effective than this 25 mg formulation made by a sole manufacturer.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for tramadol 25 mg tablets in new and current users, due to the significant cost differences compared with other available alternative agents. 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.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- a) **Atopy—dupilumab (Dupixent)**—Dupixent was recently approved for use in younger patients with eosinophilic esophagitis. The manual PA criteria were updated to allow use in pediatric patients aged 1 year and older, weighing at least 15 kilograms.
- b) **Oncological Agents: Breast Cancer—alpelisib (Piqray)**—The manual PA criteria for Piqray were updated to allow use in pre- and peri-menopausal women.
- c) **Oncological Agents: Lung Cancer—alectinib (Alecensa)**—The manual PA criteria were updated to allow use in non-metastatic disease. Additionally, the FDA-approved age range was added to the PA, similar to what is in place for other oncology drugs.
- d) **Oncological Agents—erdafitinib (Balversa)**—The manual PA criteria were updated due to two recent changes in the FDA labeling. The product labeling no longer requires a trial of platinum-containing chemotherapy, but rather requires only one line of prior systemic therapy. Additionally, the FDA indication was restricted and Balversa is no longer indicated for patients with FGFR2 genetic alterations.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Dupixent, Piqray, Alecensa, and Balversa 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) **Oncological Agents: Lung Cancer—sotorasib (Lumakras)**—The manual PA criteria for Lumakras were updated to remove the preference for the 120 mg tablets over the 320 mg tablets as there is no longer a cost justification for the preference.
- b) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis**

Factor Inhibitors (TNFs)—golimumab (Simponi)—Based on MTF provider feedback and clinical trial data, Simponi will be allowed for use as monotherapy for rheumatoid arthritis. The requirement to use Simponi in conjunction with methotrexate will be removed.

- c) **TIBs—adalimumab (Humira), etanercept (Enbrel), ixekizumab (Taltz), ustekinumab (Stelara), and secukinumab (Cosentyx)**—PA criteria for pediatric indications for several TIBs were evaluated. Opportunities to modify the PAs for Humira, Enbrel, Taltz, Stelara, and Cosentyx were identified to improve consistency, clarity, and intent. These changes include allowing Humira for additional ages (for children as young as 2 years of age for all uses), and indications (including psoriatic arthritis and plaque psoriasis) based on clinical evidence and practice guidelines; updating the other TIBs corresponding to the changes made to Humira; standardizing PA flow for pyoderma gangrenosum and hidradenitis suppurativa based on treatment guidelines; updating the criteria for ankylosing spondylitis and non-radiographic ankylosing spondyloarthritis (nr-axSpA) to follow similar NSAID treatment pathways based on guidelines; and removing research-based scoring systems for nr-axSpA. For Enbrel, Taltz and Stelara, a trial of Humira will be required for all appropriate indications regardless of age.
- d) **Growth Hormone Stimulating Agents**—The growth hormone stimulating agents were last reviewed at the February 2024 P&T Committee meeting. Currently annual renewal is required for both adult and pediatric indications. Provider feedback relayed the adult indications for growth hormone agents are usually permanent and occur as a result of pituitary disease, hypothalamic disease, trauma, surgery, or radiation therapy. Clinical and utilization data were reviewed which supported removing the annual renewal criteria for adults. Annual renewal is still required for pediatric patients.
- e) **Corticosteroid Immune Modulators—deflazacort (Emflaza)**—Emflaza was reviewed as a new drug at the February 2020 P&T Committee meeting and is approved for treating patients 2 years of age and older with Duchenne Muscular Dystrophy (DMD), similar to the new drug Agamree. The Emflaza PA criteria were updated to reflect the criteria recommended for Agamree in the new drug section.
- f) **Gastrointestinal-2 Agents—sacrosidase oral solution (Sucraid)**—At the May 2023 P&T meeting, PA criteria were originally added to Sucraid to ensure appropriate use of this medication. Sucraid utilization and prescribing trends were reviewed. Based on MTF provider feedback, the following edits were recommended in new and current users: gastroenterologist specialist prescribing, diagnostic confirmation of congenital sucrase-isomaltase deficiency (CSID) by biopsy or genetic testing with documentation submitted, dietary restriction of sucrose, and annual PA expiration.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, MEDICAL NECESSITY CRITERIA, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Lumakras, Simponi, Humira, Enbrel, Taltz, Stelara, Cosentyx, growth hormone stimulating agents and Emflaza in new users, and updates to the Sucraid PA in new and current users. Implementation will be effective the first Wednesday 60 days after signing of the minutes. Patients affected by the Sucraid updated PA criteria will receive letters. See Appendix C for the full criteria.

5. Removal of PA

Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors—empagliflozin/linagliptin (Glyxambi) and empagliflozin/linagliptin/metformin XR (Trijardy XR)—Currently, both Glyxambi and Trijardy XR are designated as UF requiring PA. Empagliflozin (Jardiance) is the step-preferred SGLT-2 inhibitor. At the February 2021 P&T meeting, the PA was removed from empagliflozin and empagliflozin/metformin combinations. A cost analysis showed that Glyxambi and Trijardy XR are now more cost-effective than the individual component agents taken separately.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for Glyxambi and Trijardy XR. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Line Extensions

The P&T Committee clarified the formulary status for one product line extension 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.

Antihemophilic Factors—designating emicizumab-kxwh (Hemlibra) 12 mg/0.4 mL and 300 mg/2 mL vials with the same formulary status (UF), PA, QL, and Specialty status as the parent Hemlibra strengths.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, Specialty status and EMMPI program status for Hemlibra. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR LISDEXAMFETAMINE (VYVANSE)

Lisdexamfetamine (Vyvanse) capsules and chewable tablets are designated as UF and require a PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agents. Therefore, the branded Vyvanse capsules and chewable tablets will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization. The Tier 1 copay for brand Vyvanse is recommended.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) requiring brand Vyvanse capsules and chewable tablets over the generics 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 Vyvanse capsules and chewable tablets. 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.

VIII. RE-EVALUATION OF NF GENERICS: CALCIUM CHANNEL BLOCKERS, TOPICAL CORTICOSTEROIDS, PROTON PUMP INHIBITORS, AND SELECTIVE SEROTONIN REUPTAKE INHIBITORS

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 calcium channel blockers, topical corticosteroids, proton pump inhibitors, and selective serotonin reuptake inhibitors (SSRI).

COMMITTEE ACTION: CALCIUM CHANNEL BLOCKERS, TOPICAL CORTICOSTEROIDS, PROTON PUMP INHIBITORS, AND SELECTIVE SEROTONIN REUPTAKE INHIBITORS FORMULARY STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 2 absent) making the following changes to formulary status, step therapy status, and prior authorization criteria and medical necessity criteria, effective the first Wednesday 30 days after signing of the minutes. (See Appendix G for implementation dates).

- a) Calcium Channel Blockers (CCBs)

- Return to UF status. The following CCBs are considerably more costly than the far more commonly used CCB amlodipine (Norvasc, generics), but are less costly than similar agents on the UF and utilization is very low
 - diltiazem 24h extended release (ER) tablets (Cardizem LA generics)
 - verapamil 24h sustained release pellet-filled capsules (Verelan generics)
 - nisoldipine 24h ER tablets, controlled release (Sular generics)
 - Retain the following dihydropyridine CCBs as NF; even though both are available in generic formulations, they remain extremely costly
 - isradipine (Dynacirc generics)
 - nicardipine (Cardene generics)
- b) High- and medium-potency “hair-friendly” topical corticosteroids (solutions, foams, shampoos)
- Return to UF status: betamethasone valerate 0.12% foam (Luxiq, generics; GCN 32052); generic formulations are now the least costly medium potency alternative
 - Retain as NF with PA: clobetasol propionate/emollient 0.05% foam (Olux-E, generics); several alternatives (clobetasol propionate 0.05% solution, shampoo, and foam) are UF
 - Retain as completely excluded
 - halobetasol propionate 0.05% foam (Lexette, generic)
 - clobetasol propionate 0.05% shampoo/cleanser kit (Clodan Kit)
- c) High- and medium-potency topical corticosteroids (creams, gels)
- Return to UF status, based on comparable costs relative to other high-potency topical corticosteroids
 - fluocinonide 0.1% cream (Vanos, generics)
 - halobetasol propionate 0.05% cream (Ultravate, generics)
- d) Proton Pump Inhibitors (PPIs)
- Move from UF, non-step-preferred to UF step-preferred status (i.e., the PA will be removed), to reduce administrative burden and due to relatively low use, as well as making necessary changes to PA requirements requiring the use of the step-preferred PPIs prior to non-preferred PPIs
 - rabeprazole tabs
 - esomeprazole caps
 - lansoprazole caps

- Retain as NF, non-step-preferred but exempt from the NF mandatory TMOP requirement based on cost effectiveness (they are substantially less costly at retail), thus removing them from the TRICARE Maintenance List:
 - omeprazole/bicarb caps (Zegerid, generics) – the PA will be updated to also include lansoprazole caps as one of the step preferred products
 - lansoprazole rapidly dissolving tabs (Prevacid, generics) – the PA will be updated to also include lansoprazole caps as a step-preferred product
 - Making no changes to the status of the following except as noted:
 - omeprazole/bicarb packets (Zegerid, generics) [NF non-step-preferred and on the TRICARE Maintenance Drug List] – update the PA to include lansoprazole caps as
 - omeprazole/bicarb suspension (Konvomep) [UF with a PA]
 - vonoprazan (Voquezna) [NF with a PA and on the TRICARE Maintenance Drug List]
 - dexlansoprazole caps (Dexilant, generics) [completely excluded]
- e) SSRIs—fluoxetine
- Return to UF status: fluoxetine 10 and 20 mg tablets; while they remain less cost effective than the far more commonly used 10, 20, and 40 mg caps, costs have dropped substantially, and utilization is relatively low.
 - Retain as NF: Generic fluoxetine 90 mg DR tabs (Prozac Weekly generics)

IX. TRICARE MAINTENANCE DRUG LIST UPDATES

Nonformulary medications are generally restricted to TMOP 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 TRICARE pharmacy contractor managed TMOP. Medications subject to either the nonformulary requirement or added to the EMMPI program are combined as the TRICARE Maintenance Drug List, formerly known as the Select Maintenance Drug List.

The P&T Committee reviewed the list of drugs added to the TRICARE Maintenance Drug List on a contingent basis that were implemented as of March 1, 2024. These agents are outlined in Appendix F, Table 2, along with a running list of medications added or recommended for addition to the TRICARE Maintenance Drug List on a contingent basis. The P&T Committee also reviewed additional individual medications and classes/subclasses of medications for potential addition to the TRICARE Maintenance Drug List.

COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) addition of the following agents to the TRICARE Maintenance Drug List, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing from TMOP):

- *By subclass*
 - Oncological agents: non-Brutons Tyrosine Kinase Inhibitors (non-BTKI) for Chronic Lymphocytic Leukemia (CLL)
- *By individual agent*
 - decitabine/cedazuridine (Inqovi)
 - larotrectinib sulfate (Vitrakvi)
 - nintedanib (Ofev)
- *Added to TRICARE Drug List but removed from TRICARE Specialty Drug List*
 - lotilaner 0.25% ophthalmic solution (Xdemvy)

Note: The TRICARE Specialty Drug List defines medications for which specialty care pharmacy services are provided at TMOP under the current TRICARE pharmacy contract (TPharm5).

The TRICARE Specialty Drug list is a comprehensive specialty drug list based on the definition of a specialty drug previously agreed upon by the P&T Committee at the Aug 2014 meeting and it supersedes the previous Specialty Agent Reporting list.

X. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

Annual Utilization Management Review: The Committee reviewed a summary of approximately 100 UM actions from the four P&T Committee meetings held in FY2023 (November 2022 to August 2023). A focused review of actions showed that while there were more PA additions than removals, more patients were affected by PA removals than PA additions. Additionally, several oncology drugs had indications removed by the FDA due to a lack of positive confirmatory trials. The Committee reviewed detailed analysis of the effects of PAs on MHS utilization and spend.

XI. ADJOURNMENT

The meeting adjourned at 1545 hours on May 2nd. The next meeting will be in August 2024.

Appendix A—Attendance: May 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)**

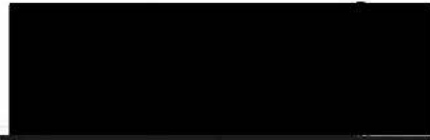
**Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications
Designated Formulary or Nonformulary during the May 2024 DoD
P&T Committee Meeting**

Appendix G—Implementation Dates

Appendix H—Completely Excluded Agents and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY:



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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

Telita Crosland LTG, MC, USA
Director

29 July 2024
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
MAJ Megan Donahue, MC (Day #1)	Army, Physician at Large
MAJ Danielle Zsido, MSC, for COL Aatif Sheikh, MSC	Army, Pharmacy Consultant Alternate
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
CAPT Peter Cole, MC (Day #2)	Navy, Physician at Large
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
Lt Col Brooke van Eeghen, BSC, for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
LCDR Shira Paul, MC	Navy, Oncology Physician
Beth Days, RPh, BCOP	DHA, Oncology Pharmacist
CAPT Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA	TRICARE Health Plan Chief Medical Officer

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Ms. Marsha Peterson	DHA Contracting Officer
Eugene Moore, PharmD	Tpharm5 Clinical COR
CAPT Bill Kelly, MSC, USN	Defense Logistics Agency
Pete Glassman, MD	Department of Veteran’s Affairs
Guests	
CDR Derek Larson, MC	Navy, Internal Medicine Physician Alternate
CDR Christopher McKnight, USCG	Coast Guard, Pharmacy Consultant Alternate
CAPT Chris Lamer	Indian Health Service
CAPT Marisol Martinez	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
CAPT Carl Olongo	Immigration and Customs Enforcement (ICE) Health Service Corps
Others Present	
CAPT Tiffany Cline	DHA POD Beneficiary Advisory Panel DFO
COL Aatif Sheikh, MSC	Army Pharmacy Consultant
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
CDR Giao Phung, MSC	DHA POD Formulary Management Branch
Heather Johnson, PharmD, BCPS	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
Mr. David Folmar	DHA POD Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA POD Formulary Management Branch Contractor

Appendix A—Attendance

Mr. Michael Lee	DHA POD Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA POD Formulary Management Branch Contractor
Fakhrudin Valibhai, PharmD	DHA POD Purchased Care Branch
Mr. Eric Parsons, R.Ph.	DHA POD Purchased Care Branch
Julia Trang, PharmD	DHA Contracting
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Julianne Canaley	DHA Contracting
Ms. Shiela Mirrieles	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
- insulin detemir (Levemir) - insulin glargine (Basaglar) - insulin glargine (Semglee) - insulin glargine-yfqn (Semglee) Insulins: Basal Insulin Analogs	Changes from May 2024 are in bold and ~~strikethrough~~ - Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure ~~Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control~~ ~~For Levemir only: No formulary alternative: The patient is pregnant and not able to use insulin glargine (Lantus)~~ Formulary alternatives: insulin glargine (Lantus), insulin glargine (Rezvoglar), insulin glargine-yfqn (unbranded), insulin glargine (unbranded)
insulin degludec (unbranded) Insulins: Basal Insulin Analogs	Changes from May 2024 are in bold and ~~strikethrough~~ - Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure - No formulary alternative: Patient is younger than 6 years of age and cannot take Lantus. ~~Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control~~ Formulary alternatives: insulin glargine (Lantus), insulin glargine (Rezvoglar), insulin glargine-yfqn (unbranded), insulin glargine (unbranded), insulin glargine U-300 (Toujeo, and unbranded U-300)
insulin degludec (Tresiba) Insulins: Basal Insulin Analogs	Changes from May 2024 are in bold and ~~strikethrough~~ - Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure - No alternative formulary agent: Patient is younger than 6 years of age and cannot take Lantus. ~~Patient has been adherent to insulin glargine (Lantus) and Toujeo, and has failed to achieve glycemic control~~ Formulary and nonformulary alternatives: insulin glargine (Lantus), insulin glargine (Rezvoglar), insulin glargine-yfqn (unbranded), insulin glargine (unbranded), insulin glargine U-300 (Toujeo, and unbranded U-300), insulin degludec (unbranded) – <i>note nonformulary</i>
- liraglutide (Saxenda) - orlistat (Xenical, generics) Weight Loss Agents	- Use of all formulary agents is contraindicated for patients 18 years of age or older - Use of Qsymia and Wegovy is contraindicated for patients 12 years of age or older and younger than 17 years of age - Use of all formulary agents resulted in therapeutic failure Formulary alternatives: phentermine products (phentermine, benzphetamine, diethylpropion IR/SR, phendimetrazine IR/SR) Qsymia, Contrave, Wegovy, and Zepbound.

Appendix B—Table of Medical Necessity Criteria

• beclomethasone (Qvar Redihaler) • budesonide (Pulmicort Flexhaler) • fluticasone furoate (Arnuity Ellipta) Pulmonary Is: Inhaled Corticosteroids (ICS)	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • Formulary agents result in therapeutic failure • Patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk • No alternative formulary agent: For Pulmicort Flexhaler only - the patient is pregnant and requires Pulmicort Flexhaler Formulary alternatives: ciclesonide (Alvesco), fluticasone propionate, mometasone (Asmanex HFA, Asmanex Twisthaler)
New Drugs MN Criteria	
• bosutinib capsules (Bosulif) Oncological: Chronic Myelogenous Leukemia	• Use of formulary agents is contraindicated Formulary alternatives: bosutinib tablets (Bosulif)
• cyclosporine 0.1% ophthalmic suspension (Vevye) Ophthalmic: Dry Eye	• Patient has experienced significant adverse effects from formulary agents • Use of formulary agents resulted in therapeutic failure Formulary alternatives: cyclosporine 0.05% (Restasis/Restasis Multidose), cyclosporine 0.09% (Cequa), lifitegrast (Xiidra)
• iptacopan injection (Fabhalta) 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: pegcetacoplan (Empaveli)
• roflumilast 0.3% topical foam (Zoryve) Psoriasis 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: generic ketoconazole 2% cream, foam, or shampoo; topical corticosteroid
• sitagliptin free base (Zituvio and Zituvio AG) Diabetes Non-Insulin: DPP-4 Inhibitors	• Patient has experienced significant adverse effects from formulary agents Formulary alternatives: sitagliptin phosphate (Januvia)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
insulin glargine U-300 (Toujeo SoloStar, Toujeo Max SoloStar, unbranded U-300) Insulins: Basal Insulin Analogs	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of insulin glargine U-300 (Toujeo SoloStar, Toujeo Max SoloStar, unbranded insulin glargine U-300) <u>Manual PA Criteria:</u> Coverage for Toujeo SoloStar, Toujeo Max SoloStar and unbranded insulin glargine U-300 are approved if: The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay - The patient is 6 years of age or older - The patient has a diagnosis of diabetes and is using a minimum of 100 units of ~~basal insulin glargine (Lantus)~~ insulin glargine, insulin degludec per day (i.e., insulin glargine, insulin degludec) OR - The patient has diagnosis of diabetes and is using a minimum of 80 units of basal insulin ~~requires a dosage increase with Lantus~~ and has experienced a clinically significant, severe hypoglycemia episode, ~~despite splitting the Lantus dose~~ - The patient, parent, or caregiver has been counseled regarding the risk of dosing errors - The following are not acceptable reasons for receiving Toujeo: - Nonadherence to previous insulin treatment OR - Patient or prescriber preference for the use of Toujeo OR - Patient or prescriber preference for a smaller injection volume - 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) Non-FDA-approved uses are not approved Prior authorization does not expire
- insulin glargine (Rezvoglar) - insulin glargine-yfgn (unbranded) - insulin glargine U-100 (unbranded by Winthrop) - insulin glargine (Basaglar) - insulin glargine (Semglee) - insulin glargine-yfgn (Semglee) Insulins: Basal Insulin Analogs	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of Basaglar, Semglee, Semglee-yfgn, Rezvoglar, insulin glargine-yfgn (unbranded), or insulin glargine (unbranded Winthrop) <u>Manual PA Criteria:</u> Coverage for Basaglar, Semglee, Semglee-yfgn, Rezvoglar, insulin glargine-yfgn (unbranded), or insulin glargine (unbranded by Winthrop) are approved if The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay - The patient has tried and ~~failed~~ had an inadequate response to insulin glargine (Lantus) Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

insulin detemir (Levemir) Insulins: Basal Insulin Analogs	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of Levemir <u>Manual PA Criteria:</u> Coverage for Levemir is approved if The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay The provider acknowledges that branded Levemir will be discontinued from the market in 2024 - The patient has tried and ~~failed~~ had an inadequate response to insulin glargine (Lantus) ~~The patient is pregnant and cannot use insulin glargine~~ Non-FDA-approved uses are not approved Prior authorization does not expire
insulin degludec (unbranded) Insulins: Basal Insulin Analogs	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of insulin degludec (unbranded) <u>Manual PA Criteria:</u> Coverage for insulin degludec (unbranded) is approved if The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay - The patient has tried and ~~failed~~ had an inadequate response to insulin glargine (Lantus) - The patient is one year of age or older - The provider must explain why the patient cannot use Lantus (fill in the blank) AND - The provider must explain why the patient cannot use Toujeo (fill in the blank) Acceptable responses include the following: The patient has experienced clinically significant hypoglycemia with insulin glargine (Lantus) and insulin glargine U-300 (Toujeo) that is not expected to occur with insulin degludec OR The patient works an alternating or inconsistent work shift schedule resulting in substantially varied meal times on a day-to-day bases resulting in an increased risk for level 2 or 3 hypoglycemia Level 2 (moderate) hypoglycemia defined as glucose level less than 54 mg/dL Level 3 (severe) hypoglycemia define a person is unable to function due to mental/physical changes from a low glucose level and requires assistance Note the following are not acceptable reasons for receiving insulin degludec Non-adherence to previous insulin treatment OR Patient or prescriber preference for the use of insulin degludec Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

insulin degludec (Tresiba) Insulins: Basal Insulin Analogs	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of insulin degludec (Tresiba) <u>Manual PA Criteria:</u> Coverage for insulin degludec (Tresiba) is approved if - The provider acknowledges that insulin glargine (Lantus) is DoD's preferred basal insulin and is available without a PA at the lowest Tier 1 copay - The patient has tried and ~~failed~~ had an inadequate response to insulin glargine (Lantus) - The patient is one year of age or older - The provider must explain why the patient cannot use Lantus (fill in the blank) - The provider must explain why the patient cannot use Toujeo (fill in the blank) - The provider must explain why the patient cannot use unbranded insulin degludec (fill in the blank) - Acceptable responses include the following: - The patient has experienced clinically significant hypoglycemia with insulin glargine (Lantus), insulin glargine U-300 (Toujeo) and insulin degludec (unbranded) that is not expected to occur with insulin degludec OR ~~The patient works an alternating or inconsistent work shift schedule resulting in substantially varied meal times on a day-to-day bases resulting in an increased risk for level 2 or 3 hypoglycemia~~ ~~Level 2 (moderate) hypoglycemia defined as glucose level less than 54 mg/dL~~ ~~Level 3 (severe) hypoglycemia define a person is unable to function due to mental/physical changes from a low glucose level and requires assistance~~ - Note the following are not acceptable reasons for receiving insulin degludec (Tresiba) - Non-adherence to previous insulin treatment OR - Patient or prescriber preference for the use of insulin degludec (Tresiba) Non-FDA-approved uses are not approved Prior authorization does not expire
bupropion/naltrexone (Contrave) Weight Loss Agents	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of Contrave <u>Manual PA Criteria:</u> Coverage for Contrave is approved if: - The patient is 18 years of age or older - The patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) - Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy - The patient must have tried and failed to achieve a 5 percent reduction in baseline weight after 12-week course of phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR OR - The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension, hyperthyroidism) OR

Appendix C—Table of Prior Authorization (PA) Criteria

	• The patient has experienced an adverse reaction to phentermine that is not expected to occur with Contrave the requested agent • The patient is not receiving concurrent opioid therapy, and does not have a seizure disorder • The patient is not currently on a monoamine oxidase inhibitor (e.g., Emsam, Marplan, Nardil), or another formulation of bupropion or naltrexone • Patient is not pregnant • ~~If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin~~ Non-FDA-approved uses are not approved PA expires in 12 months ~~after 4 months~~ for initial therapy, ~~renewal therapy approves for 12 months;~~ annual renewal required Renewal PA Criteria: Contrave will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient lost greater than or equal to 5 percent of baseline body weight since starting medication • The patient is not pregnant
• phentermine/topiramate (Qsymia) Weight Loss Agents	May 2024 changes are in bold and strikethrough Manual PA criteria apply to all new users of Qsymia <u>Manual PA Criteria:</u> Coverage for Qsymia is approved if: • Patient is 12 years of age or older and younger than 18 years of age with BMI greater than or equal to 95th percentile standardized for age and sex OR • Patient is 18 years of age or older with a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss and will remain engaged throughout course of therapy • The patient must have tried and failed to achieve a 5 percent reduction in baseline weight after 12-week course of phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension, hyperthyroidism) OR • The patient has experienced an adverse reaction to phentermine that is not expected to occur with the requested agent • ~~Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension, hyperthyroidism)~~ • ~~Patient has tried generic phentermine for 3 months and had an inadequate response if they are older than 18 years OR~~ • Patient is not pregnant. • Provider agrees to monitor the rate of weight loss in pediatric patients. If weight loss exceeds 2 pounds (0.9 kg)/week, consider dosage reduction

Appendix C—Table of Prior Authorization (PA) Criteria

	• Prescriber will abide by and the patient has been informed of the Risk Evaluation and Mitigation Strategy (REMS) program and safety concerns associated with this agent: – Use in combination with other products intended for weight loss has not been established – Use in patients with increased cardiovascular risk has not been established – Qsymia is pregnancy category X and is associated with increased risk of teratogenicity • ~~If patient has impaired glucose tolerance or diabetes, must have tried metformin first or is concurrently taking metformin.~~ Non-FDA approved uses are not approved PA expires after ~~four~~ in 12 months for initial therapy, ~~renewal therapy approves for 12 months,~~ annual renewal required Renewal PA Criteria: Qsymia will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost greater than or equal to 5 percent of baseline body weight since starting medication • For patients initially receiving Qsymia 7.5 mg/46 mg: discontinue Qsymia or escalate to 15 mg/92 mg if a percent reduction in baseline body weight is not achieved or a pediatric patient has not experienced a reduction of at least 3% of baseline BMI at 12 weeks • For patients receiving Qsymia 15 mg/92 mg: discontinue if a 5 percent reduction in baseline body weight is not achieved or a pediatric patient has not experienced a reduction of at least 5% of baseline BMI at 12 weeks • The patient is not pregnant
• semaglutide (Wegovy) • tirzepatide (Zepbound) Weight Loss Agents	May 2024 changes are in bold and strikethrough Manual PA criteria apply to all new users of Wegovy and Zepbound <u>Manual PA Criteria:</u> Coverage for Wegovy or Zepbound is approved if: For Wegovy and Zepbound for adults • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response ~~all of the following (generic phentermine, and Qsymia, and Contrave)~~ – Phentermine: Date _____ Duration of therapy _____ - OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension) ~~OR to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug)~~

Appendix C—Table of Prior Authorization (PA) Criteria

	• ~~Qsymia: Date _____ Duration of therapy _____~~ • ~~Contrave: Date _____ Duration of therapy _____~~ • ~~If the patient is diabetic, must have tried and failed metformin and the DoD's preferred GLP1RAs (Trulicity)~~ • The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) • Patient is 12 years of age or older and younger than 18 years of age • Patient has a BMI greater than or equal to 95th percentile standardized for age • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy For all patients • Concomitant use of this medication with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus ~~Initial prior authorization expires after 4 months and then annually.~~ PA expires in 12 months for initial therapy; annual renewal required <u>Renewal PA Criteria:</u> Wegovy and Zepbound will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication ~~despite 16 weeks of therapy~~ with full dosage titration • For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant
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Appendix C—Table of Prior Authorization (PA) Criteria

• liraglutide (Saxenda) Weight Loss Agents	May 2024 changes are in bold and ~~strikethrough~~ Manual PA criteria apply to all new users of Saxenda <u>Manual PA Criteria:</u> Coverage for Saxenda is approved if Adults • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried and failed all of the following (generic phentermine [or benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR], Qsymia, and Contrave) or has experienced an adverse reaction or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) – Phentermine, benzphetamine, diethylpropion (IR/SR), or phendimetrazine (IR/SR: Date _____ Duration of therapy _____) – Qsymia (or one of its individual generic components phentermine or topiramate): Date _____ Duration of therapy _____ – Contrave (or one of its individual generic components bupropion or naltrexone): Date _____ Duration of therapy _____ – Wegovy: Date _____ Duration of therapy _____ – Zepbound: Date _____ Duration of therapy _____ • ~~If the patient is diabetic, must have tried and failed metformin and the DoD's preferred GLP1RAs (Trulicity)~~ Adolescents • Patient is 12 years of age or older and younger than 18 years of age with BMI greater than or equal to 95th percentile standardized for age • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • Patient has tried and failed Qsymia or its individual generic components OR • Patient has a contraindication or has had an adverse reaction to Qsymia or its individual generic components (Note: provider must include the date of use and duration of therapy or contraindication to the drug) and Wegovy – Qsymia (or one of its individual generic components, phentermine or topiramate): Date _____ Duration of therapy _____ – Wegovy: Date _____ Duration of therapy _____ For all patients • Concomitant use of Wegovy with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2
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Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus ~~Initial prior authorization expires after 4 months and then annually.~~ PA expires in 12 months for initial therapy, annual renewal required <u>Renewal PA Criteria:</u> Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Patient is older than 12 years of age and younger than 18 years of age: the patient has lost greater than or equal to 4% of baseline body weight since starting medication despite 16 weeks of therapy with full dosage titration • Patient is older than 18 years of age: the patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant
• orlistat (Xenical) Weight Loss Agents	May 2024 changes are in bold and strikethrough Manual PA criteria apply to all new users of Xenical <u>Manual PA Criteria:</u> Coverage for Xenical is approved if <u>For adults:</u> • The patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity ~~for those with risk factors in addition to obesity~~ (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and will remain engaged throughout course of therapy. • Patient has tried and failed all of the following (generic phentermine, Qsymia, Contrave, Wegovy, and Zepbound) or has experienced an adverse reaction or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) – Phentermine: Date _____ Duration of therapy _____ – Qsymia (or one of its individual generic components phentermine or topiramate): Date _____ Duration of therapy _____ – Contrave (or one of its individual generic components bupropion or naltrexone): Date _____ Duration of therapy _____ – Wegovy: Date _____ Duration of therapy _____ – Zepbound: Date _____ Duration of therapy _____ • Patient does not have chronic malabsorption syndrome, or cholestasis • Patient is not pregnant • ~~If patient has impaired glucose tolerance or diabetes, must have tried metformin first, or is concurrently taking metformin~~ Non-FDA-approved uses are not approved PA expires after 12 months ~~4 months for initial therapy, renewal therapy approves for 12 months~~ annual renewal required Renewal Criteria

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant <u>For adolescents:</u> • The patient is 12 years of age or older and younger than 18 years of age • Patient currently has a BMI greater than or equal to 95th percentile for age and sex, or in greater than or equal to 85th percentile but less than 95th percentile for age and sex and has at least one severe co-morbidity (type 2 diabetes mellitus, premature cardiovascular disease) or has a strong family history of diabetes or premature cardiovascular disease (CVD) • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss and will remain engaged throughout course of therapy • Must have tried and failed or have adverse reaction or have a contraindication to ~~generic phentermine~~ Qsymia and Wegovy (Note: provider must include the date of use and duration of therapy or contraindication to the drug) – Qsymia (or one of its individual generic components phentermine or topiramate): Date _____ Duration of therapy _____ – Wegovy: Date _____ Duration of therapy _____ • Patient does not have chronic malabsorption syndrome, or cholestasis • Patient is not pregnant Non-FDA-approved uses are not approved PA expires after 12 months ~~4 months~~ for initial therapy, ~~renewal therapy approves for 12 months;~~ annual renewal required Renewal Criteria • Patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient current BMI percentile decreased for age and weight (considering the patient is increasing in height and will have a different normative BMI from when Xenical was started) • The patient currently has a BMI greater than 85th percentile • The patient is not pregnant
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Appendix C—Table of Prior Authorization (PA) Criteria

Newly Approved Drug PAs	
birch triterpenes 10% topical gel (Filsuvez) Skin Preps	Manual PA criteria apply to all new users of Filsuvez <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 6 months of age or older - Prescribed by or in consultation with a dermatologist or wound care specialist - Patient has a diagnosis of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) - Patient has one or more open wounds that will be treated - Patient's wound is clean in appearance and does not appear to be infected ~~Patient's wound is 10 cm² to 50 cm²~~ ~~Patient's wound is at least 21 days old and less than 9 months old~~ ~~Squamous cell and/or basal cell carcinoma have been ruled out~~ Non-FDA approved uses are NOT approved PA expires in ~~three~~ 6 months Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met: - The patient has had disease stabilization or improvement in disease on therapy - Renewal prescription is written by a dermatologist or wound care specialist
bosutinib capsules (Bosulif) Oncological Agents: CML	Manual PA criteria apply to all new users of Bosulif capsules <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Bosulif capsules are prescribed by or in consultation with a hematologist/oncologist - Patient is 1 years of age or older with chronic phase Ph+ chronic myelogenous leukemia, that is either newly diagnosed or resistant or intolerant to prior therapy OR - Patient is 18 years of age or older with accelerated or blast phase Ph+ chronic myeloid leukemia with resistance or intolerance to prior therapy - Patient cannot swallow tablets due to a documented medical condition (e.g., dysphagia) - The provider is aware of all warnings, screening, and monitoring precautions for Bosulif - 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 Other non-FDA approved uses are NOT approved except as noted above PA does not expire
budesonide 2 mg/10 mL oral suspension (Eohilia) GI-1 Agent	Manual PA criteria apply to all new users of Eohilia <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Prescribed by a gastroenterologist or allergy/immunology specialist - Patient has a documented diagnosis of eosinophilic esophagitis (EoE) by endoscopic biopsy - Patient has tried and had an inadequate response, intolerance, or contraindication to a Proton Pump Inhibitor ~~Patient has tried and had an inadequate response, intolerance, or contraindication to a formulary topical glucocorticoid (e.g., fluticasone HFA or budesonide respule)~~

Appendix C—Table of Prior Authorization (PA) Criteria

	~~that is not expected to occur with Eohilia; note: an intolerance does not include preferences for flavor or taste of medication for pediatric patients~~ Non-FDA approved uses are NOT approved PA does not expire
cyclosporine 0.1% ophthalmic solution (Vevye) Ophthalmic Dry Eye Disease	Manual PA criteria apply to all new users of Vevye <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Medication is prescribed by an ophthalmologist or optometrist - Patient has a diagnosis of moderate to severe dry eye disease - Patient had positive symptomology screening for dry eye disease from an appropriate measure - Patient has at least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) - Patient has had at least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) - Patient has had at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) - Patient has had at least a 3 month trial of cyclosporine (Restasis) cyclosporine 0.09% (Cequa) AND lifitegrast (Xiidra) Non-FDA approved uses are not approved PA does not expire
eflornithine tablets (Iwifin) Oncological Agents	Manual PA criteria apply to all new users of Iwifin <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Prescribed by or in consultation with an oncologist - Patient has high-risk neuroblastoma - Medication is being used to reduce the risk of relapse - Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy - The provider is aware of all warnings, screening, and monitoring precautions for Iwifin - 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 Other non-FDA approved uses are not approved except as noted above PA does not expire
eplontersen injection (Wainua) Miscellaneous Neurological Agents	Manual PA criteria apply to all new users of Wainua <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - The patient is 18 years of age or older - Drug is prescribed by or in consultation with a specialist who manages hereditary transthyretin amyloidosis (hATTR), such as a neurologist, cardiologist, and/or medical geneticist - The patient has documented evidence of hATTR polyneuropathy as confirmed by the following: - Genetically confirmed transthyretin mutation resulting in Coutinho stage 1 or 2 hereditary transthyretin-mediated amyloidosis (hATTR) - The patient has polyneuropathy secondary to hereditary transthyretin-mediated amyloidosis

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ The patient has a Neuropathy Impairment Score between 10-130 • The patient is not receiving concurrent treatment with Tegsedi (inotersen), Onpattro (patisiran), Amvuttra (vutrisiran) or Vyndaqel/Vyndamax (tafamidis) • The provider acknowledges that the patient will receive an oral Vitamin A supplement at the recommended daily allowance while receiving the requested medication Non-FDA approved uses are not approved including hATTR cardiomyopathy PA expires in one year Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient has demonstrated improvement in neuropathy
• infliximab-dyyb injection (Zymfentra) TIBs: TNF inhibitors	Manual PA criteria apply to all new users of Zymfentra <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has moderate to severely active ulcerative colitis or moderate to severe Crohn's disease • The provider acknowledges Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis and Crohn's disease • Patient has experienced one of the following: ▪ Patient has had an inadequate response to Humira ▪ Patient has had an adverse reaction to Humira that is not expected to occur with the requested agent ▪ Patient has a contraindication to Humira ▪ Patient is clinically stable on IV infliximab and changing to Humira would incur unacceptable risk • Patient has received infliximab product administered intravenously as induction therapy and has demonstrated positive response • 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 infliximab-dyyb (Zymfentra) 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
• iptacopan (Fabhalta) Hematological Agents	Manual PA criteria apply to all new users of Fabhalta <u>Manual PA criteria:</u> Coverage is approved if all criteria are met • Patient is 18 years of age or older • Prescribed by a hematologist or oncologist • Patient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

Appendix C—Table of Prior Authorization (PA) Criteria

	- Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements - Patient is not receiving C3 or C5 inhibitors with Fabhalta, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or pegcetacoplan (Empaveli) Non-FDA approved uses are NOT approved PA expires after 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - Patient meets initial criteria, has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, or reductions in hemolysis
nedosiran injection (Rivfloza) Nephrology Agents	Manual PA criteria apply to all new users of Rivfloza <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation - The medication is prescribed by or in consultation with a nephrologist or urologist - The medication is prescribed for an FDA-approved age - Patient has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m² Patient has trialed pyridoxine and has experienced an inadequate response or intolerance OR patient has a contraindication to pyridoxine - Rivfloza will not be used in combination with lumasiran (Oxlumo) Non-FDA approved uses are NOT approved PA expires after one year; annual renewal required Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for continuation of therapy if all the criteria are met: - The patient has had disease stabilization or improvement in disease on therapy
omalizumab autoinjector (Xolair) Atopy Agents	Updates from the May 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Xolair autoinjector <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: There were no changes to the PA criteria for Xolair indications other than the new indication for food allergy. <u>For food allergy:</u> - Xolair is prescribed by an allergist or immunologist - The patient has a documented history of food allergy Provider acknowledges clinical trials excluded those with ~~The patient does not have a~~ history of severe anaphylaxis, uncontrolled or severe asthma, uncontrolled atopic dermatitis, or eosinophilic gastrointestinal disease ~~The patient does not have a history of severe anaphylaxis to the food allergen being treated~~ - The patient is not currently receiving oral, IM, or IV corticosteroids, tricyclic antidepressants, or beta-blockers (oral or topical) - The patient is not currently receiving or has not received in the last 6 months any immunotherapy [e.g., oral immunotherapy (OIT), sublingual immunotherapy (SLIT) or epicutaneous immunotherapy (EPIT)] to the food allergen being treated

Appendix C—Table of Prior Authorization (PA) Criteria

	- The patient is not currently receiving or has not received in the last 6 months other immunomodulatory therapy - Provider acknowledges that the patient will be counseled on the following: Xolair does NOT eliminate food allergy and the patient must continue to avoid food allergen - The need for access to an epinephrine injector - Xolair is not intended to treat emergencies <u>For all indications:</u> ~~For food allergy:~~ ~~Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents (except foods), such as drugs, biologics, etc.~~ ~~For asthma, chronic rhinosinusitis with nasal polyps, chronic idiopathic urticaria:~~ ~~Provider ensures that patient has no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc.~~ Provider acknowledges Xolair carries a black box warning for anaphylaxis, should be initiated in a healthcare setting, and self-administration of Xolair should be based on criteria to mitigate risk from anaphylaxis. - Patient has received or will receive at least 3 doses of Xolair under the guidance of a healthcare provider without experiencing any hypersensitivity reactions - Provider agrees to ensure that the patient or caregiver is able to recognize symptoms of anaphylaxis. ~~presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue. Provider agrees to counsel the patient that anaphylaxis has occurred up to 2 hours post administration and appropriate monitoring will occur.~~ - Provider agrees to ensure that the patient or caregiver is able to treat anaphylaxis appropriately ~~and consider with~~ co-prescribing epinephrine. - Provider agrees to ensure that the patient or caregiver is able to perform subcutaneous injections with requested medication with proper technique according to the prescribed dosing regimen - For all indications the patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or dupilumab [Dupixent]) - For the Xolair prefilled syringe formulation, the provider acknowledges: - Patients 1 to 11 years of age: must be administered by a caregiver. - Patients older than 12 years: may be self-administered, or under adult supervision for pediatric patients - For the Xolair autoinjector formulation the provider acknowledges: - Patients less than 12 years of age: not authorized - Patients older than 12 years: may be self-administered, or under adult supervision for pediatric patients Non-FDA approves uses are not approved PA expires in one year Renewal criteria for food allergies Note that initial TRICARE PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met: - Food allergy: Provider acknowledges that the patient will continue to be counseled on the following: Xolair does NOT eliminate food allergy and patient must continue to avoid food allergen - The need for access to an epinephrine injector - Xolair is not intended to treat emergencies
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Appendix C—Table of Prior Authorization (PA) Criteria

roflumilast 0.3% topical foam (Zoryve) Psoriasis Agents	Manual PA criteria apply to all new users of <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 9 years of age or older - Prescribed by or in consultation with a dermatologist - Patient has diagnosis of moderate to severe seborrheic dermatitis - The patient must have tried for at least 2 weeks and failed, or have a contraindication to, or have had an adverse reaction to both of the following: - at least one topical corticosteroid (e.g., mometasone furoate 0.1% solution) - at least one topical antifungal (e.g., ketoconazole 2% shampoo) Non-FDA approved uses are not approved PA expires in one year; new PA must be submitted
sitagliptin free base (Zituvio, Zituvio authorized generic) DPP-4 inhibitors	Manual PA criteria apply to all new users of Zituvio and Zituvio authorized generic <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges that Januvia is TRICARE's preferred dipeptidyl peptidase-4 inhibitor and are available to TRICARE beneficiaries without requiring prior authorization - Provider must document why the patient cannot use Januvia, Janumet or Janumet XR. (blank write-in) - Acceptable responses include that the patient has had an adverse reaction to an excipient in brand sitagliptin phosphate (Januvia, Janumet or Janumet XR) that would not be likely to occur with Zituvio Non-FDA approved uses are NOT approved PA does not expire
vamorolone oral suspension (Agamree) Corticosteroids-Immune Modulators	Manual PA criteria apply to all new users of Agamree <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 2 years of age or older - Prescribed by a neurologist - Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) that has been confirmed by genetic testing or muscle biopsy - Patient has a contraindication to, intolerance to, or has failed a trial for at least 3 months of at least one of the following: - prednisone or - deflazacort (Emflaza) - Provider acknowledges the FDA safety alerts, warnings, precautions, drug interactions, and monitoring recommendations for the requested medication Non-FDA approved uses are NOT approved PA does not expire
zilucoplan injection (Zilbrysq) Miscellaneous Neurological Agent	Manual PA criteria apply to all new users of Zilbrysq <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by a neurologist - Patient has documented diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive - Patient is not known to be muscle-specific tyrosine kinase antibody-positive - Patient has had insufficient response or intolerance to pyridostigmine

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient has had insufficient response or intolerance to glucocorticoid sparing therapy such as azathioprine, mycophenolate, cyclosporine, or tacrolimus • Patient has had insufficient response or intolerance to a neonatal Fc receptor antagonist such as efgartigimod alfa or rozanolixizumab (Rystiggo) • Patient has been vaccinated against certain encapsulated bacteria (for example, <i>Streptococcus pneumoniae</i>, <i>Neisseria meningitidis</i> types A, C, W, Y, and B, and <i>Haemophilus influenzae</i> type B) • Patient is not receiving neonatal Fc receptor antagonists or other C5 inhibitors with Zilbrysq, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), efgartigimod (Vyvgart), efgartigimod alfa and hyaluronidase (Vyvgart Hytrulo) Non-FDA approved uses are not approved PA expires in 6 months <u>Renewal Criteria:</u> Note that initial Tricare PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met: • Patient is continuing to derive benefit from Zilbrysq, according to the prescriber (Examples of derived benefit include reductions in exacerbations of myasthenia gravis; improvements in speech, swallowing, mobility, and respiratory function)
Utilization Management New PAs	
• brivaracetam (Briviact) Anticonvulsants- Antimania Agents	PA criteria apply to all new users of Briviact tablets and oral solution. <u>Automated PA Criteria:</u> The patient has filled a prescription for any formulation of levetiracetam at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND <u>Manual PA criteria:</u> If automated criteria are not met, coverage for Briviact is approved if all criteria are met: • The drug is prescribed by an adult or pediatric neurologist • The patient has a diagnosis of partial onset seizures • Patient has a contraindication to, intolerance to, or has had an inadequate response to a trial of levetiracetam Non-FDA-approved uses are not approved. Prior authorization does not expire.
• tramadol 25 mg tablets Narcotic Analgesics and Combinations	Manual PA criteria apply to all new and current users of tramadol 25 mg tablet. <u>Manual PA criteria:</u> tramadol 25 mg tablet is approved if all criteria are met: • Provider is aware and acknowledges that tramadol 50 mg tablets are available to DoD beneficiaries without the need of prior authorization. Providers are encouraged to consider changing the prescription to the preferred tramadol 50 mg. • Provider must explain why the patient requires tramadol 25 mg and cannot take the cost-effective generic tramadol 50 mg formulations (fill-in the blank) ▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg tablets Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management Updated PAs	
• dupilumab (Dupixent) Atopy	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA apply to all new users of Dupixent. Note that there were no changes to the PA criteria for the indications of asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis, or prurigo nodularis. <u>Manual PA criteria:</u> Coverage for Eosinophilic Esophagitis (EoE) is approved if all criteria are met: • The patient is one 12 years of age or older and weighs at least 15 40 kilograms (~33 88lbs) • The drug is prescribed by or in consultation with a gastroenterologist or allergy/immunology specialist • Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy • For EoE, the patient has tried and failed an adequate course of both the following: ▪ Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND ▪ Topical glucocorticoids [e.g., fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, clinically significant adverse effects are experienced, or in children maximal doses cannot be reached due to concerns for growth suppression or adrenal insufficiency Non-FDA approved uses are not approved Prior authorization expires in 1 year. Renewal Criteria: (Initial TRICARE PA approval is required for renewal). Coverage will be approved indefinitely for continuation of therapy if the following criteria are met: • Eosinophilic Esophagitis (EoE): ▪ For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e): a) Reduced intraepithelial eosinophil count; OR b) Decreased dysphagia/pain upon swallowing; OR c) Reduced frequency/severity of food impaction; OR d) Reduced vomiting/regurgitation; OR e) Improvement in oral aversion/failure to thrive ▪ For relapse: prior authorization form or chart notes documenting a relapse after treatment was discontinued since last approval
• alpelisib (Piqray) Oncological Agents: Breast Cancer	Updates from the May 2024 meeting are in strikethrough. Manual PA is required for all new users of Piqray. <u>Manual PA Criteria:</u> Piqray is approved if all criteria are met: • Patient must be ≥18 years. • Patient is diagnosed with advanced or metastatic HR positive, HER2 negative breast cancer with PIK3CA mutation as confirmed by an FDA-approved test. • Drug is prescribed by, or in consultation with, an oncologist/hematologist. • ~~Female patients are post-menopausal, or if pre-menopausal, they are receiving ovarian ablation/suppression.~~ • Female patients of reproductive potential will use effective contraception during therapy and for one week after the last dose.

Appendix C—Table of Prior Authorization (PA) Criteria

	• Patient has tried and failed, or is not a candidate for, adjuvant or neoadjuvant chemotherapy. • Patient has had disease progression while on or after endocrine-based therapy. • Patient will receive fulvestrant injection (Faslodex) therapy along with alpelisib (Piqray). • Patient has no history of Stevens Johnson Syndrome, Erythema Multiforme, or Toxic Epidermal Necrolysis. • Provider is aware and has informed patient of risk of serious, life-threatening skin reactions, including Stevens Johnson Syndrome; severe hyperglycemia; gastrointestinal toxicity, including severe diarrhea; kidney injury; lung injury including pneumonitis; pancreatitis; and severe hypersensitivity reactions. • Provider is aware and has informed patient that safety has not been established in type 1 or uncontrolled type 2 diabetic patients. • Male patients with female partners of reproductive potential should use condoms and effective contraception during therapy and for one week after last dose. • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• alectinib (Alecensa) Oncological Agents: Lung Cancer	Updates from the May 2024 meeting are in bold. Manual PA applies to new users of Alecensa, Alunbrig, and Zykadia. <u>Manual PA Criteria:</u> Alecensa, Alunbrig, or Zykadia is approved if all criteria are met: • The patient is 18 years of age or older • The patient has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an FDA-approved test OR • Alecensa will be used as adjuvant treatment following tumor resection of ALK-positive NSCLC as detected by an FDA-approved test • The drug is prescribed by or in consultation with a hematologist/oncologist OR • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• erdafitinib (Balversa) Oncological Agents	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Balversa. <u>Manual PA Criteria:</u> Erdafitinib (Balversa) is approved if all criteria are met: • The patient is 18 years of age or older • Patient has locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR3 ~~or FGFR2~~ mutation confirmed with an FDA-approved test • The patient has progressed during or following at least one line of prior systemic therapy ~~platinum-containing chemotherapy (including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy)~~ • Prescribed by or in consultation with an oncologist • The patient will be evaluated by an ophthalmologist before starting treatment and every month for the first 4 months; every 3 months thereafter

Appendix C—Table of Prior Authorization (PA) Criteria

	- The patient will be advised to seek emergent evaluation for new ocular symptoms - The patient will be monitored for hyperphosphatemia. (Note that 33% of patients required a phosphate binder in the trial supporting FDA approval for erdafitinib) - If the patient is female, she is not pregnant or planning to become pregnant. - Female patients will not breastfeed. - All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose. - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
sotorasib (Lumakras) Oncological Agents: Lung Cancer	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Lumakras. Manual PA criteria: Lumakras is approved if all criteria are met: - Patient is 18 years of age or older - Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test ~~The provider acknowledges that sotorasib 120 mg tablets are significantly more cost effective than sotorasib 320 mg tablets~~ ~~If the prescription is for sotorasib 320 mg, the patient cannot tolerate sotorasib (Lumakras) 120 mg tablets dispersed in water per manufacturer instructions and has documented swallowing dysfunction.~~ - The patient will be monitored for interstitial lung disease and hepatotoxicity - The drug is prescribed by or in consultation with a hematologist/oncologist - Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
golimumab (Simponi) Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of golimumab (Simponi). <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated criteria are not met, Simponi is approved if all criteria are met. Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent. and must be tried first for most indications. The patient has had an inadequate response to Humira

Appendix C—Table of Prior Authorization (PA) Criteria

	• The patient has experienced an adverse reaction to Humira that is not expected to occur with Simponi • The patient has a contraindication to Humira • ~~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 adult patients 18 years of age or older with one of the following diagnosis/indication: • Moderate to severe active rheumatoid arthritis (RA) in combination with methotrexate AND an active prescription for methotrexate • Active psoriatic arthritis (PsA) • Active ankylosing spondylitis (AS) • Moderately to severely active ulcerative colitis (UC) 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 indication does 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 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) Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• adalimumab (Humira) TIBs: TNF Inhibitors	Updates from the May 2024 meeting are in bold and strikethrough. <u>Automated PA Criteria</u>: If the provider is a Rheumatologist (Internal Medicine or Pediatric). PA is approved. <u>Manual PA Criteria</u>: If automated criteria are not met for Rheumatologist specialist prescribing, Humira is approved if all criteria are met: • Coverage is approved for adult patients 18 years of age or older with ~~one of the following diagnoses/indications~~: ▪ Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) ▪ Moderate to severe chronic plaque psoriasis (Ps) in patients who are candidates for systemic therapy or phototherapy ▪ Moderate to severely active Crohn's disease (CD) ▪ Moderate to severely active ulcerative colitis (UC) ▪ Moderate to severe hidradenitis suppurativa (HS) ▪ Non-infectious intermediate, posterior, and panuveitis ▪ Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids OR • ~~Coverage approved for pediatric patients 12-17 years of age with diagnosis of:~~ ▪ ~~Moderate to severe hidradenitis suppurativa (HS)~~ • ~~Coverage approved for pediatric patients 6-17 years of age with diagnosis of:~~ ▪ ~~Moderate to severely active Crohn's disease (CD)~~ • ~~Coverage approved for pediatric patients 5-17 years of age with diagnosis of:~~ ▪ ~~Moderately to severely active ulcerative colitis (UC)~~ • ~~Coverage approved for pediatric patients 4-17 years of age with diagnosis of:~~ ▪ ~~Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate OR~~ • Coverage is approved for pediatric patients 2-17 years of age with ~~one of the following diagnosis/indication:~~ ▪ Moderate to severe active ~~polyarticular~~ juvenile idiopathic arthritis (pJIA JIA), including subtypes ▪ Non-infectious intermediate, posterior, and panuveitis ▪ Moderate to severe plaque psoriasis in patients who are candidates for systemic or phototherapy ▪ Moderate to severe hidradenitis suppurativa (HS) ▪ Moderately to severely active Crohn's disease (CD) ▪ Moderately to severely active ulcerative colitis (UC) • Below criteria applies to AS and nr-axSpA indications only: ▪ Patient has had an inadequate response to at least two NSAIDs over a period of at least two months • Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease, ankylosing spondylitis (AS), nr-axSpA, and ~~pyoderma gangrenosum (PG)~~, psoriatic arthritis (PsA) and applies to pediatric patients with plaque psoriasis or Crohn's disease: ▪ Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]), antibiotics or anti-androgens • Below criteria applies to all patients (regardless of age): ▪ Providers acknowledge there have been cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. ▪ Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) ▪ Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: 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 (Olmiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER). • Coverage for non-FDA-approved uses not listed above: Please provide the diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire
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Appendix C—Table of Prior Authorization (PA) Criteria

etanercept (Enbrel) TIBs: TNF Inhibitors	Updates from the May 2024 meeting are in bold and strikethrough. Step therapy and manual PA criteria apply to all new users. <u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND <u>Manual PA criteria:</u> 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 Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent for adults and children AND - Coverage approved for adult patients 18 years of age or older with: - Moderate to severe active rheumatoid arthritis - Moderate to severe 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 2–17 years of age 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 4-17 years of age of age with: - Plaque psoriasis. Note that a trial of Stelara is required for pediatric patients 6 years of age or older, however for patients 4-5 years of age, 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) Prior authorization does not expire Non-FDA-approved uses are not approved
ixekizumab (Taltz) TIBs: Non-TNF Inhibitors	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of ixekizumab (Taltz). <u>Manual PA Criteria:</u> Taltz is approved if <u>ALL</u> criteria are met: Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent and must be tried first for most indications The patient has had an inadequate response to Humira, Cosentyx, AND Stelara The patient has experienced an adverse reaction to Humira, Cosentyx AND Stelara that is not expected to occur with Taltz The patient has a contraindication to Humira, Cosentyx AND Stelara ~~Humira, Cosentyx, AND, Stelara Step:~~

Appendix C—Table of Prior Authorization (PA) Criteria

	~~• Contraindication/inadequate response exists to Humira, Cosentyx, AND, Stelara~~ ~~• Adverse reactions to Humira, Cosentyx, AND, Stelara not expected with requested non-step preferred TIB~~ • Coverage is approved for adult patients 18 years of age or older with: ▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ▪ Active ankylosing spondylitis (AS): only Humira and Cosentyx step required ▪ Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation: only Humira and Cosentyx step required ~~• With evidence of elevated CRP and/or MRI evidence of sacroiliitis and ASDAS ≥ 2.1~~ • Coverage is approved for pediatric patients 6 years of age and older with: ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ~~(6 years of age or older)~~ ~~• *Trial of Humira AND Cosentyx NOT required for age 6 to 17 years AND trial of Stelara NOT required for age 6 to 11 years~~ • Has the patient had an inadequate response to non-biologic systemic therapy? (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine], etc.)? • Negative TB test result in past 12 months (or TB 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) Prior authorization does not expire Non-FDA-approved uses are not approved
• ustekinumab (Stelara) TIBs: Non-TNF Inhibitors	Updates from the May 2024 meeting are in bold and strikethrough. Note that Humira is the Department of Defense's preferred targeted biologic agent. <u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved for Stelara if: • Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent and must be tried first for most indications. • The patient has had an inadequate response to Humira • The patient has experienced an adverse reaction to Humira that is not expected to occur with Stelara • The patient has a contraindication to Humira ~~• Contraindications exist to Humira~~ ~~• Inadequate response to Humira (need for different anti-TNF or non-TNF)~~

Appendix C—Table of Prior Authorization (PA) Criteria

	~~Adverse reactions to Humira not expected with requested non-step-preferred TIB~~ AND - Coverage approved for patients 18 years of age or older with: - Active psoriatic arthritis - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy - Moderate to severe active Crohn's disease who have failed or intolerant to immunomodulators, corticosteroids, or Humira. Alternatively, for moderate to severe ulcerative colitis (UC); infliximab may be used first in lieu of Humira - Coverage approved for patients 6-17 years of age ~~≤ 18 years~~ with: - Active psoriatic arthritis (patients between the ages of 6 and 17 may receive Stelara for active psoriatic arthritis without the requirement to try Humira first) - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy (patients between the ages of 6 and 17 may receive Stelara for plaque psoriasis without the requirement to try Humira first) - 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), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade) Prior authorization does not expire Non-FDA-approved uses are not approved
secukinumab (Cosentyx) TIBs: Non-TNF Inhibitors	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of secukinumab (Cosentyx). <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated criteria are not met, Cosentyx is approved if all criteria are met. Provider acknowledges that brand adalimumab (Humira) is the Department of Defense's preferred targeted biologic agent and must be tried first for most indications. The patient has had an inadequate response to Humira The patient has experienced an adverse reaction to Humira that is not expected to occur with Stelara The patient has a contraindication to Humira ~~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)

Appendix C—Table of Prior Authorization (PA) Criteria

	- 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 sacroiliitis and ASDAS ≥ 2.4~~ - Moderate to severe hidradenitis suppurativa (HS) 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.), antibiotics, anti-androgens, 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 including, but not limited to, adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade) Prior authorization does not expire Non-FDA-approved uses are not approved
sacrosidase oral solution (Sucraid) Gastrointestinal-2 Agents	Updates from the May 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new and current users of sacrosidase (Sucraid) Manual PA criteria: Coverage is approved if all criteria are met: - Sucraid is prescribed by ~~or in consultation with~~ a gastroenterologist ~~or geneticist~~ - Patient has congenital sucrase-isomaltase deficiency (CSID) as diagnosed by endoscopic biopsy or genetic testing Submit documentation that confirms that the patient has CSID (i.e., can submit the progress note documenting that CSID was diagnosed via biopsy, and Sucraid recommended) - Prior to starting therapy with Sucraid, patient had symptomatic CSID (e.g., diarrhea, bloating, abdominal cramping) despite appropriate dietary modification Non-FDA approved uses are NOT approved. PA expires annually. Renewal Criteria: Initial TRICARE approval required for renewal. PA will be approved for an additional year if: Patient continues to follow dietary modification and symptoms have improved with Sucraid therapy

Appendix C—Table of Prior Authorization (PA) Criteria

• deflazacort (Emflaza) Corticosteroids Immune Modulators	Changes from the May 2024 meeting are in BOLD and strikethrough. Manual PA criteria applies to all new users of Emflaza. <u>Manual PA Criteria:</u> Emflaza is approved if all criteria are met: • Patient is 2 years of age or older • The drug is prescribed by a neurologist • The patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) that has been confirmed by genetic testing or muscle biopsy • Patient has a contraindication to, intolerance to, or has had an inadequate response to a trial for at least 3 months of prednisone • Provider acknowledges the FDA safety alerts, warnings, precautions, drug interactions, and monitoring recommendations for the requested medication • ~~Patient has tried prednisone for at least 6 months and has experienced at least 1 of the following adverse events:~~ • ~~Unmanageable weight gain OR~~ • ~~Experienced severe behavioral adverse events that requires a reduction in prednisone dose~~ Non-FDA-approved uses are not approved. Prior authorization does not expire
• generic lisdexamfetamine capsules and chewable tablets Attention Deficit Hyperactivity Disorder (ADHD): Stimulants	Manual PA criteria applies to new users of lisdexamfetamine capsule and chewable tablet at all points of service <u>Manual PA criteria:</u> lisdexamfetamine generics are approved if all criteria are met: The following will be added to existing PA criteria • Provider acknowledges that brand Vyvanse capsule and chewable tablet are the preferred products over generic lisdexamfetamine capsule and chewable tablet and are 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 Vyvanse is a branded product, it will be covered at the generic formulary copayment or cost share) • The prescriber must provide a patient-specific justification as to why brand Vyvanse cannot be used in this patient. _____ (fill-in the blank). ▪ Acceptable responses include the patient has had an adverse reaction to an excipient in brand Vyvanse that would not be likely to occur with generic lisdexamfetamine

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
birch triterpenes 10% topical gel (Filsuvez) Skin Preps	Retail/MTF/TMOP: 60-day supply
bosutinib capsules (Bosulif) Oncological Agents for CML	Retail/MTF/TMOP: 60-day supply
cyclosporine 0.1% ophthalmic solution (Vevye) Ophthalmic Dry Eye	Retail/MTF/TMOP: 30-day supply
eflornithine (Iwifin) Oncological Agents	- Retail/MTF/TMOP: 60-day supply - Note: although Iwifin dosage adjustments occur every 90 days, a 60-day supply is recommended as only one dosage strength is available
eplontersen injection (Wainua) Miscellaneous Neurological Agents	Retail/MTF/TMOP: 30-day supply
infliximab-dyyb injection (Zymfentra) TIBs TNF Inhibitors	Retail/MTF/TMOP: 60-day supply
iptacopan (Fabhalta) Hematological Agents	Retail/MTF/TMOP: 60-day supply
nedosiran injection (Rivfloza) Nephrology Agents	Retail/MTF/TMOP: 2 vials per month or 1 syringe per month
omalizumab autoinjector (Xolair) Atopy	- MTF/TMOP: 60-day supply - Retail: 60-day supply

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

Drug / Drug Class	Quantity Limits
roflumilast 0.3% topical foam (Zoryve) Psoriasis Agents	Retail/MTF/TMOP: 60-day supply
vamorolone oral suspension Corticosteroids-Immune Modulators for DMD	Retail/MTF/TMOP: 60-day supply
zilucoplan injection (Zilbrysq) Miscellaneous Neurological Agents	Retail/MTF/TMOP: 56-day supply
- beclomethasone (QVAR Redihaler) - fluticasone propionate diskus - fluticasone furoate (Arnuity Ellipta) - mometasone (Asmanex HFA, Asmanex Twisthaler) Pulmonary Is: ICS	quantity per dispensing event - Retail: 1 inhaler per fill - MTF/TMOP: 3 inhalers per fill
- budesonide dry powder inhaler (Pulmicort Flexhaler) - ciclesonide (Alvesco) - fluticasone propionate HFA Pulmonary Is: ICS	quantity per dispensing event - Retail: 2 inhalers per fill - MTF/TMOP: 6 inhalers per fill

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
- birch triterpenes 10% w/w topical gel (Filsuvez) - Skin Preps: Irritants/ Counter-irritants	Vyjuvek	- Topical gel: 10 % - Dosing: Apply a 1 mm layer to affected wound surface and cover with wound dressing or apply directly to dressing	Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatrics patients 6 months of age and older	ADRs (>2%): application site reactions	- Filsuvez is the first agent approved for the treatment of wounds associated with JEB, and the second agent approved for wounds associated with DEB - Demonstrated marginal efficacy for complete wound healing; results mainly driven by efficacy in RDEB - Efficacy not demonstrated in DDEB or JEB compared to placebo; however, there were small numbers of patients in these groups - Filsuvez was well tolerated - The only other medication approved for this indication, Vyjuvek, would not be effective in patients with JEB and can only be given by a healthcare provider - Filsuvez is a drug for patients with a rare, serious disease that has limited available treatment options	- UF - PA - QL - Do not add to EMMPI list
- bosutinib capsules (Bosulif) - Oncological: Chronic Myelogenous Leukemia	Bosulif tab	- Oral capsule: 50 mg 100 mg - Dosing: varies based on indication	Adult and pediatric patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia, newly-diagnosed or resistant or intolerant to prior therapy. Adult patients with accelerated phase, blast phase Ph+ CML with resistance or intolerance to prior therapy	ADRs ($\geq$20%): - diarrhea - abdominal pain - vomiting - nausea - rash - fatigue - hepatic dysfunction - headache - pyrexia - decreased appetite - respiratory tract infection - constipation	- New capsule formulation of bosutinib for use in adults and pediatric patients 1 year of age or older that shares the same indications as the tablets - Phase 1/2 study demonstrated efficacy in pediatric patients as young as 1 year of age with tolerability profile consistent with data known in adults - Tablets must be swallowed whole while the capsules can be opened and mixed with applesauce or yogurt for patient who have difficulty swallowing - Provides another bosutinib formulation for patients with swallowing difficulties	- NF - PA - MN - QL - EMMPI
budesonide 2 mg/10 mL oral suspension (Eohilia)	- budesonide ER capsule - budesonide neb - fluticasone HFA - Dupixent	- Oral suspension: 2 mg/10 ml - Dosing: 2mg twice	12 weeks of treatment in adult and pediatric 11 years of age and older with	ADRs (>2%): respiratory tract infection	- First corticosteroid FDA-approved for the treatment of EoE - In two studies Eohilia demonstrated significant symptomatic and histologic improvements	- 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
Gastrointestinal- 1 Agents: Gastrointestinal Steroids		daily x 12 weeks	eosinophilic esophagitis (EoE)	- gastrointestinal mucosal candidiasis - headache - gastroenteritis - throat irritation - adrenal suppression - erosive esophagitis	when compared with placebo following a 12-week treatment period - No data to address the time frame at which another 12-week course of Eohilia would be appropriate in patients who initially respond to treatment, but relapse following discontinuation - Budesonide inhalation suspension (compounded into a slurry and swallowed) and fluticasone propionate inhalation aerosol (actuated into the mouth and swallowed) have been used off-label for this condition - No data comparing Eohilia with off-label agents that are widely used in clinical practice and recommended in guidelines - Eohilia is a therapeutic alternative to budesonide and fluticasone oral inhalers for EoE	
cyclosporine 0.1% ophthalmic solution (Vevye) Ophthalmic: Dry Eye	- cyclosporine ophthalmic soln 0.05 % - Cequa droperette 0.09% - Xiidra droperette 5 % - Verkazia droperette 0.1%	- Ophthalmic soln: 0.1 % - Dosing: 1 drop every 12 hours in each eye	Treatment of the signs and symptoms of dry eye disease	ADRs (>8%) instillation site reaction	- Vevye is 4th ophthalmic cyclosporine product; it is approved for dry eye disease - FDA approval included multiple clinical studies - Two studies demonstrated statistically significant evidence of superiority to vehicle in treating dry eye signs, but both studies failed with regards to symptom improvement of dry eye disease - The FDA approval is based on the post-hoc analysis of proportion of Schirmer's tear test responders - Vevye has a well-tolerated safety profile, consistent with other ophthalmic dry eye treatments - Provides an additional treatment option among an array of agents available for patients with dry eye disease, but has no compelling advantages over other products for dry eye disease	- 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
eflornithine tablets (Iwifin) Oncological Agents: N/A	n/a	- Tablet: 192 mg - Dosing: varies based on BSA	Reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy	ADRs ($\geq 5\%$): - hearing loss - otitis media - pyrexia - pneumonia - diarrhea	- Iwifin is indicated to reduce the risk of relapse in patients with high-risk neuroblastoma - Efficacy was demonstrated in an externally controlled trial comparing outcomes of two separate studies; statistically significant improvements in event free survival (EFS) and overall survival were demonstrated in the Iwifin group compared with the control group - Safety signals are difficult to interpret in the open label, single arm study design of Iwifin; however most reported adverse events were mild in nature - FDA Oncologic Drug Advisory Committee voted 14 to 6 that sufficient evidence was provided to demonstrate EFS benefit of Iwifin to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma - Provides a pharmacologic treatment option to reduce the risk of relapse for this high mortality disease state	- UF - PA - QL - EMMPI
eltrombopag 9 mg, 18 mg, 35 mg and 54 mg tablets (Alvaiz) Hematological Agents: Platelets	- Promacta - Doptelet - Tavalisse - Mulpleta	- Oral tablets: 9 mg, 18 mg, 36 mg, 54 mg - ITP and AA Dosing: 36 mg daily and adjust based on platelet count - Hep C Dosing: Dosing: 18 mg daily and adjust based on platelet count	- Thrombocytopenia in adults & children ≥ 6 yrs with persistent or chronic immune thrombocytopenia (ITP) with an insufficient response to steroids, immunoglobulins, or splenectomy - Thrombocytopenia (adults) with chronic hepatitis C for interferon-based tx (initiation & maintenance) - Severe aplastic anemia (adults) with an insufficient response to immunosuppressive therapy	ADRs ($\geq 20\%$): - anemia - nausea - pyrexia - alanine aminotransferase increased - cough - fatigue - headache - diarrhea	- Another tablet formulation of eltrombopag that is not substitutable/interchangeable with other eltrombopag products on a mg per mg basis due to the observed bioavailability in studies conducted on Alvaiz - No new clinical studies; approved via 505(b)(2) - Promacta and Alvaiz have different strength tablets and max doses for each indication - Promacta has an additional indication for first line treatment of severe aplastic anemia and comes in an oral suspension - Promacta can be used in patient as young as 1 years old for ITP while Alvaiz in only indicated in patients as young as 6 years old for the same indication - Both agents have a boxed warning for hepatotoxicity - Provides no compelling clinical advantage over existing agents	- UF - 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
eplontersen injection (Wainua) Neurological Agents Misc: N/A	- inotersen (Tegsedi) - Onpatro (medical benefit) - Amvuttra (medical benefit)	- Autoinjector: 45 mg/0.8 ml - Dosing: 45 mg SC once monthly	Treatment of polyneuropathy due to hereditary transthyretin-mediated amyloidosis (hTTRA) in adults	Serious ADRs: - atrioventricular block - complete AV block	- Second pharmacy benefit drug approved for treatment of polyneuropathy in adults with hTTRA; is administered SQ once monthly - The NEURO-TTRansform study used for FDA approval showed a statistically significant reduction in neuropathic impairment and improved quality of life scores compared to historical placebo which used data from inotersen (NEURO-TTR study) - Limitations include lack of published head-to-head trials, use of historical placebo and small active treatment group, plus question of clinical relevance of the results - Inotersen (Tegsedi) was the 1st pharmacy benefit drug for this condition, but is administered daily, and has a REMS program due to risk of thrombocytopenia and glomerulonephritis. Tegsedi voluntary market removal in Sept 2024. - FDA post-marketing studies are required to determine adverse effects, (thrombocytopenia, glomerulonephritis, vitamin A deficiency, ocular impairment, pregnancy/lactation) - Under investigation for hTTR-cardiomyopathy. If Wainua does obtain the cardiomyopathy indication, indirect comparisons with tafamidis (Vyndaqel/Vyndamax) would be warranted - The current place in therapy and long-term safety remain to be determined	- 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
Infliximab-dyyb injection (Zymfentra) TIBS: TNF Inhibitors	- Renflexis IV - Humira - Rinvoq - Stelara - Entyvio	- Prefilled syringe: 120 mg/ml - Dosing: 120 mg SC every 2 weeks from week 10 and after	- Moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously - Moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously	ADRs $\geq 3\%$): - COVID-19 - anemia - arthralgia - injection site reactions $\uparrow$ alanine aminotransferase - abdominal pain - diarrhea - URI - Headache $\uparrow$ CPK - Hypertension - UTI - neutropenia - dizziness - leukopenia	- First infliximab product administered SC and appears to have similar efficacy as infliximab IV for the maintenance treatment of ulcerative colitis (UC) and Crohn's Disease (CD) in adults - Zymfentra demonstrated similar clinical remission rates and safety profiles as those of infliximab IV - Zymfentra can only be used in adults while IV infliximab can be used in patients as young as 6 years of age for CD and UC - Unlike the IV formulation, Zymfentra must be stored in the refrigerator - Zymfentra has a more limited place in therapy and is an alternative to infliximab IV for the maintenance treatment of CD or UC in adults	- UF non-step-preferred - PA - QL - EMMPI
iptacopan (Fabhalta) Hematological Agents: N/A	- Ultomiris Vial - Empaveli Vial - Soliris Vial	- Capsule: 200 mg - Dosing: 200 mg PO Daily	Treatment of adults with paroxysmal nocturnal hemoglobinuria	ADRs ($\geq 10\%$) - headache - nasopharyngitis - diarrhea - abdominal pain - bacterial infection - viral infection - nausea - rash	- Oral complement Factor B inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) that controls both intravascular and extravascular hemolysis - Soliris, Ultomiris, Empaveli, and Fabhalta all control intravascular hemolysis and are available only via REMS programs - Fabhalta and Empaveli both additionally control extravascular hemolysis which improves hemoglobin and decreases transfusion requirements - Fabhalta is orally administered while Empaveli is administered via SC infusion - Phase 3 active comparator study demonstrated $\uparrow$ of Hb ≥ 2 g/dL from baseline in 82.3% of patients given Fabhalta vs. 0% for those who remained on Soliris/Ultomiris - Phase 3 single arm study demonstrated 77.5% of patients had a sustained increase in Hb ≥ 2 g/dL from baseline - No head-to-head study versus Empaveli - Provides an oral option for extravascular and intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)	- NF - PA - QL - 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
nedosiran injection (Rivfloza) Nephrology Agents: N/A	Oxlumo	- Prefilled syringe: 128 mg 160 mg - SDV: 80 mg - Dosing: varies based on age and actual body weight once monthly	Lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 and relatedly preserved kidney function	ADRs (≥20%) injection site reactions	- Rivfloza is the second drug approved for treating primary hyperoxaluria type 1 (PH1) - Phase 2 study demonstrated change from baseline in 24-hour urinary oxalate excretion improvement for patients on Rivfloza vs. placebo - Additionally, normalization or near normalization of 24-hour urinary oxalate excretion on ≥ two consecutive visits was observed in 65% of patients given Rivfloza vs. 0% in the placebo arm (p < 0.001) - No head-to-head studies versus Oxlumo, a medical benefit drug for PH1; however, both agents decrease urinary oxalate concentrations to near normal levels compared with placebo - Provides a therapeutic alternative to Oxlumo for the treatment of PH1	- UF - PA - QL - EMMPI
omalizumab autoinjector (Xolair) Atopy: NA	Palforzia	- Autoinjector: 75 mg/0.5 ml; 150 mg/ml; 300 mg/ml - Dosing: varies based on serum total IgE level and body weight	- Mod-sev persistent asthma in pts ≥6 yr with a + skin test or in vitro reactivity to a peren aeroallergen & inadequately controlled with ICS. - CRSwNP in adults with inadequate response to nasal steroids, as add-on maintenance treatment. - IgE-mediated food allergy in pts ≥1 yr for reduction of allergic reactions (Type I), to one or more foods. - Chronic spontaneous urticaria in ≥12 yr who remain symptomatic despite H1 antihistamine treatment	Common ADRs: - injection site reaction - pyrexia	- The autoinjector is another formulation with similar indications as the prefilled syringe - Xolair single-dose prefilled syringes are administered by a caregiver for patients 1-11 years of age; single dose Xolair autoinjectors are not intended for use in patients younger than 12 years old - Summary for the newly approved indication - Omalizumab is newly approved for patients 1 year of age and older for the reduction IgE-mediated food allergy and is to be used in conjunction with continued food allergen avoidance - Clinical data demonstrated omalizumab treatment for 16 weeks was superior to placebo in increasing the reaction threshold for peanut, cashew, egg, and milk; however, the sustained benefit is currently unknown - Provides an option for patients for the reduction of allergic reactions with IgE-mediated food allergy	- UF - PA - QL - 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
roflumilast 0.3% topical foam (Zoryve) Psoriasis: N/A	- ketoconazole shampoo - betamethasone foam - desonide lotion - Zoryve cream - Verdeso Foam	- Topical foam: 0.3 % - Dosing: Apply thin layer once daily to affected area	Seborrheic dermatitis in adult and pediatric patients 9 years of age and older	ADRs (≥1%) - nasopharyngitis - nausea - headache	- Another topical formulation of Zoryve approved to treat seborrheic dermatitis - Two phase 2 studies demonstrated significantly more roflumilast-treated patients than vehicle-treated patients achieved the primary end point of IGA success at week 8 - Zoryve is well tolerated with a mild adverse event profile, to include nasopharyngitis, nausea and headache - Provides no compelling clinical advantage over existing agents	- NF - PA - MN - QL - EMMPI
sitagliptin free base (Zituvio & Zituvio Authorized Generic) Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	- Januvia - Tradjenta - Nesina - Onglyza	- Oral tablet: 25 mg 50 mg 100 mg - Dosing: 100 mg daily	Adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes Mellitus	ADRs (≥5%) - Upper respiratory tract infection - Nasopharyngitis - Headache	- Another formulation of sitagliptin approved via the 505(b)(2) pathway using data from Januvia. No clinical trial data available - Available in the same dosage strengths as sitagliptin phosphate (Januvia) - Prior to approval, Zituvio underwent quality testing to ensure it was not contaminated with nitrosamine impurities - Provides no compelling clinical advantage over existing agents	- NF non-step-preferred - PA - MN - EMMPI
vamorolone oral suspension (Agamree) Corticosteroid s—Immune Modulators: N/A	- prednisone - Emflaza	- Oral suspension: 40 mg/ml - Dosing: 6 mg/kg once a day with meal	Treatment of Duchenne Muscular Dystrophy (DMD) in patients 2 years of age and older	ADRs (≥10%) - cushingoid features - psychiatric disorders - vomiting - weight gain - vitamin D deficiency	- Second corticosteroid approved for the treatment of patients with DMD; deflazacort (Emflaza) was the first - A Phase 2b study demonstrated statistically significant improvement in TTSTAND velocity with Agamree compared with placebo at 24 weeks - No head-to-head studies comparing Emflaza or prednisone are available - Adverse events are mostly consistent with chronic corticosteroid administration - Provides an additional pharmacologic corticosteroid option for the treatment of patients with DMD	- UF - PA - QL - 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
zilucoplan injection (Zilbrysq) Neurological Agents Misc	- Rystiggo inj - Vyvgart Hytrulo inj	- Prefilled syringes: 16.6 mg/0.416 mL, 23 mg/0.574 mL, 32.4 mg/0.81 mL - Dosing: varies based on patient weight	Treatment of generalized myasthenia gravis in adult patients who are antiacetylcholine receptor antibody positive	ADRs ($\geq 10\%$) - injection site reaction - upper respiratory track infection - diarrhea	- Third complement C5 inhibitor and first self-administered SC formulation indicated for the treatment of generalized myasthenia gravis - Phase 3 study demonstrated significant and clinically meaningful improvement in MG-ADL - Guidelines do not address Zilbrysq, Ultomiris IV, or the neonatal Fc receptor blockers - Fc receptor blockers (Rystiggo, Vyvgart, Vyvgart Hytrulo) do not have a Boxed Warning and are generally viewed as having a more favorable safety profile compared with complement C5 inhibitors - Soliris, Ultomiris and Zilbrysq have a Boxed Warning regarding serious meningococcal infections and all three agents are only available through a REMS program - Zilbrysq has a unique warning about pancreatitis and other pancreatic conditions - No head-to-head studies with Soliris, Ultomiris or neonatal Fc receptor blockers, nor any guidance when to use one class over the other - Zilbrysq is an option for the treatment of anti-AChR antibody-positive generalized myasthenia gravis and is a therapeutic self-administered alternative to other complement C5 inhibitors and neonatal Fc receptor blockers	- UF - PA - QL - EMMPI

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Mail Order Pharmacy (TMOP) 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 TRICARE Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from TMOP Requirement)
May 2024	Drug Class Reviews Insulin Class: Basal Insulin Subclass Designated UF <i>Retain on the TRICARE Maintenance Drug List:</i> - insulin glargine (Lantus) - insulin glargine U-300 (Toujeo) - insulin glargine U-300 (unbranded) - insulin glargine (Rezvoglar) - insulin glargine-yfgn (unbranded) - insulin glargine U-100 (unbranded) Designated NF <i>Retain on the TRICARE Maintenance Drug List - no reason to exempt from NF requirement</i> - insulin detemir (Levemir – <i>impending market discontinuation</i>) - insulin degludec U-100, U-200 (Tresiba) - insulin degludec U-100, U-200 (unbranded) - insulin glargine (Basaglar) - insulin glargine (Semglee – <i>impending market discontinuation</i>) - insulin glargine-yfgn (Semglee) Pulmonary -1s: Inhaled Corticosteroids Designated UF <i>Retain all branded on the TRICARE Maintenance Drug List (included authorized generics)</i> - ciclesonide (Alvesco) - fluticasone propionate authorized generics (brand Flovent discontinued) - mometasone furoate (Asmanex HFA) - budesonide nebulization solution (brand Pulmicort Respules) Designated NF <i>Retain on the TRICARE Maintenance Drug List - no reason to exempt from NF requirement</i> - beclomethasone (QVAR Redihaler) - budesonide inhaler (Pulmicort Flexhaler) - fluticasone furoate (Arnuity Ellipta) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)	Drug Class Reviews Weight Loss Agents Designated UF <i>Not cost advantageous to government</i> - bupropion/naltrexone (Contrave) - phentermine (Qsymia) - semaglutide injection (Wegovy) - tirzepatide injection (Zepbound) Designated NF <i>Exempt from NF requirement (not cost advantageous to government)</i> - orlistat (Xenical) - somatropin injection (Humatrope, Nutropin, liraglutide injection (Saxenda) Utilization Management/Re-evaluation of NF Generics Calcium Channel Blockers <i>Remove generic agents moving to UF status</i> - diltiazem 24 hr extended release (Cardizem LA, generics) - verapamil 24 hr sustained release pellet-filled capsules (Verelan, generics) - nisoldipine 24 hr ER tablets, controlled release (Sular, generics) Proton Pump Inhibitors <i>Exempt from NF requirement (not cost advantageous to the government)</i> - omeprazole/bicarbonate capsules (Zegerid, generics) - lansoprazole rapidly dissolving tabs (Prevacid, generics)

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary

DoD P&T Meeting	ADD to the TRICARE Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from TMOP Requirement)
	Designated NF <i>No reason to exempt from NF requirement</i> - cyclosporine 0.1% ophthalmic solution (Vevye) - roflumilast 0.3% topical foam (Zoryve) - sitagliptin free base (Zituvio, and authorized generics) TRICARE Maintenance Drug List Updates - lotilaner 0.25% ophthalmic solution (Xdemvy)	

* 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 TMOP. Medications subject to EMMPI program requirements are listed on the TRICARE Maintenance Drug List.

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary

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

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from TMOP Requirement)
May 2024	Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF - eltrombopag 9-, 18-, 35, 54- mg tablets (Alvaiz) - eflornithine (Iwlifin) - nedosiran (Rivfloza) - eplontersen (Wainua) - zilucoplan (Zilbrysq) Designated NF <i>No reason to exempt from NF requirement; similar agents already on the list</i> - bosutiniib capsules (Bosulif) - infliximab-dyyb (Zymfentra) - iptacopan (Fabhalta) Drugs or Drug Classes Designated by the P&T Committee as Generally Suitable for Inclusion Designated UF Added as Individual Agents - decitabine/cedazuridine (Inqovi) - larotrectinib sulfate (Vitrakvi) - nintedanib (Ofev) Added by subclass - Oncological agents: non-Bruton Tyrosine Kinase Inhibitors (non-BTKI) for Chronic Lymphocytic Leukemia (CLL)	Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Acute or limited duration of use</i> - birch triterpenes topical gel (Filsuvez) <i>For future consideration</i> - vamorolone oral suspension (Agamree) - omalizumab autoinjector (Xolair) - budesonide 2 mg/10 mL oral suspension (Eohilia)
Medications previously on the contingent list that were added to the TRICARE Maintenance Drug List since the last P&T meeting, by class and subclass		
March 1, 2024	- Atopy (Adbry) - Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors (Ibrance, Kisqali, Kisqali Femara Co-Pack, Verzenio) - Corticosteroids-Immune Modulators: Hereditary Angioedema Agents (Takhzyro) - FSH-LH Fertility Agents (Follistim AQ, Gonal-F, Gonal-F RFF Redi-Jec. Menopur) - Growth Stimulating Agents (Voxzogo) - Hematological Agents: Platelets (Promacta) - Immunosuppressives (Benlysta) - Neurological Agents Misc: Movement Disorders (Austedo, Vyndamax, Vyndaqel) - Oncological Agents	

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary Minutes & Recommendations of the DoD P&T Committee Meeting May 1-2, 2024

Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated Formulary or Nonformulary

	○ 2nd-Gen Antiandrogens (Erleada, Nubeqa, Xtandi) ○ Acute Myelogenous Leukemia (Daurismo, Idhifa, Onureg, Rydapt) ○ Breast Cancer (Piqray) ○ Chronic Myelogenous Leukemia (Bosulif, Scemblix) ○ Colorectal Cancer (Lonsurf) ○ Cyp-17 Inhibitors (Yonsa) ○ Epidermal Growth Factor Receptor (EGFR)+ Non-Small Cell Lung Cancer (NSCLC) (Gilotrif, Tagrisso) ○ Lung Cancer (Gavreto, Lumakras, Tabrecta, Tepmetko, Xalkori, Zykadia) ○ Melanoma (Cotellic, Mektovi, Zelboraf) ○ Myelofibrosis (Inrebic) ○ Poly Adenosine Diphosphate-Ribose Polymerase (Parp) Inhibitors (Lynparza, Talzenna) ○ Renal Cell Carcinoma (Inlyta, Votrient) ○ No Subclass (Hycamtin, Mekinist, Tafinlar, Odomzo, Zolinza) • Sphingosine 1 Phosphate (S1p) Receptor Modulators (Mayzent, Zeposia) • Targeted Immunomodulatory Biologics ○ Non-Tumor Necrosis Factor Inhibitors (Cosentyx Unoready Pen) ○ Tumor Necrosis Factor Inhibitors (Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimra)
Medications placed on the contingent list at prior meetings but not yet implemented, by class and subclass	
May 2023 – Feb 2024	• Oncological Agents ○ Acute Myelogenous Leukemia (Xospata, Tibsovo, Rezlidhia, Vanflyta) ○ Breast Cancer (Truqap, Orserdu, Nerlynx, Tukysa) ○ Chronic Myelogenous Leukemia (Lytgobi, Turalio, Inclusig, Tassigna) ○ CYP-17 Inhibitors (Zytiga) ○ EGFR+ Non-Small Cell Lung Cancer (Vizimpro) ○ Lung Cancer (Krazati, Alunbrig, Rozlytrek, Lorbrena) ○ Melanoma (Braftovi) ○ Multiple Myeloma (Ninlaro, Revlimid, Pomalyst, Xpovio, Thalomid) ○ Myelofibrosis (Vonjo, Jakafi) ○ Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors (Zejula, Rubraca) ○ Renal Cell Carcinoma (Cabometyx, Cometriq, Afinitor, Afinitor Disperz, Lenvima, Nexavar, Fotivda) ○ No Subclass (Vioice, Tafinlar, Fruzaqla, Ojjaara, Akeega, Stivarga, Erivedge) • Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitors (Bimzelx, Bimzelx Autoinjector, Siliq, Omvoh Pen, Arcalyst, Enspryng, Entyvio Pen)
Drug Classes or Subclasses Designated by the P&T Committee at prior meetings, as generally suitable for inclusion on the contingent list	
May 2023 – Feb 2024	• Atopy • Breast Cancer: Cyclin Dependent Kinase Inhibitors • LHRH agonists/antagonists • MS agents • Oncological agents ○ 2nd Generation Antiandrogens ○ Acute Myelogenous Leukemia ○ Breast Cancer ○ Chronic Myelogenous Leukemia ○ Colorectal Cancer ○ CYP-17 Inhibitors ○ EGFR+ Non-Small Cell Lung Cancer ○ Lung Cancer ○ Melanoma ○ Multiple Myeloma ○ Myelofibrosis ○ Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors ○ Renal Cell Carcinoma • Neurological Misc: Movement Disorders

**Appendix F—TRICARE Mail Order Pharmacy (TMOP) Status of Medications Designated
Formulary or Nonformulary**

	• Targeted Immunomodulatory Biologics
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Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: July 29, 2024

Two weeks after signing: August 14, 2024

30 days after Signing: August 28, 2024

60 days after signing: October 1, 2024

90 days after signing: October 30, 2024

120 days after signing: November 27, 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	Completely Excluded Products	Formulary Alternatives	Implementation
May 2024	Pulmonary Is: Inhaled Corticosteroids	fluticasone Armon Air Digihaler	- beclomethasone (QVAR Redihaler) [nonformulary] - budesonide dry powder inhaler (Pulmicort Flexhaler) [nonformulary] - ciclesonide (Alvesco) - fluticasone propionate diskus - fluticasone propionate HFA - fluticasone furoate (Arnuity Ellipta) [nonformulary] - mometasone (Asmanex Twisthaler)	N/A previously Completely Excluded Nov 2020

*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 TMOP 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 health.mil website.

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

MINUTES AND RECOMMENDATIONS

August 2024

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on August 7th and 8th, 2024.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of May 2024 Minutes—LTG Telita Crosland, Director, DHA, approved the minutes from the May 2024 DoD P&T Committee meeting on July 29th, 2024.

B. Clarification of previous meeting minutes

- **May 2024**
 - **Basal Insulins—insulin degludec (Tresiba, unbranded Tresiba):** The prior authorization criteria was updated to include the definitions of level 2 and level 3 hypoglycemia, as outlined in the Endocrine Society Guidelines.
 - **Newly Approved Drug—iptacopan (Fabhalta):** The medical necessity criteria was updated to include no alternative formulary agent where the patient is unable to access an infusion center.
 - **Weight Loss Drugs:** The prior authorization criteria were updated to include an adverse event to phentermine as an allowable reason to receive one of the step-preferred drugs.

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 TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g (a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, 10 USC 1074g (a)(9), added by Section 702(c)(2) of the NDAA for FY 2015 requires beneficiaries generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

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

Background—The P&T Committee evaluated the relative clinical effectiveness of the BTKi subclass, which was previously reviewed for formulary status in August 2021. The agents within the class include ibrutinib (Imbruvica), acalabrutinib (Calquence), zanubrutinib (Brukinsa), and pirtobrutinib (Jaypirca).

The BTKi agents are used for a variety of oncologic disease states, however the review specifically focused on treatment of chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL).

The comprehensive evidence review included information from individual clinical trial data, guidelines from the National Comprehensive Cancer Network (NCCN), available meta-analyses, FDA-labeling, current Military Health System (MHS) patterns of use, and MHS provider feedback.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

Clinical Practice Guidelines

- NCCN treatment recommendations are similar for CLL/SLL and diverge based on the presence or absence of deletion (17p) and/or TP53 mutation.
- For patients with or without deletion (17p) and/or TP 53 mutation, first-line treatment of CLL/SLL includes Imbruvica, Calquence, and Brukinsa. Jaypirca is reserved for treatment of refractory CLL/SLL patients who have received at least two other systemic therapies, including a BTKi.
- Two of the newer agents, Calquence and Brukinsa, are suggested as a preferred regimen for CLL/SLL due to their more favorable toxicity profiles compared to Imbruvica.

Efficacy

- Imbruvica and Calquence are the earliest approved agents, offering more robust long-term data, while Brukinsa has ongoing extension data.
- Indirect comparison between agents is challenging due to the varying study treatment arms, trial durations, and inclusion criteria for high-risk features.

- There is limited head-to-head data between agents for the various treatment pathways required for CLL/SLL treatment.
- Where data is available, by indirect comparison, via network meta-analysis, and in head-to-head trials, Imbruvica, Calquence, and Brukinsa do not appear to have clinically relevant differences in efficacy.

Safety

- While the safety profiles largely overlap, each drug has unique features requiring specialists to tailor their treatment choice based on patient comorbidities.
- Imbruvica carries overall higher rates of adverse reactions including nausea, rash, bruising and fatigue, compared to Calquence and Brukinsa. Calquence is more likely associated with headache while Brukinsa uniquely requires no dose modification for patients with severe renal failure.

Other Factors

- Imbruvica is available in a variety of formulations, including capsules, oral suspension and tablets and is dosed once daily. It also covers the most FDA-approved and off-label indications.
- Calquence and Brukinsa are each available as a single formulation and may be given either once or twice daily.
- Jaypirca is indicated for relapsed or refractory treatment of CLL/SLL.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, at least one BTKi agent for the specific indication of CLL/SLL treatment is required on the formulary.

Relative Cost Effectiveness Analysis and Conclusion—The 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 (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that acalabrutinib (Calquence) is the most cost effective BTKi agent, followed by zanubrutinib (Brukinsa), ibrutinib (Imbruvica), and pirtobrutinib (Jaypirca).
- 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 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 (19 for, 0 opposed, 0 abstained, 1 absent) the following.
 - UF
 - acalabrutinib (Calquence)
 - ibrutinib (Imbruvica)
 - pirtobrutinib (Jaypirca)
 - zanubrutinib (Brukinsa)
 - NF - None
 - Completely Excluded - None
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—Existing PA criteria currently apply to all four drugs. For the Imbruvica tablet formulation, further justification is required on the PA to state why the capsules cannot be used first. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the changes below. See Appendix C for the full criteria.
 - For all four BTKi drugs, the PA criteria were streamlined in the sections pertaining to FDA-indications and safety monitoring.
 - For Imbruvica, the current criteria preferring the capsules over the tablets was removed.
 - For Calquence and Brukinsa, if the prescribing physician specialty is identified as an oncologist or hematologist during adjudication, no PA will be required. The provider's specialty is identified through an automated system that searches for specific specialty information in the claim. This will hereafter be referred to as automated specialist bypass. Manual PA will also allow approval solely based on the prescribing physician being identified as an oncologist or hematologist. Additionally, for prescriptions initially written by an oncologist or hematologist, an automated drug lookback for Calquence or Brukinsa will allow PA approval if the patient has received the drug in the past 720 days, to allow continuation of therapy for prescriptions subsequently written by non-specialists.
3. **COMMITTEE ACTION: QUANTITY LIMITS**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QLs for all agents. See Appendix D for the full QLs.
4. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS**—The P&T Committee recommended (19 for, 0

opposed, 0 abstained, 1 absent) addition to the program, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing from TMOP).

- 5. COMMITTEE ACTION: UF, PA, QL, TRICARE MAINTENANCE DRUG LIST PROGRAM, and IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G for the actual implementation date.

B. Antilipidemic-1s Class: Statins and Non-statins and Combinations

Background—The P&T Committee evaluated the relative clinical effectiveness of the Antilipidemic-1 drug class, comprised of the statins along with the non-statins and combinations subclasses. For the statins, there is significant generic availability, with only five branded products remaining. The non-statins include ezetimibe, bempedoic acid, bempedoic acid/ezetimibe and combinations with statins. The evidence review focused on the low-density lipoprotein (LDL)-lowering effects of the products, published cardiovascular (CV) outcomes data, and recent data available with bempedoic acid.

Note the proprotein convertase subtilisin/kexin type-9 (PCSK9) inhibitors were reviewed for formulary status in May 2023, and were not included here.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Statins

- Since the last class review in 2013, statin therapy remains the key component of treating hyperlipidemia to reduce adverse CV outcomes of coronary heart disease (CHD), myocardial infarction (MI), and stroke in the primary and secondary prevention settings.
- In terms of adverse effects, the prevalence of complete statin intolerance might often be overestimated. Most patients can tolerate a statin and many patients reporting statin intolerance may be experiencing a placebo effect (where there are perceived negative symptoms experienced by patients when anticipating a treatment to be harmful).
- In order to meet the needs of MHS patients, atorvastatin, simvastatin, pravastatin, and rosuvastatin are required on the formulary due to compelling clinical evidence from CV outcomes trials and recommendations from the 2018 Multi-Society guidelines. Inclusion of these products will allow for differences in safety profiles and drug interactions. Positive CV outcomes

have also been reported with fluvastatin and lovastatin, although fewer trials are available. Robust published CV outcomes data is lacking for pitavastatin.

- The remaining branded products, lovastatin extended release (ER) (Altoprev), atorvastatin oral suspension (Atorvaliq), simvastatin oral suspension (FloLipid), rosuvastatin sprinkle capsules (Ezallor), and pitavastatin magnesium (Zypitamag) do not offer compelling clinical advantages compared to the other generic statins.

Non-statins and Combinations

- The 2022 American College of Cardiology (ACC) Expert Consensus Decision Pathway for non-statins continue to support use of high intensity statins first-line for patients with atherosclerotic cardiovascular disease (ASCVD) (secondary prevention setting) and in the primary prevention setting.
 - PCSK-9 inhibitors either alone or with ezetimibe can be considered in patients receiving maximally tolerated statin therapy who require a greater than 50% reduction in LDL cholesterol.
- Bempedoic acid (Nexletol) is a non-statin that when used as monotherapy reduces LDL to a similar extent as ezetimibe (Zetia) by 18%-20%. The LDL-lowering approaches 38% when bempedoic acid is added on to ezetimibe (Nexlizet).
- The results of a CV outcomes trial (CLEAR OUTCOMES) showed bempedoic acid benefitted adults with CV disease or those at high risk for CV disease who were statin intolerant. The majority of patients (70%) had existing CV disease (secondary prevention). The outcomes were primarily driven by a reduction in non-fatal myocardial infarction (MI) and coronary revascularization; the reduction in stroke or CV death was not statistically significant.
 - Limitations to the trial include the use of low dose statins in 25% of patients, the high drop-out rate (approximately 29%), the high baseline LDL level of 139 mg/dL, and the homogenous patient population.
 - The CLEAR OUTCOMES trials results have not yet been incorporated into the professional guidelines.
- The long-term adverse event profile of bempedoic acid is unknown, however the rate of statin-associated muscle symptoms appears similar to placebo. Unique adverse events associated with bempedoic acid include gout, renal impairment and elevated hepatic enzymes.
- Use of PCSK-9 inhibitors prior to bempedoic acid should be considered due to current ACC guideline recommendations, their ability to reduce LDL

cholesterol by more than 60% and the more favorable safety profile based on published CV outcomes trials.

- Bempedoic acid should be reserved for use in patients with statin intolerance or those who have failed to reach LDL goals after ezetimibe and PCSK-9 inhibitor.
- Ezetimibe is recognized in most professional society guidelines as the first statin add-on or in those who cannot tolerate a statin, due to its generic availability and well tolerated adverse event profile.
- The fixed dose combination of simvastatin/ezetimibe has positive CV outcomes data from the IMPROVE-IT trial.
- The remaining branded products, atorvastatin/amlodipine and rosuvastatin/ezetimibe (Roszet) do not provide compelling clinical evidence compared to the other drugs in the subclass.

Relative Cost Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

For the statins

- The committee reviewed the CMA results for atorvastatin, atorvastatin oral suspension (Atorvaliq), fluvastatin, lovastatin ER (Altoprev), lovastatin, pitavastatin calcium (Livalo, generics), pitavastatin magnesium (Zypitamag), pravastatin, rosuvastatin, rosuvastatin sprinkle (Ezallor), simvastatin oral suspension (Flolipid), and simvastatin.
- 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 statin agents in accordance with the formulary recommendation below demonstrated benefit to the MHS.

For the non-statins and combinations

- The committee reviewed the CMA results for amlodipine/atorvastatin, bempedoic acid (Nexletol), bempedoic acid/ezetimibe (Nexlizet), ezetimibe, ezetimibe/rosuvastatin (Roszet, generics), and ezetimibe/simvastatin.
- 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 non-statin and combination agents in accordance with the formulary recommendation below demonstrated cost-avoidance for the MHS.

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

Statins

- UF
 - atorvastatin
 - fluvastatin
 - lovastatin
 - pravastatin
 - simvastatin
 - rosuvastatin
 - fluvastatin ER *moves from NF to UF*
- NF
 - lovastatin ER (Altoprev)
 - pitavastatin calcium (Livalo, generic)
 - pitavastatin magnesium (Zypitamag)
 - atorvastatin oral suspension (Atorvaliq)
 - rosuvastatin sprinkle capsules (Ezallor)
 - simvastatin oral suspension (Flolipid)
- Complete exclusion - None

Non-statins and Combinations

- UF
 - bempedoic acid (Nexletol) *moves from NF to UF*
 - bempedoic acid/ezetimibe (Nexlizet) *moves from NF to UF*
 - simvastatin/ezetimibe (Vytorin) *moves from NF to UF*
 - ezetimibe
 - atorvastatin/amlodipine
- NF - None
- Complete exclusion
 - rosuvastatin/ezetimibe (Roszet)

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—For the statins, automated step therapy has been in place for the branded products (Livalo,

Zypitamag, Altoprev, Lescol XL, Altoprev, Atorvaliq, FloLipid, and Ezallor) for several years, requiring a trial of generic statin first. For the non-statins, current PA criteria for bempedoic acid allows use only in the secondary prevention setting, plus requires a trial of concurrent statin and ezetimibe prior to use, unless the patient has statin intolerance or a contraindication to statin. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Statins

- Maintaining the current automated step therapy for pitavastatin calcium (Livalo, generic) and pitavastatin magnesium (Zypitamag), requiring a trial of generic statins first.
- Removing the PA for fluvastatin ER (Lescol XL)
- Maintaining the current manual PA criteria for Atorvaliq, FloLipid and Ezallor

Non-statins and Combinations

- For bempedoic acid, maintaining the requirement for ezetimibe plus maximally tolerated statin unless there is a contraindication or statin intolerance; expanding the criteria to include primary prevention in high-risk patients; and requiring concurrent PCSK-9 inhibitor. There will be automated drug look back for a PCSK-9 inhibitor (Repatha or Praluent). The updated PA criteria will apply to new patients. (See Appendix C for full criteria).
- Updates to the PA for the PCSK-9 inhibitors evolocumab (Repatha) and alirocumab (Praluent) were also recommended, to include use for patients at high risk for ASCVD, based on the PA updates for bempedoic acid. (See Appendix C for full criteria).
- Removing the PA for simvastatin/ezetimibe (Vytorin, generic) and atorvastatin/amlodipine (Caduet, generic)

2. COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current MN criteria for Altoprev, Livalo, Zypitamag, Atorvaliq, Ezallor, and FloLipid.

3. COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS—

The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 1 absent) maintain Nexletol, Nexlizet, Altoprev, Atorvaliq, Ezallor, Zypitamag, ad FloLipid; and removing Livalo, Vytorin, and Lescol XL. See Appendix F.

4. COMMITTEE ACTION: UF, PA, MN, TRICARE MAINTENANCE DRUG LIST PROGRAM and IMPLEMENTATION PERIOD—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent)

an effective date the first Wednesday 90 days after signing of the minutes in all points of service. See Appendix G for the actual implementation date.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (20 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 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 (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- UF
 - diazepam buccal film (Libervant) – Anticonvulsants – Antimania Agents
 - elafibranor (Iqirvo) – Gastrointestinal-2 Agents
 - mavorixafor (Xolremdi) – Hematological Agents
 - mycophenolate mofetil 200 mg/mL oral suspension (Myhibbin) – Immunosuppressives
 - naloxone 4 mg nasal spray (Rextovy) – Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists
 - resmetirom (Rezdiffra) – Gastrointestinal-2 Agents
 - sotatercept-csrk (Winrevair) – Pulmonary Arterial Hypertension Agents
 - tocilizumab-aazg syringe (Tyenne) – Targeted Immunomodulatory Biologics (TIBS): Non-Tumor Necrosis Factor Inhibitors
 - tovorafenib (Ojemda) – Oncological Agents
- NF
 - adalimumab-ryvk (Simlandi) – TIBS: Tumor Necrosis Factor Inhibitors
 - danicopan (Voydeya) – Hematological Agents
 - givinostat (Duvyzat) – Corticosteroids-Immune Modulators
 - macitentan/tadalafil (Opsynvi) – Pulmonary Arterial Hypertension Agents

- sitagliptin/metformin authorized generic (Zituvimet) – Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors
 - spesolimab-sbzo syringe (Spevigo) – TIBS: Miscellaneous Interleukins
 - Complete exclusion
 - adalimumab (Cordavis brand of Humira) – TIBS: Tumor Necrosis Factor Inhibitors
2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Simlandi, Voydeya, Duvyzat, Opsynvi, Zituvimet authorized generic, and Spevigo. See Appendix B for the full criteria.
3. **COMMITTEE ACTION: PA CRITERIA**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria (see Appendix C for the full criteria):
- Applying manual PA criteria to new users of the oncology/hematology drugs Voydeya, Xolremdi, and Ojemda; and for new users of Iqirvo, Duvyzat, Rezdiffra, and Winrevair.
 - Applying manual PA criteria to new and current users of Opsynvi, requiring a trial of the individual components separately.
 - Applying manual PA criteria to new users of Spevigo requiring a trial of Humira and Cosentyx first.
 - Applying manual PA criteria to new users of Tyenne requiring a trial of Humira for moderate to severely active RA and active polyarticular juvenile idiopathic arthritis (pJIA) first. Additionally, a trial of Tyenne will be required before the originator Actemra formulation in new users (see the UM section on page 15).
 - Applying manual PA criteria to new and current users of the Humira biosimilar Simlandi, 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 Zituvimet authorized generic, requiring a trial of Januvia, similar to the other NF, non-step-preferred DPP-4 inhibitors in the class.
4. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) QLs for Duvyzat, Iqirvo, Libervant, Ojemda, Opsynvi, Rextovy, Rezdiffra, Simlandi, Spevigo, Tyenne, Voydeya, Winrevair, and Xolremdi. See Appendix D for the QLs.

5. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List 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 TRICARE Maintenance Drug List program which includes the NF medications subject to the mail requirement.
6. **COMMITTEE ACTION: UF, MN, PA, QL, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding an effective date of the following:
- **New Drugs Recommended for UF, NF and Completely Excluded Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

- a) **White Blood Cell (WBC) Stimulants—eflapragrastim-xnst (Rolvedon)**—Rolvedon was FDA approved in September 2022. Initially Rolvedon required administration by a healthcare professional and was covered under the TRICARE medical benefit. In June 2023, the FDA updated the Rolvedon label to allow for self-administration therefore, it now falls under TRICARE pharmacy benefit coverage, and will be designated as UF. The committee reviewed PA criteria for Rolvedon, based on existing step therapy in the WBC stimulant class.

In reviewing available clinical data, Rolvedon demonstrated noninferior efficacy and similar adverse effects compared to pegfilgrastim. Rolvedon is less cost-effective than the step-preferred pegfilgrastims. PA criteria for Rolvedon will require use of all the step-preferred WBC stimulants first in new users.

COMMITTEE ACTION: EFLAPEGRASTIM-XNST (ROLVEDON) PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) PA criteria in new users of eflapragrastim-xnst (Rolvedon) prefilled syringe, requiring use of the step-preferred WBC stimulants first. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full PA 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 six recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. 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. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

- a) **Endocrine Agents Miscellaneous—lanreotide 120 mg/0.5 mL syringe**—Other versions of lanreotide 120 mg/0.5 mL syringe are available, including Somatuline Depot, that are more cost-effective than this version made by a sole manufacturer.
- b) **Pain Agents: Pain Topical—lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V)**—Numerous other more cost-effective lidocaine 5% patches are available. BCF status does not apply to these specific formulations.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION

PLAN—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for lanreotide 120 mg/0.5 mL syringe, lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V in new and current users, due to the significant cost differences compared with other available alternative agents. 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.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 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) **Atopy: Oral JAK-1—upadacitinib (Rinvoq)**—The manual PA were updated to allow for use in polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older and to expand the psoriatic arthritis indication to include pediatric patients 2 years of age and older. Both indications are for use in patients who have had an inadequate response or intolerance to one or more tumor necrosis factor inhibitors. A trial of Humira will be required for both indications.
- b) **Atopy—benralizumab (Fasenra)**—The manual PA criteria for Fasenra were expanded to include patients 6 years of age or older with severe asthma with an eosinophilic phenotype.
- c) **TIBs: Non-TNFs—vedolizumab (Entyvio)**—The manual PA criteria were updated to allow use of Entyvio to treat Crohn's Disease in adults.

- d) **TIBs: Non-TNFs—sarilumab (Kevzara)**—Kevzara is now indicated for the treatment of active polyarticular JIA in patients who weight at least 63 kg. The manual PA were updated to reflect this new indication.
- e) **Metabolic Agents Miscellaneous—maralixibat (Livmarli)**—The manual PA criteria were updated to allow for use in patients 12 months of age and older with cholestatic pruritus due to Progressive Familial Intrahepatic Cholestasis.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Rinvoq, Fasenra, Entyvio, Kevzara, and Livmarli 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 and MN Criteria for Reasons other than New Indications

- a) **Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones—corticotropin (Acthar Gel SelfJect)**—The manual PA criteria were updated to exclude use of the new Acthar Gel SelfJect formulation for the treatment of infantile spasms, as it is not FDA approved for this indication.
- b) **Antiemetic-Antivertigo Agents—doxylamine/pyridoxine (Diclegis, Bonjesta)**—The PA was updated to inform prescribers that the more cost-effective OTC doxylamine is available under the TRICARE pharmacy benefit without a copay at the MTF and retail points of service; a prescription is required for coverage.
- c) **Oncological Agents—trametinib (Mekinist), dabrafenib, (Tafinlar), neratinib (Nerlynx), vemurafenib (Zelboraf), venetoclax (Venclexta), nilutamide (Nilandron), belzutifan (Welireg), tucatinib (Tukysa), glasdegib (Daurismo), erdafitinib (Balversa) and Prostate Cancer drugs—abiraterone (generic and Zytiga), enzalutamide (Xtandi), darolutamide (Nubeqa), and apalutamide (Erleada)**—Based on a review of MHS data and feedback from providers, several oncology PA were reviewed in order to standardize and streamline the criteria. Future meetings will address the other oncology PAs.

As part of this standardization effort, the following actions were taken: adding the requirement that the PAs be written by appropriate specialist in the PAs that lacked this, editing the NCCN guideline question to cite specific guideline version and page number to ease approvals for new indications, updating indications to more closely match FDA label language, and removing lengthy clinical monitoring and counseling questions based on provider feedback.

For the prostate cancer drug abiraterone (Zytiga and generic), automated specialist bypass and drug lookback criteria were added to allow PA

approval if the prescriber is an oncologist, hematologist or urologist and continuation by a non-specialist.

- d) **TIBs: Non-TNFs—anakinra (Kineret)**—The manual PA criteria for Kineret were updated to allow for treatment of adult-onset Still’s Disease (AOSD) without requiring a trial of Humira. This update is based on the approved indication in Europe, updates from the 2024 British Society of Rheumatology treatment recommendations of AOSD, available clinical data, and specialist feedback.
- e) **Sleep Disorders: Wakefulness Promoting Agents—solriamfetol (Sunosi)**—The manual PA criteria were updated to allow for alternative treatments and prescribing providers for patients with obstructive sleep apnea and excessive daytime sleepiness. This update is based on review of current guidelines and literature, as well as specialist feedback. Additional edits were made to better align the Sunosi PA with existing PA criteria in the class.
- f) **Sleep Disorders: Wakefulness Promoting Agents—pitolisant (Wakix)**—The manual PA criteria were updated to allow use in children as young as 6 years for the updated indication of narcolepsy with excessive daytime sleepiness. Additional edits were made to better align the Wakix PA with existing PA criteria in the class.
- g) **TIBs: TNFs—adalimumab (Humira)**—At the May 2023 meeting, automated specialist bypass PA criteria were added to Humira to allow for rheumatologists to bypass PA requirements, which was implemented on May 15, 2024. At this meeting, the automated specialist bypass was expanded to include dermatologists and gastroenterologists. Additionally, the manual PA criteria were expanded to allow for off-label use of Humira for generalized pustular psoriasis (GPP) in children and adults based on guidelines and provider feedback.
- h) **TIBs: Non-TNFs—secukinumab (Cosentyx)**—Similar to Humira, the manual PA criteria for Cosentyx were updated to allow for off-label use of Humira for generalized pustular psoriasis (GPP) in children and adults based on guidelines and provider feedback.
- i) **TIBs: Non-TNFs—tocilizumab (Actemra)**—The manual PA and MN criteria for Actemra were updated due to the recent availability of a cost-effective tocilizumab biosimilar (see new drugs section on page 11). The PA updates require a trial of the biosimilar tocilizumab-aazg (Tyenne) prior to Actemra. Other updates were made to standardize the PA, consistent with what was done with other TIBs (e.g., removing the monitoring and counseling questions). The Actemra MN criteria were updated to include adding Tyenne as a formulary alternative.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent)

updates to the manual PA and/or MN criteria for Acthar Gel, Diclegis, Bonjesta, Mekinist, Nerlynx, Nilutamide, Tafenlar, Zelboraf, Venclexta, Welireg, Tukysa, Daurismo, Balversa, Xtandi, Nubeqa, abiraterone, Kineret, Sunosi, Wakix, Humira, Cosentyx, and Actemra in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix C for the full criteria.

B. Line Extensions

The P&T Committee clarified the formulary status for nine product line extensions by the original manufacturer. Line extensions have the same FDA indication(s) as the “parent” drug and retain the same formulary and copayment status as the “parent” drug.

- 1. Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones**
Subclass—designating **corticotropin (Acthar Gel SelfJect) injection** with the same formulary status (UF), PA, QL, and Specialty status as the parent Acthar vials.
- 2. Neurological Agents Miscellaneous: Movement Disorders**—designating **deutetrabenazine (Austedo XR) 18, 30, 36, 42, and 48 mg tablets** with the same formulary status (UF), PA, QL, Specialty status, and TRICARE Maintenance Drug List status as the parent Austedo XR tablet strengths.
- 3. TIBs: TNFs**—designating **adalimumab-adbm (Cyltezo) 40 mg/0.4 mL prefilled syringe and prefilled autoinjector** with the same formulary status (NF), PA, QL, Specialty status, and TRICARE Maintenance Drug List status as the parent Cyltezo low-concentration formulation.
- 4. Neurological Agents Miscellaneous: Movement Disorders**—designating **valbenazine (Ingrezza Sprinkle) capsules** with the same formulary status (UF), PA, QL, and Specialty status as the parent Ingrezza capsule.
- 5. TIBs: Interleukin 23**—designating **mirikizumab-mrkz (Omvo) prefilled syringe** with the same formulary status (UF), non-step preferred, PA, QL, and Specialty status as the parent Omvo prefilled pen.
- 6. Atopy: Oral JAK-1**—designating **upadacitinib (Rinvoq LQ) oral solution** with the same formulary status (UF), PA, QL, Specialty status, and TRICARE Maintenance Drug List status as the parent Rinvoq tablet.
- 7. White Blood Cell Stimulant: Pegfilgrastim**—designating **pegfilgrastim-cbqv (Udenyca) on-body injector** with the same formulary status (UF) and Specialty status as the parent Udenyca prefilled syringe.
- 8. Oncological Agents**—designating **alpelisib (Vijoice) oral granules** with the same formulary status (UF), PA, QL, and Specialty status as the parent Vijoice tablets.
- 9. Anticonvulsants-Antimania Agents**—designating **cenobamate (Xcopri) 25 mg tablet** with the same formulary status (UF) as the parent Xcopri tablet strengths.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, Specialty status, and TRICARE Maintenance Drug List status for Acthar Gel SelfJect, Austedo XR, Cyltezo, Ingrezza Sprinkle, Omvoh, Rinvoq LQ, Udenyca, Viojoy, and Xcopri. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR ADDITION FOR MIRABEGRON (MYRBETRIQ) AND REMOVAL FOR TOPIRAMATE (TROKENDI XR)

Overactive Bladder Agents: Mirabegron (Myrbetriq) tablets are designated as UF and require a 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 Myrbetriq tablets will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. The Tier 1 copay for brand Myrbetriq is recommended.

Anticonvulsant and Anti-Mania Agents: At the May 2023 P&T meeting, brand over generic criteria and a Tier 1 copay were recommended for topiramate ER (Trokendi XR). At this time, the branded Trokendi XR is no longer more cost-effective than the generics, and the Tier 1 copay and brand over generic PA criteria for Trokendi XR will be removed at all three points of service.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- **Mirabegron (Myrbetriq):** requiring brand Myrbetriq tablets over the generics in new and current 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 Myrbetriq tablets. 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.
- **Topiramate ER (Trokendi XR):** For Trokendi XR, the removal of the Tier 1 copay and brand over generic PA criteria will take place no later than 60 days after the signing of the minutes.

VIII. UTILIZATION MANAGEMENT: HEPATITIS C VIRUS (HCV) DIRECT ACTING ANTIVIRALS (DAAS) SUBCLASS

The HCV DAA subclass was reviewed in May 2015, February 2017, and most recently in August 2018. A summary of the utilization trends and cost of the HCV DAAs were presented during the August 2024 meeting. The Committee also reviewed the 2023 American

Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidelines for HCV.

Based on the above, provider feedback, and changes in commercial practice, several changes were recommended for the PA criteria and QLs for the HCV DAAs. These changes included removing the PA requirements for glecaprevir/pibrentasvir (Mavyret) and adding automated specialist bypass criteria allowing HCV specialists to bypass the PA for sofosbuvir/velpatasvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier), sofosbuvir (Sovaldi), and sofosbuvir/velpatasvir/voxilaprevir (Vosevi).

Additionally, the PA criteria were streamlined by removing the requirement for minimum age and HCV diagnosis. For Epclusa, non-specialists will be able to prescribe without specialist consultation for all patients except for patients with both genotype 3 and cirrhosis. Harvoni, Zepatier, Vosevi, and Sovaldi will still require prescribing by or in consultation with a specialist. For Vosevi and Sovaldi, non-specialists will only be able to prescribe for retreatment. The QLs were also increased for all the HCV DAAs to allow up to a typical full treatment course to be dispensed at one time (i.e., up to 56-day supply for Mavyret and up to 84-day supply for the other DAAs).

COMMITTEE ACTION: HCV DAAs MAVYRET PA REMOVAL, PA UPDATED CRITERIA, QLs, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for Epclusa, Harvoni, Zepatier, Sovaldi and Vosevi, with an implementation of the first Wednesday 60 days after signing of the minutes at all points of service.

The Mavyret PA removal and QL limits increases for Mavyret, Epclusa, Harvoni, Zepatier, Sovaldi and Vosevi will be implemented the first Wednesday two weeks after the signing of the minutes at all points of service. The PA and QL changes will increase beneficiary access under the TRICARE pharmacy benefit and reduce provider administrative time. See Appendix C and D for the full criteria.

IX. PROCESS FOR EVALUATING BIOSIMILARS AND BIOLOGICS

Background—The DoD P&T Committee previously established the process and procedures for reviewing biosimilar and biologic agents in November 2021. Additional information regarding the interchangeability of biosimilar agents and a process to engage in Joint National Contracting initiatives for biosimilars was presented during this meeting.

The P&T Committee reviews newly approved drugs per 32 CFR 199.21(g)(5) to include new drugs approved through the 505(b) New Drug Applications (NDA) as well as 351(a) Biologics License Applications (BLA) pathways. These two pathways have follow-on approvals. For biologics, follow on products are approved via the 351(k) biosimilar or 351(k) interchangeable pathway. Unbranded biologics are considered equivalent to the branded product and fall under the same 351(a) BLA.

Both biosimilar and interchangeable biosimilars are highly similar to the reference biologic with an identical amino acid sequence. Inherent variation is observed in both the reference and biosimilar product due to the biologic manufacturing process. Both

reference and biosimilar products will have lot-to-lot variation. Lot-to-lot variation has not impacted efficacy, safety, or immunogenicity when switching patients from reference-to-biosimilar or biosimilar-to-biosimilar products. Real-world evidence from multiple other countries with more experience with biosimilars than in the United States also supports that lot-to-lot variation and does not result in clinically relevant differences between biosimilars.

The Committee concluded the following regarding biologics and their biosimilars.

- FDA approved biosimilar products, whether officially designated as interchangeable or not, are equally safe and efficacious when compared to the reference product.
- Data has not demonstrated increased antidrug antibody formation related to biologic manufacturing updates or biologic switching.
- Switching between the biosimilar agents and the reference product has not demonstrated clinically meaningful difference in outcomes.
 - Indications may be extrapolated between reference products and biosimilars.
 - In terms of efficacy and safety, a reference biologic and its biosimilars are interchangeable.
 - This includes biosimilar-to-biosimilar and reference-to-biosimilar switches.
- Similar to current U.S. FDA, European Medicines Agency, and the United Kingdom Medicines and Healthcare Regulatory Agency guidance, the DoD P&T Committee will consider all approved biosimilars as highly interchangeable to the reference product for both efficacy and safety, which have been previously evaluated for clinical effectiveness by the DoD P&T Committee. This includes but is not limited to the following reference products and their biosimilars:
 - Insulins: Lantus, Humulin, Novolin
 - TNF inhibitors: Humira, Enbrel, Remicade/Zymfentra, Cimzia, Simponi
 - Interleukins: Stelara, Cosentyx, Actemra, Taltz
 - Filgrastim/Pegfilgrastim: Granix, Neupogen, Neulasta
 - Others: Herceptin, Rituxan, Oncia

1. COMMITTEE ACTION: CLINICAL EFFECTIVENESS—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- The clinical conclusions as stated above will apply to all biosimilar products.
- Reference biologics and their biosimilar products are interchangeable.
- The DoD P&T Committee agrees to accept these conclusions as the clinical effectiveness review for all future biosimilar agents.

2. **COMMITTEE ACTION: COST EFFECTIVENESS**—Cost is the defining factor for selecting biosimilar agents for inclusion on the UF given the clinical conclusions above. The P&T Committee supports participation in future Joint National Contracts (JNC) to secure optimal pricing for biosimilars. If the JNC cost is less than the reference product, it meets the intent of 32 CFR 199.21(e)(2). The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent):
- The Joint National Contract (JNC) processes meet the requirements for determining the relative cost effectiveness for biosimilar agents.
 - The P&T Committee agrees to accept the relative cost effectiveness as determined by a JNC.
3. **COMMITTEE ACTION: IMPLEMENTATION PLAN**—The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) the implementation plan will be based on the details within the JNC, taking into consideration the implementation timeline for P&T Committee recommendations regarding PA criteria, MN criteria, QLs and other formulary management actions.
4. **COMMITTEE ACTION: ADMINISTRATIVE AUTHORITIES**—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent):
- The clinical efficacy is the same between biosimilar agents, and that cost effectiveness and formulary placement may be solely recommended by contracting actions and the completion of relevant cost analysis [i.e., DoD/VA Joint National Contract (JNC)].
 - To allow Formulary Management Branch (FMB) of the DHA Pharmacy Operations Division (POD) the administrative authority to implement temporary PA/MN criteria preferring the selected product(s) from the national contract in new users.
 - To allow FMB the administrative authority, after consultation with the P&T Chair, to apply the temporary PA criteria to new and current users, noting that initially the PA criteria for preferred drugs will apply to new users, until patient notification can occur.
 - To allow FMB the administrative authority to designate, if necessary (e.g., if the selected product is currently designated as NF), the JNC selected product(s), to adjudicate as UF.
 - To allow FMB the administrative authority to implement, if necessary, addition of an agent to the TRICARE Maintenance Drug List (Mandatory Mail) and Quantity Limits.
 - The results of such actions and analysis will be submitted to the UF Beneficiary Advisory Panel for comment, and to the Director, DHA for final approval. The Director's determination will be returned to the P&T Committee for awareness, without the need for additional vote from the P&T Committee.

X. MHS GENESIS OVER-THE-COUNTER (OTC) LIST NON-HORMONAL VAGINAL MOISTURIZER (REPLENS)

Background—The DoD P&T Committee reviewed an MTF request to add a long-acting vaginal moisturizer (Replens) to the MHS GENESIS OTC List, which would allow dispensing of the product at MTFs but not Retail or TMOP points of service. The P&T Committee noted that:

- Vaginal dryness is commonly reported post menopause and with breast cancer treatment.
- The North American Menopause Society and the American College of Obstetricians and Gynecologists support routine use of long-acting vaginal moisturizers for vaginal symptoms associated with menopause, particularly in patients with less severe symptoms and those for whom vaginal hormonal therapies are unacceptable or inappropriate.
- Vaginal estrogens are considered safer than systemic products but likely still have risks compared to non-hormonal products like vaginal moisturizers; clinical trial data supporting safety of vaginal estrogen products beyond one year are lacking.
- Although data are limited, studies specifically comparing Replens to estrogenic vaginal inserts or cream have demonstrated improvements with both treatments in vaginal dryness, pH balance, and elasticity, as well as reductions in itching, irritation, and dyspareunia.
- Feedback from OBGYN and Oncology support availability of a vaginal moisturizer on the MHS GENESIS OTC List.
- While multiple vaginal moisturizers are available as OTC products, the requested agent Replens is both listed in First DataBank (a requirement for adjudication) and available to MTFs through the national prime vendor.

COMMITTEE ACTION: MHS GENESIS OTC LIST AND

IMPLEMENTATION—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) adding glycerin/mineral oil/polycarbophil gel (e.g., Replens gel; GCN 04939) to the MHS GENESIS OTC list (the NDC currently available through Cencora is 22600000104). Implementation will occur on the first Wednesday two weeks after signing of the minutes.

XI. COMPLETELY EXCLUDED DRUGS: ANNUAL REVIEW

The P&T Committee reviewed all drugs completely excluded from the pharmacy benefit program under 32 CFR 199.21(e)(3), which allows the Committee to recommend special Uniform Formulary actions “to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending.” This specifically includes “a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD.”

Drugs designated as completely excluded are not available at the MTFs or TMOP points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies. The Committee plans to review completely excluded drugs on an annual basis. Note: these medications were previously referred to as Tier 4 drugs; the terminology has been changed to “completely excluded” to better align with the statutory authority.

The P&T Committee reviewed all the completely excluded drugs. The P&T Committee found no significant new clinical data, guidelines, or indications for any of the completely excluded drugs that would change the previous conclusion that the drug offers little or no clinical effectiveness relative to similar agents. The Committee also found that all the completely excluded drugs remain substantially more costly than similar agents, although prices have decreased for a few generically available products, which will continue to be monitored.

- *Nephrology Agents Miscellaneous—budesonide 4 mg delayed release capsules (Tarpeyo)*: The Committee specifically reviewed new clinical trial results for Tarpeyo, which resulted in an updated indication to reduce the loss of kidney function in patients with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. Treatment with Tarpeyo did not change the long-term rate of decline in kidney function. The product labeling was also updated to include new safety warnings for immunosuppression. Professional treatment guidelines for IgAN have not been updated.

After considering this additional clinical data, as well as relative cost effectiveness, the P&T Committee concluded that additional studies are required to establish the role of Tarpeyo in patients with IgAN, particularly in comparison to other oral systemic glucocorticoids as well as the other drugs approved or under investigation for IgAN.

COMMITTEE ACTION: UF RECOMMENDATION FOR DRUGS CURRENTLY DESIGNATED AS COMPLETE EXCLUDED—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining completely excluded status for all drugs currently designated as completely excluded.

XII. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

A. DoD/VA Continuity of Care List

The DoD/VA Continuity of Care Drug List is a joint list of medications for pain, sleep disorders, psychiatric conditions, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by Section 715 of the NDAA 2016. Additions, deletions, and clarifications to the list are based on ADSM prescription utilization patterns, formulary and clinical considerations, and discussions between DoD and VA subject matter experts. The P&T Committee was notified that no new additions or deletions were identified for the list during this year’s review of FY 23 utilization trends. The list is posted on www.health.mil.

B. Pharmacy Benefit Management Clarification

The DoD P&T Committee determines formulary placement and respective tiered coverage of medications covered under the TRICARE pharmacy benefit (i.e., pharmaceutical agents dispensed to patients for self-administration by pharmacies, including MTF pharmacies). Pharmaceutical agents supplied by physicians and other appropriate clinicians, and pharmaceutical agents provided in support of home health care (e.g., home infusion therapy) are processed under the TRICARE Health Plan (THP) under the medical benefit. The TRICARE Pharmacy contractor may not process medical benefit pharmaceutical agents at any point of service except under limited circumstances.

Pharmaceutical agents identified on the commercial self-administrated injectable list and those specifically addressed and determined to be pharmacy benefits through a formal decision by the DoD P&T Committee may be processed. With the full implementation of MHS GENESIS, private sector care processing restrictions to injectables, devices, and implants will now be placed on the MTF point of service.

Pharmaceutical agents may be pre-authorized by the THP managed care support contractor for coverage by the TRICARE pharmacy benefit under the Home Infusion Therapy (HIT) program.

Pursuant to Department of Defense Instruction 6490.03, the TRICARE pharmacy contractor may process claims for pharmaceutical agents that are not available to the general public (e.g., not on the TRICARE uniform formulary) that are part of force health protection, at military medical treatment facility pharmacies only.

Furthermore, the TRICARE pharmacy contractor may cover travel vaccines only for active-duty family members traveling with their sponsor on permanent change of duty station orders or other official travel. For private sector care the TRICARE pharmacy contractor is responsible for verifying beneficiary category and orders prior to coverage. For travel vaccines dispensed by MTF pharmacies, the MTF pharmacy is responsible for verifying documentation for official travel.

XIII. ADJOURNMENT

The meeting adjourned at 1545 hours on August 8th. The next meeting will be in November 2024.

Appendix A—Attendance: August 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—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary during the August 2024 DoD P&T Committee Meeting

Appendix G—Implementation Dates

Appendix H—Completely Excluded Agents and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

Matthew Case
RDML, USN
Acting Assistant Director, Health Care
Administration

Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
LTC Charles Lin, MC	Army, Internal Medicine Physician
COL Aatif Sheikh, MSC	Army, Pharmacy Consultant
CDR Derek Larson, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
CAPT Peter Cole, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Major Andrew Gaillardetz, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Col Larissa Weir, MC	Air Force, Obstetrics and Gynecology
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
COL Jason Burris, MC	Oncology Physician
Laura Au, PharmD, BCOP	DHA, Oncology Pharmacist
CAPT Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA (Day #2)	TRICARE Health Plan Chief Medical Officer
COL Yang Xia, MC (Day #1)	TRICARE Health Plan
Nonvoting Members Present	
Ms. Megan Gemunder, DHA	Attorney Advisor, Contract Law
Mr. Dennis Dyke DHA	Attorney Advisor, Contract Law
Ms. Marsha Peterson	DHA Contracting Officer
Eugene Moore, PharmD	Tpharm5 Clinical COR

Appendix A—Attendance

CAPT Bill Kelly, MSC, USN	Defense Logistics Agency
Guests	
COL James Masterson, MSC	Army, Pharmacy Consultant Alternate
CAPT Tiffany Cline, MSC	DHA POD Beneficiary Advisory Panel DFO
CDR Kendra Jenkins	Bureau of Prisons
CDR Aaron Cardenaz	Indian Health Service
Hazel Richardson, PharmD	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
CDR Giao Phung, MSC	DHA POD Formulary Management Branch
Heather Johnson, PharmD, BCCP, BCCCP	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
LT Yasdel Ortiz Rivera	DHA POD Formulary Management Branch
Mr. David Folmar	DHA POD Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA POD Formulary Management Branch Contractor
Mr. Michael Lee	DHA POD Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA POD Formulary Management Branch Contractor
LT Saline Lay	Navy Pharmacy Resident San Diego
Ms. Savanna Pittman	University of the Incarnate Word PharmD Student
Ms. Tracy Banks	DHA Contracting
Julia Trang, PharmD	DHA Contracting

Appendix A—Attendance

Ms. Stephanie Erpelding	DHA Contracting
Ms. Patricia Tyson	DHA Contracting
Mr. Keith Marasigan	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
- atorvastatin oral suspension (Atorvaliq) - simvastatin oral suspension (FloLipid) - rosuvastatin sprinkle capsules (Ezallor) - lovastatin ER (Altoprev) - fluvastatin ER (Lescol XL) - pitavastatin calcium (Livalo, generics) - pitavastatin magnesium (Zypitamag) Antilipidemic-Is Statins, Non-statins, and Combinations	Note no changes to the MN criteria currently in place for these drugs
New Drugs MN Criteria	
adalimumab-ryvk (Simlandi) TIBS: Tumor Necrosis Factor Inhibitors	Patient has experienced significant adverse effects from formulary agents Formulary alternatives: adalimumab (Humira)
danicopan (Voydeya) Hematological Agents	- Use of formulary agent is contraindicated - Patient has experienced significant adverse effects from formulary agent - Formulary agent resulted in therapeutic failure Formulary alternatives: pegcetacoplan (Empaveli)
givinostat (Duvyzat) Corticosteroid-Immune Modulators	- 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: prednisone, deflazacort (Emflaza)
macitentan/tadalafil (Opsynvi) Pulmonary Arterial Hypertension	- 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: macitentan, tadalafil

Appendix B—Table of Medical Necessity Criteria

• sitagliptin/metformin (Zituvimet and Authorized Generics) Diabetes Non-Insulin: DPP-4 Inhibitors	• Patient is more likely to experience significant adverse effects from formulary agents • Formulary alternatives: sitagliptin phosphate/metformin (Janumet)
• spesolimab-sbzo syringe (Spevigo) TIBS: Interleukins Miscellaneous	• 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), secukinumab (Cosentyx)
Utilization Management MN Criteria	
• tocilizumab (Actemra) TIBs: Non-TNFs	Updates from August 2024 are in bold and strikethrough • Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • ~~Use of formulary agents resulted in therapeutic failure~~ • ~~Patient previously responded to the nonformulary agent and changing to a formulary agent would incur unacceptable risk~~ • ~~Patient is transitioning from I.V. tocilizumab~~ Formulary alternatives: adalimumab (Humira), tocilizumab-aazg (Tyenne)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
acalabrutinib (Calquence) Leukemia and Lymphoma Agents: BTK Inhibitors	Changes from the August 2024 meeting are in bold and strikethrough Automated PA Criteria: When prescribed by a hematologist or oncologist, prior authorization is not required. Once therapy is initiated by a hematologist or oncologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA apply to all new users of Calquence Manual PA Criteria: If automated criteria are not met for hematologist or oncologist specialist prescribing, coverage is approved if all criteria are met: - If the physician is a hematologist or oncologist, PA is approved OR - If the prescriber is not a hematologist or oncologist and the drug is prescribed in consultation with a hematologist/oncologist, then continue with the questions below: - Patient is 18 years of age or older - Patient has a diagnosis of either chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or Mantle Cell Lymphoma (MCL) and received at least one prior therapy - Patient meets one of the following categories: ~~Patient must have pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) with documentation of monoclonal B cells that have a chromosome translocation t(11;14)(q13;q32) and/or overexpress cyclin D1 that had a short response duration to prior therapy (< median progression free survival).~~ ~~Patient will use acalabrutinib as frontline or relapsed refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation~~ ~~Patient fits one of following categories:~~ ~~Frail patient with significant comorbidity (not able to tolerate purine analogues)~~ ~~Patient ≥ 65 years old with significant comorbidity~~ ~~Patients < 65 years old~~ ~~Patient will use acalabrutinib as frontline or relapsed refractory therapy for CLL/SLL with del(17p)/TP53 mutation~~ ~~If the patient has CLL, the patient's disease has no evidence of a BTK C481S mutation nor prior ibrutinib refractory disease~~ ~~Patient must not have significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of screening, or any Class 3 or 4 cardiac disease as defined by the New York Heart Association Functional Classification, or corrected QT interval (QTc) > 480 msec~~ ~~Monitor for bleeding, infection, cardiac arrhythmias, and cytopenias~~ ~~If the patient is female and of childbearing potential, advise the patient of the risk of significant fetal harm~~ ~~Female patients will not breastfeed during treatment and for at least 2 weeks following cessation of treatment~~ - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA-approved uses are not approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• ibrutinib capsules, tablets and oral suspension (Imbruvica) Leukemia and Lymphoma Agents: BTK Inhibitors	Changes from the August 2024 meeting are in bold and strikethrough Manual PA apply to all new users of Imbruvica <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • ~~The provider acknowledges that Imbruvica capsules are more cost effective than Imbruvica tablets for TRICARE patients (at the 140 mg and 280 mg strengths).~~ • ~~If the Rx is for Imbruvica tablets at the 140 mg or 280 mg strengths, please state why the patient cannot take the capsule formulation _____, then continue with the PA criteria below.~~ • ~~If the Rx is for the Imbruvica capsules or for the higher strengths of Imbruvica tablets (420 mg and 560 mg), please continue with the PA criteria below.~~ • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 1 to ~~17 years of age~~ year of age or older with a diagnosis of chronic graft-versus-host disease OR • Patient is 18 years of age or older and has a diagnosis of either chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or Waldenström's macroglobulinemia (WM) • ~~Will be used in one of the following contexts:~~ • ~~Pretreatment to limit the number of cycles of RhyperCVAD/rituximab maintenance therapy for Mantle Cell Lymphoma~~ • ~~Second line (or subsequent therapy) for Mantle Cell Lymphoma~~ • ~~Second line (or subsequent therapy) for Marginal Zone Lymphoma~~ • ~~Second line (or subsequent therapy) for non-germinal center B cell-like Diffuse Large B Cell Lymphoma if unable to receive chemotherapy~~ • ~~Frontline or relapsed/refractory therapy for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) without del(17p)/TP53 mutation~~ • ~~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~~ • ~~Patients < 65 years old~~ • ~~Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation~~ • ~~Waldenström macroglobulinemia~~ • ~~Chronic graft versus host disease~~ • Monitor for bleeding, infection, hypertension, cardiac arrhythmias, cytopenias, and Tumor Lysis Syndrome • ~~If the patient is female, she is not pregnant or planning to become pregnant~~ • ~~Breastfeeding female patients will be advised that the potential harm to the infant is unknown~~ • ~~All patients (males and females) of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA-approved uses are not approved, except as noted above PA does not expire
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Appendix C—Table of Prior Authorization (PA) Criteria

zanubrutinib (Brukinsa) Leukemia and Lymphoma Agents: BTK Inhibitors	Updates from the August 2024 meeting are in bold and strikethrough. Automated PA Criteria: When prescribed by a hematologist or oncologist, prior authorization is not required. Once therapy is initiated by a hematologist or oncologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA criteria apply to all new users of pirtobrutinib (Brukinsa) Manual PA Criteria: If automated criteria are not met for hematologist or oncologist specialist prescribing, coverage is approved if all criteria are met: If the physician is a hematologist or oncologist, PA is approved OR If the prescriber is not a hematologist or oncologist and the drug is prescribed in consultation with a hematologist/oncologist, then continue with the questions below: - Patient is 18 years of age or older - Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) OR - Patient has Waldenström's macroglobulinemia (WM) ~~a rare non-Hodgkin lymphoma~~ OR - Patient has relapsed or refractory marginal zone lymphoma (MZL) and has ~~have~~ received at least 1 anti-CD20-based regimen OR - Patient has chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) ~~Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias~~ ~~Patient will use sun protection in sun-exposed areas~~ ~~Female patients of childbearing age and are not pregnant confirmed by () HCG.~~ ~~Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment~~ ~~Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment~~ - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis.~~ To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA approved uses are not approved, except as noted above PA does not expire
pirtobrutinib (Jaypirca) Leukemia and Lymphoma Agents: BTK Inhibitors	Updates from the August 2024 meeting are in bold and strikethrough. 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 - Drug 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~~

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	~~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: _____~~ To facilitate approval, please list the diagnosis, guideline version and page number: _____. Other non-FDA approved uses are not approved, except as noted above PA does not expire
- bempedoic acid (Nexletol) - bempedoic acid/ezetimibe (Nexlizet) Antilipidemic-1s: Non-statins and combinations	Updates from the August 2024 meeting are in bold PA criteria apply to new users of Nexletol and Nexlizet <u>Automated PA criteria:</u> The patient has filled a prescription for Repatha or Praluent at any MHS pharmacy point of service (MTFs, retail pharmacies, or network TRICARE Mail Order Pharmacy) during the previous 720 days <u>Manual PA Criteria:</u> If automated PA criteria are not met Nexletol or Nexlizet is approved if all criteria are met: - Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization) - Patient has one of the following diagnoses: - Patient has established atherosclerotic cardiovascular disease (ASCVD) including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA) or peripheral arterial disease (PAD), OR Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following: type 1 or type 2 diabetes or 10-year ASCVD risk score (Pooled Cohort Equation – PCE) >20% or Reynolds Risk score > 30% or SCORE risk score >7.5% over 10 yrs. or Coronary calcium score >400 Agatston units at any time in the past - Patient has Heterozygous Familial Hypercholesterolemia (HeFH) AND - For Nexletol: - Patient is taking concurrent ezetimibe OR - Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks AND - Patient is on concurrent statin therapy at the maximum tolerated dose and dose hasn't reached LDL goals OR - Patient is statin intolerant based on one of the following: - Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, muscle cramps), with at least 2 statins OR - History of creatine kinase (CK) levels greater than 10 x the upper limit of normal (ULN) unrelated to statin use OR - History of statin-associated rhabdomyolysis - Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) AND Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR

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	▪ Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCSK-9 inhibitor • For Nexlizet: ▪ Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) AND ▪ Patient is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal OR ▪ Patient is statin intolerant based on one of the following: ○ Patient has experienced intolerable (muscle pain, cramp) with at least 2 statins OR ○ History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR ○ History of statin-associated rhabdomyolysis OR ○ Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) AND ▪ Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR ▪ Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCSK-9 inhibitor Non-FDA-approved uses are not allowed Prior authorization does not expire
• evolocumab (Repatha) • alirocumab (Praluent) PCSK-9 Inhibitors	Changes from August 2024 meeting are in BOLD and strikethrough. Note that there were no changes to the PA criteria for patients with existing ASCVD, homozygous familial hypercholesterolemia (HoFH), or heterozygous familial hypercholesterolemia (HeFH). For Praluent, there were no changes to the requirement for a trial of Repatha first. Manual PA criteria apply to all new users of Repatha <u>Manual PA Criteria:</u> evolocumab (Repatha) is approved if all criteria are met <i>For HoFH and HeFH</i> • For heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH), the patient is 10 years of age or older. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. <i>For ASCVD</i> • The patient is at least 18 years of age for clinical atherosclerotic cardiovascular disease (ASCVD). • The patient has established ASCVD with the following LDLs, despite maximally tolerated statin doses: • Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high risk conditions. <i>Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information</i>) OR • Not at very high risk of events: LDL > 70 mg/dL AND • The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR

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	- The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR - If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND - The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy For patients at high risk for ASCVD - The patient has LDL >190 mg/dL or - Patient has diabetes and LDL <190 mg/dL or - Patients with LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD >7.5% or - Patients with LDL < 190 mg/dL and evidence of significant subclinical atherosclerosis defined as: - Significant atherosclerotic plaque observed in an asymptomatic patient on any of the following diagnostic studies: coronary artery calcification noted on computed tomography (CT) studies, including calcium scoring, cardiac CT coronary angiography, chest CT for ruling out pulmonary embolism, chest CT for lung cancer screening, or diagnostic chest CT; carotid plaque noted on carotid ultrasound or angiography; or abnormal ankle-brachial index or plaque noted on peripheral arterial angiography. AND - The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR - The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR - If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND - The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. For both HoFH and ASCVD all uses: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: - Intolerance - The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND - The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR - The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. - Contraindication to statin - The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) For all FDA-approved indications ~~Repatha is not approved for any indication other than HoFH, HoFH, or clinical ASCVD.~~ - Repatha is not approved for patients who are pregnant or lactating. - The dosage must be documented on the PA Form as either: 140 mg every 2 weeks, or 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. PA does not expire
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- atorvastatin 20 mg/5 mL suspension (Atorvaliq) - rosuvastatin sprinkle (Ezallor Sprinkle) - simvastatin oral suspension (Flolipid) - pitavastatin calcium (Livalo, generics) - pitavastatin magnesium (Zypitamag) Antilipidemic-1s: Statins	Note no changes were made to the existing PA criteria.
Newly Approved Drug PAs	
adalimumab-ryvk (Simlandi) TIBS: Tumor Necrosis Factor Inhibitors (TNFs)	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

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	• 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
• danicopan (Voydeya) Hematological Agents	Manual PA criteria apply to all new users of danicopan (Voydeya). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Prescribed by a hematologist/oncologist • Patient is 18 years of age or older • Patient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • Patient has tried and failed monotherapy with a C5 inhibitor for six months (e.g., eculizumab, ravulizumab), and has residual anemia • Patient will receive C5 inhibitor therapy (eculizumab, ravulizumab) concurrently with Voydeya • Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and Risk Evaluation and Mitigation Strategies (REMS) requirements • Patient is not receiving C3 or Complement Factor B inhibitors with Voydeya, including but not limited to the following: iptacopan (Fabhalta), or pegcetacoplan (Empaveli) Non-FDA approved uses are NOT approved PA expires after 6 months then annually <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for another year if all the criteria are met: • Patient ~~meets initial criteria~~, has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis.

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• elafibranor (Iqirvo) Gastrointestinal (GI)-2 Agents	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of elafibranor (Iqirvo). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician • Patient has a diagnosis of primary biliary cholangitis (PBC) • Diagnosis has been confirmed by at least TWO of the following: ▪ alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values ▪ positive anti-mitochondrial antibodies (AMAs) ▪ histologic evidence of PBC from a liver biopsy • Patient been receiving ursodiol therapy for one year or greater and has had an inadequate response OR • Patient is unable to tolerate ursodiol therapy • Patient has a contraindication to, intolerability to, or has failed a trial of obeticholic acid (Ocaliva) Non-FDA approved uses are NOT approved PA expires after 1 year <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient has responded to Iqirvo as determined by the prescribing physician (for example, improved biochemical markers of PBC: alkaline phosphatase, bilirubin, gamma-glutamyl transpeptidase, aspartate aminotransferase, alanine aminotransferase)
• givinostat (Duvyzat) Corticosteroids-Immune Modulators	Manual PA criteria apply to all new users of givinostat (Duvyzat). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 6 years of age or older • Prescribed by a neurologist • Patient has a diagnosis of Duchenne Muscular Dystrophy (DMD) that has been confirmed by genetic testing or muscle biopsy • Patient is ambulatory • Patient has a contraindication to, intolerability to, or has failed a trial of deflazacort (Emflaza) • Provider acknowledges the FDA safety alerts, warnings, precautions, drug interactions, and monitoring recommendations for the requested medication Non-FDA approved uses are NOT approved PA does not expire
• macitentan/tadalafil (Opsynvi) Pulmonary Arterial Hypertension Agents	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new and current users of macitentan and tadalafil (Opsynvi). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with cardiologist or a pulmonologist • Patient has had a right heart catheterization with documentation provided • Results of right heart catheterization confirm diagnosis of World Health Organization (WHO) Group 1 PAH • Patient has WHO Functional Class II or III PAH

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	- If patient is a female, then prescriber is enrolled in Risk Evaluation and Mitigation Strategy (REMS) program - Female patient is not pregnant - Females of childbearing age are using adequate contraception up to 1 month after therapy Provider must describe why the patient requires a fixed dose combination and cannot take the individual components separately (write-in) Acceptable responses include the following: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience Non-FDA approved uses are NOT approved PA does not expire
mavoxiafor (Xolremdi) Hematological Agents	Manual PA criteria apply to all new users of mavoxiafor (Xolremdi). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by an immunologist or hematologist - Patient has diagnosis of WHIM syndrome - Patient's diagnosis has been confirmed by genotype variant of CXCR4 - Patient has absolute neutrophil count (ANC) $\leq$ 400 cells/microliter Non-FDA approved uses are NOT approved PA expires after 6 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - Patient has documentation of positive clinical response defined as one of the following: - improvement in absolute neutrophil count (ANC) - decrease in infections
resmetirom (Rezdiffra) GI-2 Agents	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of resmetirom (Rezdiffra). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by or in consultation with hepatologist or gastroenterologist - Patient has biopsy-proven non-alcoholic steatohepatitis (NASH) OR - Patient has fibrosis stage of F2 or F3 diagnosed with appropriate assessment (e.g., FibroScan, MRI-PDFF)~~confirmed by imaging (e.g., VCTE, MRI PDFF)~~ The patient has metabolic risk factors that are managed by standard of care (e.g., lifestyle modifications, glucagon-like peptide 1-receptor agonists (semaglutide, tirzepatide), or statins) Non-FDA approved uses are NOT approved. ~~PA does not expire.~~ PA expires in 1 year <u>Renewal Criteria:</u> Initial TRICARE approval is required for renewal. Rezdiffra is approved for an additional year if all criteria are met: Patient has documentation of positive clinical response to include improvement in fibrosis or stabilization of fibrosis AND Patient has continued consultation with a hepatologist or gastroenterologist

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• sitagliptin/metformin (Zituvimet authorized generic) Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	Manual PA criteria apply to all new users of sitagliptin and metformin (Zituvimet authorized generic) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that Januvia and its combination products are DoD's preferred dipeptidyl peptidase-4 inhibitor and are available to TRICARE beneficiaries without requiring prior authorization • Provider must document why the patient cannot use the brand Januvia or Janumet XR. (write-in) ▪ Acceptable responses include that the patient has had an adverse reaction to an excipient in brand Januvia, Janumet or Janumet XR that would not be likely to occur with sitagliptin/metformin authorized generic Non-FDA approved uses are NOT approved PA does not expire
• sotatercept-csrk (Winrevair) Pulmonary Arterial Hypertension Agents	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of sotatercept-csrk (Winrevair). <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with cardiologist or pulmonologist • Patient has documented diagnosis of WHO group 1 PAH • Patient has WHO functional class II or III PAH • Patient has had right heart catheterization • Documentation provided to confirm that patient has had right heart catheterization and confirms diagnosis of WHO Group 1 PAH • Documentation is provided to confirm the patient is on stable background therapy for PAH (i.e., monotherapy, double therapy, triple therapy) • Documentation is provided to confirm patient has been on stable doses of diuretics for more than 90 days. A stable dose of diuretic is defined as no addition of a new diuretic and no switching of an oral diuretic to parenteral administration. Dose adjustments for oral diuretics are acceptable. • Females of childbearing potential must use contraception up to 4 months after the last dose Non-FDA approved uses are NOT approved PA does not expire
• spesolimab-sbzo syringe (Spevigo) TIBS: Non-TNFs	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of spesolimab-sbzo <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Prescribed by a dermatologist • Patient is 12 years of age or older and weighs 40 kilograms or greater • Provider acknowledges that Humira is the Department of Defense's preferred targeted biologic agent. • The patient has 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 AND • The patient had an inadequate response to Cosentyx OR • The patient experienced an adverse reaction to Cosentyx that is not expected to occur with the requested agent OR • The patient has a contraindication to Cosentyx

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	• Patient has had an inadequate response to non-biologic systemic therapy. (For example – cyclosporine, methotrexate, acitretin, isotretinoin, systemic glucocorticoids, or mycophenolate) • Patient has generalized pustular psoriasis and is not currently experiencing a flare as defined by a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1 • Patient has history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past while on biologic suppressive maintenance therapy • ~~Patient has 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: certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), ustekinumab (Stelara), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), tildrakizumab (Ilumya), risankizumab (Skyrizi) Non-FDA approved uses are NOT approved PA expires in 1 year Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional year if all the criteria are met: • Patient has had a documented reduction in generalized pustular psoriasis symptoms or • Patient has had a reduction in generalized pustular psoriasis flares.
• tocilizumab-aazg syringe (Tyenne) TIBS: Non-Tumor Necrosis Factor Inhibitors	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira • The patient has 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 AND • Patient has moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs ~~AND patient has platelets greater than 400,000/mm3 or liver transaminase less 1.5 UNL OR~~ • Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR • Patient has a diagnosis for which adalimumab is not approved including ~~AND greater than 18 years of age~~ ▪ Giant cell arteritis OR ▪ Systemic sclerosis-associated lung disease ~~then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL OR~~ ▪ Patient has systemic Juvenile Idiopathic Arthritis (sJIA) OR ▪ If "other" diagnosis, ~~does patient have a contraindication to Humira?~~ please provide appropriate literature-based support documentation for the indication and utilization ○ ~~If yes and if moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ○ ~~If yes and If giant cell arteritis OR systemic sclerosis-associated lung disease then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~

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	• ~~Patient has not tried Humira AND less than 18 years of age but greater than 2 years of age~~ • ~~Patient has systemic Juvenile Idiopathic Arthritis (sJIA)~~ • ~~Patient has evidence of negative TB test result in the past 12 months or TB is adequately managed~~ • Patient is not receiving other targeted immunomodulatory biologics with Tysen Non-FDA approved uses are NOT approved, except as noted above. PA does not expire
• tovorafenib (Ojemda) Oncological Agents: N/A	Manual PA criteria apply to all new users of tovorafenib (Ojemda). Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • Patient has pediatric low-grade glioma • Patient has relapsed or refractory disease • Tumor is positive for one of the following: BRAF fusion, BRAF rearrangement, BRAF V600 mutation • 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. To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA approved uses are NOT approved except as noted above PA does not expire
Utilization Management Updated PAs	
• eflapegrastim-xnst (Rolvedon) White Blood Cell Stimulants	Updates from the August 2024 meeting are in bold Manual PA criteria apply to all new users of pegfilgrastim (Neulasta) and pegfilgrastim (Neulasta OnPro, and eflapegrastim-xnst (Rolvedon)) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) are the TRICARE preferred pegfilgrastims and are available without a prior authorization. • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient requires use of an on-body injector (Neulasta OnPro) because the patient/caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration OR • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) and is expected to respond to the requested medication PA does not expire
• lanreotide 120 mg/ 0.5 mL syringe Endocrine Agents Miscellaneous	Manual PA criteria apply to all new and current users Manual PA criteria: Lanreotide acetate 120 mg injection is approved if all criteria are met: • Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization. • Provider must explain why the patient cannot use the 120 mg Somatuline Depot brand. ▪ Acceptable responses include if the patient has a hypersensitivity to an excipient in the brand that is not found in the generic Non-FDA-approved uses are not approved Prior authorization does not expire

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lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V) Pain Agents: Pain Topical	Updates from the August 2024 meeting are in bold. Manual PA criteria apply to all new and current users of lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III, Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, Tridacaine III). <u>Manual PA criteria:</u> 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, Lidocan III, Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, or Tridacaine 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
upadacitinib (Rinvoq) Atopy: Oral JAK-1	Updates from the August 2024 meeting are in bold and strikethrough. Note that there were no changes to the current Rinvoq criteria for the other indications (RA, PsA, Ulcerative Colitis, Ankylosing Spondylitis, or Atopic Dermatitis – see the August 2022 P&T Committee meeting minutes for the full criteria) Manual PA apply to all new users of Rinvoq Manual PA criteria: Rinvoq is approved if all criteria are met: Patient is 2-17 years of age and either: Patient is being treated for active polyarticular juvenile idiopathic arthritis OR Patient is being treated for psoriatic arthritis - Provider acknowledges that Humira is the Department of Defense preferred targeted biologic agent for approved indications - Patient has had an inadequate response to Humira OR - Patient has experienced an adverse reaction to Humira and that is not expected to occur with the requested agent OR - Patient has a contraindication to Humira AND For all indications ~~Patient has no evidence of active TB infection within the past 12 months~~ - Patient has no history of venous thromboembolic (VTE) disease - Provider is aware of the FDA safety alerts AND Boxed Warnings - Patient has no evidence of neutropenia (ANC < 1000) - Patient has no evidence of lymphocytopenia (ALC < 500) - Patient has no evidence of anemia (Hgb < 8) - Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved Prior authorization does not expire

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benralizumab (Fasenra) Atopy	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA is required for all new users of Fasenra Pen <u>Manual PA Criteria:</u> Fasenra Pen coverage will be approved for initial therapy for 12 months if all criteria are met: - The patient has a diagnosis of severe persistent eosinophilic asthma - The patient is ~~six~~ 42 years of age or older - The drug is prescribed by an allergist, immunologist, or pulmonologist - The patient must have an eosinophilic phenotype asthma as defined as either - Eosinophils ≥ 150 cells/mcL within past month while on oral corticosteroids OR - Eosinophils ≥ 300 cells/mcL - The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: - Hospitalization for asthma in past year OR - Two courses oral corticosteroids in past year OR - Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids - The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: - Long-acting beta agonist LABA e.g., Serevent, Striverdi), - Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or - Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) - The patient is not currently receiving another immunobiologic (e.g., mepolizumab [Nucala], dupilumab [Dupixent] or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely <u>Renewal Criteria:</u> (initial TRICARE PA approval is required for renewal) AND - The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use
vedolizumab (Entyvio) TIBs: Non-TNFs	Updates from the August 2024 meeting are in bold. Manual PA criteria apply to all new users of vedolizumab <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Patient has moderately to severely active ulcerative colitis or moderately to severely active Crohn's Disease - 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

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	• 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
• sarilumab (Kevzara) TIBs: Non-TNFs	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Kevzara <u>Manual PA criteria:</u> Kevzara is approved for Polymyalgia Rheumatica if all criteria are met: • ~~Patient is greater than or equal to 18 years of age~~ • Kevzara is prescribed by or in consultation with a rheumatologist • Provider acknowledges 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 • Patient has a diagnosis of: ▪ Moderately to severely active rheumatoid arthritis AND - Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD) ▪ Active polyarticular juvenile idiopathic arthritis (pJIA) and weighs 63 kg or more AND - Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD) ▪ Polymyalgia Rheumatica (PMR) (No trial of Humira required) AND - Patient has tried and/or failed ONE systemic corticosteroid; OR the patient is not a candidate for corticosteroid therapy • ~~Patient does not have platelets less than 150,000/mm³ or liver transaminases above 1.5 times upper limit of normal (UNL)~~ • ~~Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ • Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR Non-FDA-approved uses are not approved PA for non-PMR indications approved indefinitely.

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	Prior authorization for PMR expires after 12 months. Renewal PA criteria will be approved indefinitely <u>Renewal Criteria:</u> (initial TRICARE PA approval is required for renewal) AND the patient has had a positive response to therapy
maralixibat (Livmarli) Metabolic Agents Miscellaneous	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Livmarli. <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 3 months of age or older and has diagnosed Alagille syndrome with severe refractory pruritus OR Patient is $\geq$ 12 months and has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritis AND - The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist - The patient has been evaluated for possible orthotopic liver transplant (OLT) - The patient has previously tried and failed all of the following: - ursodiol - cholestyramine - rifampin - naltrexone - and at least one antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD), ~~progressive familial intrahepatic cholestasis (PFIC)~~, biliary atresia, and other cholestatic diseases are not-approved PA expires every 6 months Coverage will be approved for an additional six months if the following apply: <u>Renewal criteria:</u> Initial TRICARE PA approval required. PA will be approved for an additional 6 months if: - Patient must demonstrate significant improvement in pruritus symptoms.
doxylamine/pyridoxine (Diclegis, Bonjesta) Antiemetic-Antivertigo Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA applies to all new users of Bonjesta and Diclegis Manual PA criteria: Bonjesta and Diclegis are approved if ALL criteria are met. Provider acknowledges that OTC doxylamine 25 mg is covered with a prescription and without a copay under the TRICARE pharmacy benefit at the MTF and retail points of service - The patient has a diagnosis of nausea and vomiting associated with pregnancy - The patient has tried at least one non-pharmacologic treatment (for example, ginger, acupressure, high protein bedtime snack) and failed to obtain relief of symptoms - The patient has tried OTC doxylamine and pyridoxine and failed to obtain relief of symptoms. - The provider has considered a change to an alternate anti-emetic (e.g., ondansetron) prior to prescribing Bonjesta or Diclegis Non-FDA-approved uses are not approved Prior authorization will expire after 9 months

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• trametinib (Mekinist) Oncological Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria applies to all new users of Mekinist. Manual PA criteria: Coverage will be approved if: • Prescribed by or in consultation with a hematologist/oncologist • Monotherapy for treatment of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation in BRAF-inhibitor treatment naïve patients • Combination with dabrafenib (Tafinlar) for the treatment of patients with: ▪ ~~Treatment (alone or in combination with dabrafenib [Tafinlar]) of~~ unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation ▪ Adjuvant treatment of patients of melanoma with BRAF-V600E or BRAF-V600K mutation and involvement of lymph node(s), following complete resection ▪ ~~In combination with dabrafenib (Tafinlar), for the treatment of patients with~~ metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation ▪ ~~Combination with dabrafenib (Tafinlar) for~~ locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options ▪ ~~For the treatment of adult and pediatric patients 1 year of age and older with~~ unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options ▪ ~~In combination with dabrafenib (Tafinlar), For the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy~~ • Coverage not approved as a single agent in patients who have received prior BRAF inhibitor therapy • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• dabrafenib (Tafinlar) Oncological Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria applies to all new users of Tafinlar. Manual PA criteria: Coverage will be approved if: • Prescribed by or in consultation with a hematologist/oncologist • Single agent for treatment of unresectable or metastatic melanoma with BRAF V600E ~~or BRAF-V600K~~ mutation • In combination with trametinib (Mekinist) for the treatment of patients with: ▪ ~~in the treatment of~~ unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations ~~OR~~ ▪ Adjuvant treatment of patients of melanoma with BRAF-V600E or BRAF-V600K mutation and involvement of lymph node(s), following complete resection

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	~~In combination with trametinib (Mekinist), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E Mutation~~ ~~Combination with trametinib (Mekinist) for locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options~~ ~~For the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options~~ ~~In combination with trametinib (Mekinist), for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy~~ • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• neratinib (Nerlynx) Oncological Agents: Breast Cancer	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria applies to all new users of Nerlynx. Manual PA criteria: Coverage will be approved if: • Prescribed by or in consultation with a hematologist/oncologist • Patient is greater than or equal to 18 years of age • As a single agent for extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, following adjuvant trastuzumab based therapy ~~• Patient has early stage HER2 overexpressed/amplified breast cancer AND~~ ~~• Following adjuvant trastuzumab based therapy (preferably less than 1 year, but no more than 2 years after completion) OR~~ • Used in combination with capecitabine for advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer following two or more prior anti-HER2-based regimens ~~• Patient has a Advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer following AND Patient has received two or more prior anti-HER2 based regimens in the metastatic setting OR~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____ AND ~~• Counselor on significant adverse event profile AND~~ ~~• Co-prescribed antidiarrheal to mitigate for at a minimum 2 months AND~~ Non-FDA-approved uses are not approved, except as noted above PA does not expire

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vemurafenib (Zelboraf) Oncological Agents: Melanoma	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria applies to all new users of Zelboraf. Manual PA criteria: Coverage will be approved if: Prescribed by or in consultation with a hematologist/oncologist - Documented diagnosis of unresectable or metastatic melanoma with BRAF V600E mutation AND melanoma that is NOT wild-type BRAF ~~Detected by an FDA-approved test (Cobas 4800) OR~~ - Patient has Erdheim-Chester Disease with BRAF V600 mutation - Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist) - 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
venetoclax (Venclexta) Oncological Agents: Non-BTKI for Chronic Lymphocytic Leukemia	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria applies to new users of Venclexta <u>Manual PA Criteria:</u> Coverage for Venclexta is approved if all criteria are met: - Drug is prescribed by or in consultation with a hematologist/oncologist - Age greater than or equal to 18 years - Venclexta will be used for 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 is greater than or equal to 65 years of age with significant comorbidity~~ ~~Patient is less than 65 years of age~~ ~~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 is greater than or equal to 65 years of age with significant comorbidity~~ ~~Patient is less than 65 years of age~~ ~~Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation~~ Patient has newly diagnosed acute myeloid leukemia (AML) in combination with azacitidine, decitabine, or low-dose cytarabine if: and is a candidate for intensive remission induction therapy and meets the following criteria: ~~Age greater than or equal to 60 years~~ ~~Unfavorable-risk cytogenetics (exclusive of AML with myelodysplasia-related changes)~~ ~~Patient is greater than or equal to 60 years of age and has newly diagnosed AML and is not a candidate for, or declines, intensive remission induction therapy~~ ~~Patient is greater than or equal to 60 years of age and completed lower-intensity induction therapy for AML with a response~~

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	- Patient has relapsed refractory AML ~~• Will titrate to therapeutic dose in consideration of tumor lysis syndrome (TLS)~~ ~~• 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA approved uses are NOT approved, except as noted above PA does not expire
• nilutamide (Nilandron) Oncological Agents: Prostate 1	Updates from the August 2024 meeting are in bold. Manual PA criteria applies to all new users of Nilandron. Manual PA criteria: Coverage will be approved if: • Prescribed by or in consultation with a hematologist/oncologist or urologist • Patient has a contraindication to bicalutamide or flutamide OR • Patient experienced significant adverse effects from bicalutamide or flutamide • Patient experienced therapeutic failure with bicalutamide or flutamide OR • Patient has a diagnosis of metastatic prostate cancer (Stage D2) disease and the patient has undergone orchiectomy • 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• belzutifan (Welireg) Oncological Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Welireg <u>Manual PA criteria:</u> Welireg is approved if all criteria are met: • Welireg is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older ~~• Welireg is prescribed by or in consultation with an oncologist~~

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	- 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) ~~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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA approved uses are not approved, other than noted above PA does not expire
tucatinib (Tukysa) Oncological Agents: Breast Cancer	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA is required for all new users of Tukysa. Manual PA Criteria: Tukysa is approved if all criteria are met: - Medication is prescribed by or consultation with a hematologist/oncologist - Patient is 18 years of age or older - The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting AND Tucatinib will be used in combination with trastuzumab (~~Herceptin~~) and capecitabine (~~Xeloda~~) OR - The patient has a confirmed diagnosis of RAS wild-type, HER2-positive, unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy AND tucatinib will be used in combination with trastuzumab ~~Provider agrees to monitor for hepatotoxicity~~ ~~Patient has been counseled on risk of diarrhea~~ ~~Female patients of childbearing age are not pregnant confirmed by () HCG~~ ~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~ ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.

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glasdegib (Daurismo) Oncological Agents: Acute Myelogenous Leukemia	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA is required for all new users of Daurismo Manual PA Criteria: Glasdegib (Daurismo) is approved if <u>all</u> criteria are met: - Prescribed by or in consultation with a hematologist/oncologist - Treatment of newly diagnosed acute myeloid leukemia (in combination with low-dose cytarabine) in adult patients who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy. ~~Provider acknowledges and patient has been informed that limitations of use include that this drug has not been studied in patients with severe renal impairment or moderate to severe hepatic impairment.~~ ~~Patient is not pregnant or actively trying to become pregnant~~ ~~Patient will be monitored for febrile neutropenia and QTc prolongation~~ - 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
erdafitinib (Balversa) Oncological Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA Criteria apply to all new users of Erdafitinib (Balversa) Manual PA Criteria: Balversa is approved if <u>all</u> criteria are met: - Prescribed by or in consultation with a hematologist/oncologist ~~Age ≥ 18~~Patient is 18 years of age or older - Locally advanced or metastatic urothelial carcinoma that has a susceptible FGFR3 mutation ~~confirmed with an FDA-approved test~~ and - The patient has progressed during or following at least one line of prior systemic therapy ~~Patient will be evaluated by an ophthalmologist before starting and q1mo for first 4 months; q3mo thereafter and advised to seek emergent evaluation for new ocular symptoms~~ ~~Patient will be monitored for hyperphosphatemia (a third of patients required a phosphate binder in the trial supporting FDA approval for erdafitinib)~~ ~~If the patient is female, she is not pregnant or planning to become pregnant.~~ ~~Female patients will not breastfeed.~~ ~~All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for 1 month after the last dose.~~ - The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. ~~Other~~ Non-FDA-approved uses are not approved, except as noted above PA does not expire

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abiraterone (generic and Zytiga) Oncological Agents: CYP-17 Inhibitors	Updates from the August 2024 meeting are in bold and strikethrough. Automated PA Criteria: When prescribed by a hematologist, oncologist, or urologist prior authorization is not required. Once therapy is initiated by a hematologist, oncologist, or urologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA criteria applies to all new users: Manual PA coverage, if automated criteria are not met: Coverage approved if all criteria are met: If the physician is a hematologist, oncologist or urologist, PA is approved OR If the prescriber is not a hematologist, oncologist or urologist and if the drug is prescribed in consultation with a hematologist/oncologist or urologist, then continue with the questions below: - Patient is 18 years of age or older - 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) - 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 - 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire
enzalutamide (Xtandi) Oncological Agents: 2nd-Gen Antiandrogens	Updates from the August 2024 meeting are in bold and strikethrough. Note: For metastatic castration-sensitive prostate cancer (mCSPC) abiraterone acetate is listed as a category 1 recommendation for either doublet or triplet therapy. Abiraterone acetate is available as part of the Tricare benefit as a Tier 1 agent and available without a PA for hematologists, oncologists and urologists. Manual PA criteria apply to new users of Xtandi Manual PA Criteria: Xtandi is approved if all criteria are met: - Medication is prescribed by or in consultation with a hematologist/oncologist or urologist - Patient is greater than or equal to 18 years of age - Patient has documented diagnosis of: - metastatic or non-metastatic castration resistant-prostate cancer (~~m~~CRPC) OR ~~non-metastatic castration-resistant prostate cancer (nmCRPC)~~ ~~If used in (nmCRPC) patient must have: PSADT less than or equal to 10 months~~ - OR metastatic castration-sensitive prostate cancer (mCSPC)

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	- OR non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis ~~• Patient with CRPC or mCSPC must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy~~ • 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire
darolutamide (Nubeqa) Oncological Agents: 2nd-Gen Antiandrogens	Updates from the August 2024 meeting are in bold and strikethrough. Note: For metastatic castration-sensitive prostate cancer (mCSPC) abiraterone acetate is listed as a category 1 recommendation for either doublet or triplet therapy. Abiraterone acetate is available as part of the Tricare benefit as a Tier 1 agent and available without a PA for hematologists, oncologists and urologists. Manual PA is required for all new users of Nubeqa <u>Manual PA Criteria:</u> Nubeqa is approved if all criteria are met: • Drug is prescribed by or in consultation with a hematologist/oncologist or urologist AND • Patient is 18 years of age or older AND • 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 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~~ castration-sensitive prostate cancer (mCSPC) in combination with docetaxel • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy • 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Other non-FDA approved uses are not approved, except as noted above PA does not expire
apalutamide (Erleada) Oncological Agents: 2nd-Gen Antiandrogens	Updates from the August 2024 meeting are in bold and strikethrough. Note: Abiraterone acetate is available as part of the Tricare benefit as a Tier 1 agent and available without a PA for hematologist, oncologist, and urologists. Manual PA is required for all new users of Erleada <u>Manual PA Criteria:</u> Erleada is approved if all criteria are met: ~~• Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. Has the patient tried Xtandi? OR Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Xtandi that is not expected to occur with requested agent~~

Appendix C—Table of Prior Authorization (PA) Criteria

	• Drug is prescribed by or in consultation with an oncologist or urologist • Age 18 years or older • Provider acknowledges 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 Erleada AND • Patient has documented diagnosis of: • non-metastatic castration-resistant prostate cancer (nmCRPC), ~~AND PSA DT ≤ 10 months~~ • ~~Negative CT scan of abdomen/pelvis and/or negative bone scan, AND~~ • metastatic castration-sensitive prostate cancer (mCSPC) • 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 • 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. To facilitate approval if so, please list the diagnosis, guideline version, and page number: _____. Non-FDA approved uses are NOT approved, except as noted above Prior authorization does not expire
• anakinra (Kineret) TIBs: Non-TNFs	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria applies to all new users of anakinra (Kineret). <u>Manual PA Criteria:</u> Kineret is approved if all criteria are met: • Pediatric patients (all ages) with: ▪ Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryopyrin Associated Period Syndrome (CAPS). (Trial of Humira not required). ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) (Trial of Humira not required). ▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (Trial of Humira not required). • Patient is 18 years of age or older with: ▪ Adult-Onset Still's Disease (AOSD) with active systemic features of moderate to high disease activity (Trial of Humira not required) OR ▪ Moderate to severe active rheumatoid arthritis AND - Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications - The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent - The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • ~~The patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER) Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

solriamfetol (Sunosi) Sleep Disorders: Wakefulness Promoting Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA is required for all new users of solriamfetol (Sunosi). <u>Manual PA Criteria:</u> Sunosi is approved if all criteria are met: - Provider acknowledges that PA is not required for modafinil or armodafinil. - Patient is 18 years of age or older ~~Sunosi is not approved for use in children, adolescents, or pregnant patients.~~ - Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy ~~or a documented diagnosis of obstructive sleep apnea (OSA) and an Epworth Sleepiness Scale (ESS) score ≥ 10~~ - Sunosi is prescribed by a neurologist, psychiatrist, or sleep medicine specialist - For narcolepsy: narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing - For narcolepsy: Other causes of sleepiness have been ruled out or treated including but not limited to obstructive sleep apnea - The patient must have tried and failed and had an inadequate response to modafinil AND OR - The patient must have tried and failed and had an inadequate response to armodafinil - The patient must have tried and failed and had an inadequate response to stimulant-based therapy (amphetamine or methylphenidate) - For OSA: Patient's underlying airway obstruction has been treated with continuous positive airway pressure (CPAP) for at least 1 month prior to initiation, and the patient demonstrated adherence to therapy during this time - For OSA: Patient will continue treatment for underlying airway obstruction (CPAP or similar) throughout duration of treatment Sunosi is prescribed by a specialist who treats patients with obstructive sleep apnea (e.g., pulmonologist, cardiologist, sleep medicine) ~~Patient and provider agree to monitor blood pressure and heart rate at baseline and periodically throughout treatment. If the patient has hypertension, the blood pressure is controlled.~~ ~~Patient does not have unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems~~ - The patient is not concurrently taking any of the following: - Central nervous system depressants, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic ~~Monoamine oxidase inhibitor (MAOI) within the past 14 days~~ ~~Modafinil, armodafinil, or stimulant based therapy, such as amphetamine or methylphenidate~~ Non-FDA-approved uses are not approved ~~(including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, major depression, ADHD, or shiftwork disorder).~~ Prior authorization expires in 1 year <u>Renewal PA criteria:</u> No renewal allowed. A new prescription will require a new PA to be submitted.
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Appendix C—Table of Prior Authorization (PA) Criteria

• pitolisant (Wakix) Sleep Disorders: Wakefulness Promoting Agents	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA is required for all new users of pitolisant (Wakix). <u>Manual PA Criteria:</u> Wakix is approved if all criteria are met: • Provider acknowledges that PA is not required for modafinil or armodafinil. • Patient is 18 years of age or older • ~~Wakix is not approved for use in children, adolescents, or pregnant patients.~~ • Patient has a documented diagnosis of excessive daytime sleepiness Wakix is prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy AND • ~~associated with one of the following:~~ • ~~Narcolepsy and an Epworth Sleepiness Scale (ESS) score $\geq$ 14 and narcolepsy was diagnosed by polysomnography or mean sleep latency time (MSLT) objective testing~~ • ~~Cataplexy and an Epworth Sleepiness Scale (ESS) score of $\geq$ 12 and at least 3 cataplexies per week~~ • Other causes of sleepiness have been ruled out or treated, including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders • ~~Patient is not concurrently taking any of the following: Modafinil, armodafinil, or stimulant based therapy, such as amphetamine or methylphenidate~~ • Patient must have tried and failed and had an inadequate response to modafinil AND-OR • Patient must have tried and failed and had an inadequate response to armodafinil • Patient must have tried and failed and had an inadequate response to stimulant based therapy (amphetamine or methylphenidate) • Patient is 6 years of age or older AND the patient has history of failure, contraindication, or intolerance of stimulant-based therapy (amphetamine-based therapy or methylphenidate) • Drug is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • ~~Patient does not have a history of severe hepatic impairment~~ • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic (including tramadol), a benzodiazepine, or a sedative hypnotic Non-FDA-approved uses are not approved (~~including but not limited to fibromyalgia, insomnia, excessive sleepiness not associated with narcolepsy, cataplexy, obstructive sleep apnea, major depression, ADHD, or shift work disorder~~). PA expires in 1 year. <u>Renewal PA criteria:</u> No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA.
• adalimumab (Humira) TIBs: TNFs	Updates from the August 2024 meeting are in bold and strikethrough. <u>Automated PA Criteria:</u> ~~If the provider is a Rheumatologist (Internal Medicine or Pediatric), PA is approved~~ When prescribed by a Rheumatologist, Dermatologist, Gastroenterologist, prior authorization is not required. Once therapy is initiated by a rheumatologist, dermatologist, or gastroenterologist an automated drug look back will apply, allowing continuation of coverage by any

Appendix C—Table of Prior Authorization (PA) Criteria

	other prescriber if the patient has received the requested medication in the past 720 days. <u>Manual PA Criteria:</u> If automated criteria are not met, Humira is approved if all manual criteria are met: • If the physician is a rheumatologist, dermatologist or gastroenterologist, PA is approved OR • If the prescriber is not a rheumatologist, dermatologist or gastroenterologist and if the drug is prescribed in consultation with a rheumatologist, dermatologist or gastroenterologist, then continue with the questions below: • Coverage is approved for patients 18 years of age or older with one of the following diagnoses/indications: ▪ Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) ▪ Moderate to severe chronic plaque psoriasis (PsO) in patients who are candidates for systemic therapy or phototherapy ▪ Moderately to severely active Crohn's disease (CD) ▪ Moderately to severely active ulcerative colitis (UC) ▪ Moderate to severe hidradenitis suppurativa (HS) ▪ Non-infectious intermediate, posterior, and panuveitis ▪ Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation ▪ Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids ▪ Generalized pustular psoriasis (GPP) with a history of at least two GPP flares of moderate-to-severe intensity in the past OR • Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication: ▪ Moderate to severe active juvenile idiopathic arthritis (JIA), including subtypes ▪ Non-infectious intermediate, posterior, and panuveitis ▪ Moderate to severe plaque psoriasis in patients who are candidates for systemic or phototherapy ▪ Moderate to severe hidradenitis suppurativa (HS) ▪ Moderately to severely active Crohn's disease (CD) ▪ Moderately to severely active ulcerative colitis (UC) ▪ Generalized pustular psoriasis (GPP) with a history of at least two GPP flares of moderate-to-severe intensity in the past • Below criteria applies to AS and nr-axSpA indications only: ▪ Patient has had an inadequate response to at least two NSAIDs over a period of at least two months • Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease, ankylosing spondylitis (AS), nr-axSpA, psoriatic arthritis (PsA) and applies to pediatric patients without plaque psoriasis or Crohn's disease: ▪ Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]), antibiotics or anti-androgens
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Appendix C—Table of Prior Authorization (PA) Criteria

	~~Below criteria applies to all patients (regardless of age):~~ ~~Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this?~~ ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ Coverage for non-FDA-approved uses not listed above: Please provide the diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. - Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (~~Remicade~~), apremilast (Otezla), ustekinumab (~~Stelara~~), abatacept (Orencia), anakinra (Kineret), tocilizumab (~~Actemra~~), tofacitinib (Xeljanz/Xeljanz XR), rituximab (~~Rituxan~~), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER).
secukinumab (Cosentyx) TIBs: Non-TNFs	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of secukinumab (Cosentyx). <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated criteria are not met, 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 - Moderate to severe hidradenitis suppurativa (HS) Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past - 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 OR Coverage approved for pediatric patients 12-17 years of age with diagnosis of: Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past

Appendix C—Table of Prior Authorization (PA) Criteria

	- 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], antibiotics, anti-androgens, etc.) (Note: AS, nr-axSpA, ERA 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 and nr-axSpA 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, including but not limited to TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA-approved uses are not approved, except as noted above. Prior Authorization does not expire
tocilizumab (Actemra) TIBs: Non-TNFs	Updates from the August 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users tocilizumab (Actemra) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira. Has the patient tried Humira? - Patient had inadequate response OR experienced adverse reaction OR has contraindication to Humira Provider acknowledges the Department of Defense's preferred tocilizumab is Tyenne. Has the patient tried Tyenne? Patient had inadequate response OR experienced adverse reaction OR has contraindication to Tyenne - Patient has tried Humira: - Moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs ~~AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ - Active polyarticular Juvenile Idiopathic Arthritis (pJIA) - Patient has not tried Humira and has a diagnosis for which adalimumab is not approved: AND greater than 18 years of age: - Giant cell arteritis ~~OR~~ - Systemic sclerosis-associated lung disease ~~then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ~~If diagnosis "other" does patient have a contraindication to Humira?~~ ~~If yes and if moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ~~If yes and If giant cell arteritis OR systemic sclerosis-associated lung disease then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ~~Patient has not tried Humira AND less than 18 years of age but greater than 2 years of age~~ - Patient has systemic Juvenile Idiopathic Arthritis (sJIA)

Appendix C—Table of Prior Authorization (PA) Criteria

	~~• Patient has evidence of negative TB test result in the past 12 months or TB is adequately managed~~ • Patient is not receiving other targeted immunomodulatory biologics with tocilizumab Non-FDA approved uses are NOT approved, except as noted above. PA does not expire
mirabegron (Myrbetriq) Overactive Bladder Agents: Beta-3 Adrenergic Agonists	Updates from the August 2024 meeting are in bold. Manual PA criteria applies to new and current users of mirabegron generic at all points of service <u>Manual PA criteria</u> – mirabegron generics are approved if all criteria are met: The following will be added to the existing PA criteria • Provider acknowledges that the brand Myrbetriq tablet is the preferred product over generic mirabegron 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 Myrbetriq is a branded product, it will be covered at the generic formulary copayment or cost share) • Please provide a patient-specific justification as to why the brand Myrbetriq cannot be used in this patient. _____ (fill-in the blank). ▪ Reasons to allow the generic mirabegron would be the patient has had an adverse reaction to an excipient in brand Myrbetriq that would not be likely to occur with the generic mirabegron
sofosbuvir/velpatasvir (Epclusa) Hepatitis C Agents: Direct Acting Antivirals	Updates from the August 2024 meeting are in bold and strikethrough. PA criteria: Epclusa is approved if all criteria are met:*Note: The branded agent on the top of this form is the preferred agent for TRICARE. If the authorized generic of Epclusa is required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. Note: Mavyret does not require prior authorization <u>Automated PA Criteria:</u> When prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved. Manual PA Criteria: If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met: ~~• Patient is 3 years of age or older~~ ~~• Patient has laboratory evidence of chronic HCV~~ ~~• What is the HCV genotype~~ • If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR • If the prescriber ~~physician~~ is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician ~~or and if the drug is prescribed in consultation with a specialist~~, then continue with the questions below. ~~• Prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician OR~~ • Patient has a detectable hepatitis C viral load AND ▪ Patient is not cirrhotic OR ▪ Patient is cirrhotic with non-genotype 3 hepatitis c virus (HCV) infection OR ▪ Patient is cirrhotic with genotype 3 HCV infection and the prescription is prescribed by or in consultation with a gastroenterologist,

Appendix C—Table of Prior Authorization (PA) Criteria

	hepatologist, infectious disease physician, or a liver transplant physician Non-FDA-approved uses are not approved. Prior authorization ~~does not expire~~ expires in 1 year. PA must be resubmitted.
- ledipasvir/sofosbuvir (Harvoni) - elbasvir/grazoprevir (Zepatier) Hepatitis C Agents: Direct Acting Antivirals	Updates from the August 2024 meeting are in bold and strikethrough. PA criteria: PA is approved if all criteria are met: *Note: The branded Harvoni on the top of this form is the preferred ledipasvir/sofosbuvir for TRICARE. If the authorized generics of Harvoni is required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. Note: Mavyret does not require prior authorization Automated PA Criteria: When prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved. Manual PA Criteria: If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met: ~~• Patient is 3 years of age or older (Harvoni) or 12 Years of age and older or weighing at least 30 kg (Zepatier)~~ ~~• Patient has laboratory evidence of chronic HCV~~ ~~• What is the HCV genotype?~~ • If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR • If the prescriber ~~physician~~ is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician ~~or~~ and if the drug is prescribed in consultation with a specialist, then continue with the questions below. • Patient has a detectable hepatitis C viral load AND ▪ For Harvoni, patient has genotype 1, 4, 5, or 6 hepatitis C virus (HCV) infection OR ▪ For Zepatier, patient has genotype 1 or 4 HCV infection Non-FDA-approved uses are not approved Prior authorization ~~does not expire~~ expires in 1 year. PA must be resubmitted.
- sofosbuvir (Sovaldi) - sofosbuvir/velpatasvir/voxilaprevir (Vosevi) Hepatitis C Agents: Direct Acting Antivirals	Updates from the August 2024 meeting are in bold and strikethrough. PA criteria: PA is approved if all criteria are met. Note: Mavyret does not require prior authorization Automated PA Criteria: When prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved. Manual PA Criteria: If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met: ~~• Patient is 3 years of age or older (Sovaldi) or 18 Years of age and older (Vosevi)~~ ~~• Patient has laboratory evidence of chronic HCV~~ ~~• What is the HCV genotype?~~ • If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR • If the prescriber ~~physician~~ is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician ~~or~~ and if the drug is

Appendix C—Table of Prior Authorization (PA) Criteria

	prescribed in consultation with a specialist, then continue with the questions below. • Patient has a detectable hepatitis C viral load AND • ~~The patient does not have an estimated glomerular filtration rate (eGFR) $\leq$ 30 mL/min or end-stage renal disease (ESRD) requiring hemodialysis~~ • ~~The patient will not be receiving concomitant therapy with other hepatitis C drugs or rifampin~~ • ~~The treatment course will not exceed the maximum duration of treatment of 12 weeks~~ • ~~Patient was previously treated with an~~ Medication is for retreatment of hepatitis C virus (HCV) that has failed treatment with a regimen containing an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir). OR • ~~Patient has previously been treated with an~~ Medication is for retreatment of hepatitis C virus (HCV) that has failed treatment with a regimen containing sofosbuvir with or without an NS5A inhibitor (for example, daclatasvir, elbasvir, ledipasvir, ombitasvir, pibrentasvir, or velpatasvir). Non-FDA-approved uses are not approved Prior authorization ~~does not expire~~ expires in 1 year. PA must be resubmitted.
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Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
acalabrutinib (Calquence) Leukemia and Lymphoma Agents: BTK Inhibitors	Note: no changes to current status - MTF/TMOP: maximum of 180 capsules for a 45 day supply - Retail: maximum of 120 capsules for a 30 day supply
ibrutinib (Imbruvica) Leukemia and Lymphoma Agents: BTK Inhibitors	Note: no changes to current status - Tablets - MTF/TMOP: maximum of 56 tablets for a 56 day supply - Retail: maximum of 28 tablets for a 28 day supply - Oral suspension - Mail/MTF: 6 bottles/fill - Retail: 3 bottles/fill for a 60 day supply
pirtobrutinib (Jaypirca) Leukemia and Lymphoma Agents: BTK Inhibitors	Note: no changes to current status MTF/TMOP/Retail: 60 day supply
zanubrutinib (Brukinsa) Leukemia and Lymphoma Agents: BTK Inhibitors	Note: no changes to current status - MTF/TMOP: 60 day supply - Retail: 30 day supply
adalimumab-ryvk (Simlandi) TIBS: Tumor Necrosis Factor Inhibitors	Retail/MTF/TMOP: 60-day supply
danicopan (Voydeya) Hematological Agents	Retail/MTF/TMOP: 60-day supply
diazepam (Libervant) Anticonvulsants-Antimania Agents	- MTF/TMOP: 15 cartons/3 months - Retail: 5 cartons/month
elafibranor (Iqirvo) GI-2 Agents	Retail/MTF/TMOP: 60-day supply
givinostat (Duvyzat) Corticosteroids-Immune Modulators	Retail/MTF/TMOP: 30-day supply
macitentan/tadalafil (Opsynvi) Pulmonary Arterial Hypertension Agents	Retail/MTF/TMOP: 60-day supply

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

Drug / Drug Class	Quantity Limits
mavoxixafor (Xolremdi) Hematological Agents	Retail/MTF/TMOP: 60-day supply
naloxone (Rextovy) Alcohol Deterrents – Narcotic Antagonists: Narcotic Antagonists	Retail/MTF/TMOP: 2 cartons/fill
resmetirom (Rezdiffra) GI-2 Agents	Retail/MTF/TMOP: 60-day supply
sotatercept-csrk (Winrevair) Pulmonary Arterial Hypertension Agents	Retail/MTF/TMOP: 60-day supply
spesolimab-sbzo (Spevigo) TIBS: Interleukins Miscellaneous	Retail/MTF/TMOP: 60-day supply
tocilizumab-aazg (Tyenne) TIBS: Non-Tumor Necrosis Factor Inhibitors	Retail/MTF/TMOP: 60-day supply
tovorafenib (Ojemda) Oncological Agents	Retail/MTF/TMOP: 60-day supply
(glecaprevir/pibrentasvir) Mavyret Hepatitis C Agents: Direct Acting Antivirals	Retail/MTF/TMOP: up to 56-day supply
- sofosbuvir/velpatasvir (Epclusa) - ledipasvir/sofosbuvir (Harvoni) - elbasvir/grazoprevir (Zepatier) - sofosbuvir (Sovaldi) - sofosbuvir/velpatasvir/voxilaprevir (Vosevi) Hepatitis C Agents: Direct Acting Antivirals	Retail/MTF/TMOP: up to 84-day supply

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 (Cordavis brand of Humira) TIBs: Tumor Necrosis Factor Inhibitors	- adalimumab (Humira) - Other adalimumab biosimilars	- Prefilled pen: 40 mg/0.8 mL - Prefilled syr.: 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL, 80 mg/0.8 mL - Dosing: varies based on indication	- rheumatoid arthritis - juvenile idiopathic arthritis - arthritis - psoriatic arthritis - ankylosing spondylitis - adult Crohn's disease - ulcerative colitis - plaque psoriasis - hidradenitis suppurativa - uveitis	ADRs (>10%): - infection (e.g., upper respiratory, sinusitis) - injection site reactions - headache - rash	- AbbVie entered agreement to supply Cordavis with co-branded Humira - No new clinical data - CVS Health launched subsidiary named Cordavis to work with manufacturers to commercialize and/or co-produce biosimilar products - Provides no compelling clinical advantage over existing agents	- Completely Excluded - Interim PA
adalimumab-ryvk (Simlandi) TIBs: Tumor Necrosis Factor Inhibitors	- adalimumab (Humira) - Other adalimumab biosimilars	- Autoinjector: 40 mg/0.4 mL - Dosing: varies based on indication	- rheumatoid arthritis - juvenile idiopathic arthritis - arthritis - psoriatic arthritis - ankylosing spondylitis - adult Crohn's disease - ulcerative colitis - plaque psoriasis - hidradenitis suppurativa - uveitis	ADRs (>10%): - infection (e.g., upper respiratory, sinusitis) - injection site reactions - headache - rash	- Simlandi only comes in a high concentration formulation that is interchangeable with the reference product - This formulation is citrate free and latex free - No new clinical data - Provides no compelling clinical advantage over existing agents	- NF, non-step-preferred - PA - MN - QL - TRICARE Maintenance Drug List
danicopan (Voydeya) Hematological Agents	- iptacopan - pegcetacoplan - eculizumab (med benefit) - ravulizumab (med benefit)	- Tablet: 100mg, 150mg - Dosing: 150 mg to 200 mg PO TID	Add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH)	ADR ($\geq$10%) headache	- Oral complement Factor D inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) that controls extravascular hemolysis and intravascular hemolysis; when used with Soliris or Ultomiris as add-on therapy - Voydeya controls C3 mediated extravascular hemolysis whereas Soliris and Ultomiris are complement C5 inhibitors that only inhibit terminal complement-mediated intravascular hemolysis in patients with PNH - Fabhalta and Empaveli both control both C3b-mediated extravascular hemolysis and terminal complement-mediated intravascular hemolysis	- NF - PA - MN - QL - TRICARE Maintenance Drug 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
					- Voydeya is add-on therapy while Fabhalta and Empaveli are monotherapy - Phase 3 study demonstrated Voydeya plus Soliris or Ultomiris to be superior to placebo plus Soliris or Ultomiris in increasing the hemoglobin level from baseline to Week 12 - No head-to-head study versus monotherapy agents (i.e., Empaveli or Fabhalta) - Provides an add-on option to Soliris or Ultomiris for extravascular and intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)	
diazepam (Libervant) Anticonvulsant – Antimania Agents	- Diastat (generic) - Valtoco	- Film - Buccal: 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg - Dosing: weight based dosing	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age	ADR ($\geq 4\%$) - headache - somnolence	- Another formulation of diazepam for acute treatment of intermittent, stereotypic episodes of frequent seizure activity in patients with epilepsy 2 to 5 years of age - Libervant was FDA approved through the 505(b)(2) pathway, no new clinical data - Other diazepam formulations for this indication include a rectal gel and a nasal spray - Provides a buccal rescue option for seizure disorders	- UF - QL
elafibranor (Iqirvo) Gastrointestinal-2 Agents	- urso-deoxycholic acid - obeticholic acid - benzfibrate	- Tablet: 80 mg - Dosing: 80 mg PO QD w/wo food	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA	ADR (5%) - weight gain - diarrhea - abdominal pain - nausea - vomiting - arthralgia - constipation - muscle injury - fracture - GERD - dry mouth - weight loss - rash	- Iqirvo is a peroxisome proliferator-activated receptor (PPAR) agonist approved for the adult treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) for those with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA - A single phase 3 study demonstrated a statistically significant achievement in desired biochemical response in patients treated with Iqirvo compared to placebo - Accelerated approved is based on reduction of alkaline phosphatase - Currently lacking long-term data on survival or prevention or liver transplant	- UF - PA - QL - TRICARE Maintenance Drug 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
					Provides an additional pharmacologic treatment option for adults with this progressive rare disease	
givinostat (Duvyzat) Corticosteroids-Immune Modulators	- prednisone - deflazacort - vamorolone	- Oral susp: 8.86 mg/ml - Dosing: based on body weight PO BID with food	Treatment of Duchenne Muscular Dystrophy (DMD) in patients 6 years of age and older	ADR (≥10%) - nausea - vomiting - diarrhea - abdominal pain - thrombocytopenia - elevated triglyceride - pyrexia	- Duvyzat is histone deacetylase inhibitor approved for the treatment of Duchenne Muscular Dystrophy (DMD) in patients 6 years of age and older. - A single phase 3 study demonstrated statistically significant less decline in the 4-stair climb time at 18 months in patients treated with Duvyzat compared with placebo. - Clinical significance of this primary outcome and its therapeutic benefit on long term DMD disease progression is currently unclear - Provides another treatment option for this rare disorder	- NF - PA - MN - QL - TRICARE Maintenance Drug List
macitentan/ tadalafil (Opsynvi) Pulmonary Arterial Hypertension Agents	- Opsumit 10mg and tadalafil 20mg - ambrisentan - Adempas, - Upravi	- Film: 10 mg–20 mg 10 mg–40 mg - Dosing: 10 mg-20 mg QD w/wo food	Chronic treatment of pulmonary arterial hypertension (PAH, WHO Group 1) in adult patients of WHO functional class (FC) II-III	ADR (≥10%) - edema/ fluid retention (21%) - anemia (19%) - headache/ migraine (18%)	- First fixed-dose combination product for PAH comprised of a PDE-5 inhibitor (tadalafil – available as a generic) with an endothelin receptor agonist (macitentan (Opsumit) – patent expiration in Dec 2025) - Phase 3 study demonstrated that combination therapy achieved a higher treatment effect compared to each individual agent alone: no head-to-head trials with any other PAH drug - Only surrogate outcomes available (reduction in pulmonary vascular resistance); no data available that shows the fixed dose combination reduces clinical outcomes (e.g., mortality) - Other than the convenience of reducing tablet burden, provides no compelling clinical advantage over current PAH drug on the formulary	- NF - PA - MN - QL - TRICARE Maintenance Drug 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
mavorixafor (Xolremdi) Hematological Agents	n/a	- Capsule: 100 mg - Dosing: based on body weight PO daily	Patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes	ADR ($\geq 10\%$) - thrombocytopenia - pityriasis - rash - rhinitis - epistaxis - vomiting - dizziness	- FDA-approved to treat WHIM syndrome, which is a rare immunodeficiency disorder - Phase 3 study demonstrated favorable effectiveness over placebo in increasing ANC from baseline - Provides an alternative option to supportive care to treat WHIM syndrome	- UF - PA - QL - TRICARE Maintenance Drug List
Mycophenolate mofetil (Myhibbin) Immuno-suppressive	generic mycophenolate suspension	- Oral Susp: 200 mg/ml - Dosing: adult: 1 to 1.5 gm PO BID ped: 600 mg/m² to 900 mg/m² PO BID. Max dose: kidney transplant: 2 g/day for heart/liver transplant: 3 g/day	Prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants	ADR ($\geq 20\%$) - diarrhea - leukopenia - infection - vomiting - higher frequency of certain types of infections	- Another oral solution formulation of mycophenolate mofetil that is ready to use versus generic formulation that must be reconstituted by the pharmacist - CellCept is available generically and available as capsules, tablets, oral suspension and SDV for IV use - Shares same boxed warning as CellCept and Myfortic - Myhibbin and CellCept cannot be used interchangeably with Myfortic DR tablets without physician supervision - No new clinical data - Provides no compelling clinical advantage over existing agents	UF
naloxone (Rextovy) Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists	- Opvee - Narcan - Zimhi - Kloxxado - generic naloxone nasal sprays	- Nasal spray: 4 mg - Dosing: single spray intranasally. May repeat q2-5 minutes as needed	An opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and pediatric patients	ADR ($\geq 3\%$) - oral paresthesia - headache	- Another intranasal formulation of the opioid antagonist, naloxone, for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and pediatric patients - No new clinical studies - Provides no compelling clinical advantage over existing agents	- UF - QL - Tier 1 Co-pay

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
resmetirom (Rezdiffra) Gastrointestinal- 2 Agents	- Ocaliva - Wegovy - Zepbound	- Tablets: 60 mg 80 mg 100 mg - Dosing: varies based on actual body weight	Treatment of adults with noncirrhotic nonalcoholic steatohepatitis with moderate to advanced liver fibrosis	ADRs (>5%) - diarrhea - nausea - pruritus - vomiting - constipation - abdominal pain - dizziness	- First agent approved with diet and exercise for the treatment of non-cirrhotic NASH with moderate to advanced fibrosis in adults - Phase 3 study demonstrated significantly more patients with NASH with moderate to advanced fibrosis receiving Rezdiffra vs. placebo met at least one of the dual primary endpoints at Week 52 - MAESTRO-NAFLD-OLE study aims to determine long term efficacy and safety following additional 52-weeks of open label study - Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial - Provides an option for non-cirrhotic NASH with moderate to advanced fibrosis in adults	- UF - PA - QL - TRICARE Maintenance Drug List
sitagliptin/metformin (Zituvimet AG) Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	- Janumet - Janumet XR - Kazano - Jentadueto - Kombiglyze XR	- Tablet: 50-1000 mg 50-500 mg - Dosing: 1 tab daily w/food	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	ADRs ($\geq$5%) - diarrhea - upper respiratory tract infection - headache	- Another formulation of sitagliptin and metformin - No new clinical studies; approved via 505(b)(2) - Provides no compelling clinical advantage over existing agents	- NF, non-step-preferred - PA - MN
sotatercept-csrk (Winrevair) Pulmonary Arterial Hypertension Agents	- tadalafil - Opsumit - Ambrisentan - Adempas, - Upravi	- Single dose vial: 45 mg 60 mg - Dosing: Starting dose 0.3 mg/kg SC with target dose 0.7 mg/kg SC Q3W	Treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events	ADRs ($\geq$10%) - headache - epistaxis - rash - telangiectasia - diarrhea - dizziness - erythema	- PAH therapy with a new mechanism of action that targets the imbalance between pro-proliferative and antiproliferative signaling to regulate vascular proliferation - The STELLAR trial showed addition of Winrevair to background PAH therapy significantly improved exercise capacity (by showing a clinically relevant increase in 6MWD) and WHO functional class - Secondary endpoint showed a reduction in the composite risk of death or clinical worsening for patients with WHO Group 1 PAH receiving	- UF - PA - QL - TRICARE Maintenance Drug 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
					background PAH therapies, but the trial was not powered to address mortality • May be self-administered after appropriate training (SC injection q 21 days); considerable monitoring is required for the first 5 doses due to the potential for decreased Hgb and platelet counts • Mild bleeding and telangiectasias are additional adverse events with Winrevair that are not reported with other PAH therapies • Winrevair is not yet addressed in PAH clinical practice guidelines • Winrevair will likely be used as an add-on to dual PAH therapy in patients who are experiencing a suboptimal response or disease progression • Long-term data are needed to show durability of effect	
• spesolimab-sbzo (Spevigo) TIBs: Non-TNFs	• adalimumab (Humira) • secukinumab (Cosentyx)	• Prefilled syr.: 150 mg/ml • Dosing: loading dose of 600 mg followed by 300 mg SC every 4 weeks	• Treatment of general pustular psoriasis (GPP) in adult and pediatric 12 years of age and older and weighing at least 40 kg	ADRs ($\geq 9\%$): • injection site reaction • urinary tract infection • arthralgia • pruritus	• Spevigo SC is the first medication FDA approved for the treatment of generalized pustular psoriasis when not experiencing a flare • Spevigo IV is approved for treatment of generalized pustular psoriasis flares • Phase 2b study demonstrated moderate improvement with FDA approved dose of Spevigo SC vs. placebo for the primary endpoint of time to generalized pustular psoriasis flare • There is an ongoing 5-year open label extension trial which will further explore the long-term efficacy and safety of Spevigo • Spevigo is associated with the risk of infection and infusion-related reactions • Non-biologics and biologics previously used off-label in USA, several biologics approved in other countries, overall data limited • Provides an option for a rare, potentially life-threatening disorder	• NF non-step-preferred • PA • MN • QL • TRICARE Maintenance Drug 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
tocilizumab-aazg (Tyenne) TIB: Non-Tumor Necrosis Factor Inhibitors	- Actemra - Kineret - Humira - Kevzara	- Prefilled syr.: 162 mg/0.9 mL - Dosing: 162 mg SC QW or Q2W or Q3W depending on diagnosis and weight	Actemra biosimilar	ADRs ($\geq 5\%$): - URI - nasopharyngitis - headache - HTN - increased ALT - injection site reactions	2nd biosimilar of Actemra and is available as intravenous and subcutaneous formulations - First biosimilar formulation for the subcutaneous pharmacy benefit - No new clinical data - Actemra has an extra SC indication for slow rate of decline in pulmonary function in adult patients with SSc-ILD, however, this can be extrapolated to Tyenne - Tyenne and Actemra are both available in pre-filled syringes and pre-filled autoinjectors - Provides no compelling clinical advantage over existing agents	- UF, non-step-preferred - PA - QL - TRICARE Maintenance Drug List
tovorafenib (Ojemda) Oncological	Tafinlar and Mekinist	- Tablets: 100 mg - Oral Susp: 25 mg/ml - Dosing: 380 mg/m² based on BSA PO QW	Treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement or BRAF V600 mutation	ADRs ($\geq 30\%$): - rash - hair color changes - fatigue - viral infection - vomiting - headache - hemorrhage - pyrexia - dry skin - constipation - nausea - dermatitis acneiform - URI	- Sole agent FDA-approved for the treatment of patients with relapsed or refractory pediatric LGG, harboring a BRAF fusion or rearrangement or a BRAF V600 mutation - Phase 2 single arm study demonstrated ORR of 51% when Ojemda was used as a third- or fourth-line systemic therapy - Tafinlar + Mekinist are FDA-approved for BRAF V600E mutation-positive LGG only - Guidelines do not yet address Ojemda's role in therapy - Ongoing study assessing use as first line therapy for LGG - Provides an option for relapsed or refractory pediatric LGG, harboring a BRAF fusion or rearrangement or a BRAF V600 mutation	- UF - PA - QL - TRICARE Maintenance Drug List

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Maintenance Drug List 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 TRICARE Maintenance Drug List (if Formulary, Add to Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add to Program; if NF, Exempted from TMOP Requirement)
August 2024	Drug Class Reviews Antilipidemics-1 Designated NF <i>Retain on the TRICARE Maintenance Drug List - no reason to exempt from NF requirement</i> - atorvastatin oral suspension (Atorvaliq) - lovastatin extended release (Altoprev) - pitavastatin magnesium (Zypitamag) - rosuvastatin sprinkle (Ezallor) - simvastatin suspension (Flolipid)	Drug Class Reviews Antilipidemics-1 Designated UF <i>Remove/do not add to the TRICARE Maintenance Drug List - not cost advantageous to government</i> - simvastatin/ezetimibe (Vytorin, generic) - fluvastatin extended release (Lescol XL, generic) - bempedoic acid (Nexletol) - bempedoic acid/ezetimibe (Nexlizet) Designated NF <i>Exempt from NF requirement/remove from TRICARE Maintenance Drug List (not cost advantageous to government)</i> - pitavastatin calcium (Livalo, generics) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Do not add to the TRICARE Maintenance Drug List – not available at mail</i> - mycophenolate mofetil suspension (Myhibbin) <i>Do not add to the TRICARE Maintenance Drug List – acute use</i> - diazepam buccal film (Libervant) - naloxone nasal spray (Rextovy) Designated NF <i>Exempt from NF requirement (not cost advantageous to government)</i> - sitagliptin/metformin (Zituvimet authorized generic)

* 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 TMOP. Medications subject to EMMPI program requirements are listed on the TRICARE Maintenance Drug List.

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add to Program; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add to Program; if NF, Exempted from TMOP Requirement)
August 2024	Drug Class Reviews Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase Inhibitors (BTKIs) <i>Designated UF</i> • acalabrutinib (Calquence) • ibrutinib (Imbruvica) • pirtobrutinib (Jaypirca) • zanubrutinib (Brukinsa) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) <i>Designated UF</i> • elafibranor (Iqirvo) • mavorixafor (Xolremdi) • resmetirom (Rezdiffra) • sotatercept-csrk (Winrevair) • tocilizumab-aazg (Tyenne) • tovorafenib (Ojemda) <i>Designated NF</i> <i>No reason to exempt from NF-2-Mail requirement</i> • adalimumab-ryvk (Simlandi) • danicopan (Voydeya) • givinostat (Duvyzat) • macitentan/tadalafil (Opsynvi) • spesolimab-sbzo syringe (Spevigo)	None

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: October 28, 2024

Two weeks after signing: November 13, 2024

30 days after Signing: November 27, 2024

60 days after signing: January 8, 2025

90 days after signing: January 29, 2025

120 days after signing: February 26, 2025

*** 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	Completely Excluded Products	Formulary Alternatives	Implementation
August 2024	TIBs:	adalimumab Cordavis brand of Humira	other adalimumab biosimilars	2 weeks

*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 TMOP 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 [health.mil](https://www.health.mil) website.

**DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE**

**MINUTES AND RECOMMENDATIONS
November 2024**

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on November 6th and 7th, 2024.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of August 2024 Minutes—RDML Matthew Case, Acting Assistant Director, Health Care Administration DHA, approved the minutes from the August 2024 DoD P&T Committee meeting on October 28th, 2024.

B. Clarification of previous meeting minutes

- **May 2024**
 - **Implementation Plan for 60-days after signing recommendations:** The 60-days after signing implementation date occurred on October 2nd, 2024.
- **August 2024**
 - **Newly Approved Drug—Humira by Cordavis implementation plan:** The adalimumab (Humira) formulation by Cordavis was recommended for Complete Exclusion status. Due to the low numbers of patients currently receiving this formulation, the implementation will occur two weeks after signing of the August minutes, rather than the usual 120 days. Beneficiary notification will occur soon thereafter.
 - **Antilipidemic 1's—Statin and Non-Statins:** Fluvastatin ER (Lescol XL) is moving from nonformulary to uniform formulary status, so the current medical necessity criteria will be removed.

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 TRICARE Mail Order Pharmacy (TMOP) in accordance with 10 USC 1074g (a)(5) and 32 CFR 199.21(h)(3)(i) and (ii).

Additionally, 10 USC 1074g (a)(9), added by Section 702(c)(2) of the NDAA for FY 2015 requires beneficiaries generally fill select non-generic prescription maintenance medications at MTFs or the TMOP. Medications subject to either the NF or select non-generic prescription maintenance requirements are added to the TRICARE Maintenance Drug List.

IV. UF DRUG CLASS REVIEWS

A. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-17 and IL-23 Inhibitors Subclasses

Background—The Targeted Immunomodulatory Biologics (TIBs) class is comprised of several subclasses, including the tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab [Humira]) non-TNF inhibitors, and miscellaneous interleukin subclasses. The TIBs class was last reviewed at the August 2014 P&T Committee meeting and branded Humira is currently step-preferred for most indications. Since the original review, 17 new drugs with multiple new mechanisms of action have entered the market. These newer agents have strong clinical evidence in specific disease states.

Biosimilar entrants are on the horizon for ustekinumab (Stelara) and secukinumab (Cosentyx), with more products expected in the future. The advent of biosimilars is expected to reshape treatment options and create opportunities to participate in a Joint National Contract (JNC) with other Federal partners to align formularies for continuity of care and produce cost avoidance. Therefore, to support the growing complexity of the TIBs class, two additional subclasses were created based on mechanism of action, the Interleukin-17 inhibitors (IL-17s) and Interleukin-23 inhibitors (IL-23s).

The drugs in the subclass include the following:

- IL-17s: bimekizumab (Bimzelx), brodalumab (Siliq), ixekizumab (Taltz) and secukinumab (Cosentyx)
- IL-23s guselkumab (Tremfya), mirikizumab (Omvoh), risankizumab (Skyrizi), tildrakizumab (Ilumya), and ustekinumab (Stelara)

Relative Clinical Effectiveness Conclusion— The clinical review focused on clinical practice guidelines, systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Interleukin-17 Agents

- **bimekizumab (Bimzelx)** is indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and non-radiographic ankylosing spondyloarthritis in adult patients. Approval for hidradenitis suppurativa (HS) is expected imminently. (*Note following the meeting the Bimzelx label was expanded for HS on November 19, 2024*). Limitations include

lack of approval for children and adverse effects of liver abnormalities, suicidal ideation (although no risk evaluation and mitigation strategy (REMS) program is required) and oral candidiasis.

- **brodalumab (Siliq)** is solely indicated for plaque psoriasis in adults who have failed other systemic therapy. Other limitations include the requirement for a REMS program due to risk of suicidal ideation and behavior.
- **ixekizumab (Taltz)** is indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and non-radiographic ankylosing spondyloarthritis. Advantages include approval for both adults and pediatric patients as young as six years old. Taltz is associated with a higher incidence of injection site reactions compared to other products.
- **secukinumab (Cosentyx)** is indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, non-radiographic ankylosing spondyloarthritis, enthesitis-related arthritis, and hidradenitis suppurativa. Advantages include approval for both adult and pediatric patients as young as two years old. Unique adverse reactions include risk of eczematous eruptions.
 - *Biosimilars:* Based on patent expiration, secukinumab will likely have the first IL-17 biosimilar.

Interleukin-23 Agents

- **ustekinumab (Stelara)** is indicated for plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease. Its mechanism of action includes both IL-23 and IL-12 inhibition. Advantages include approval for both adults and pediatric patients as young as six years old. Stelara is well accepted for use in pregnant women. Unique safety concerns include risk of non-infectious pneumonia and posterior reversible encephalopathy syndrome (PRES) and infections related to inhibition of IL-12.
 - *Biosimilars:* There are five FDA-approved Stelara biosimilars (Wezlana, Selarsdi, Pyzchiva, Otulfi, and Imuldosa), but market launch will not occur until 2025. Current evidence shows that the biosimilars are therapeutically equivalent with their reference products, allowing for a high degree of therapeutic interchangeability. (Refer to the November 2022 and August 2024 DoD P&T Committee meeting minutes for the "Process for Evaluating Biosimilars and Biologics").
- **guselkumab (Tremfya)** is indicated for plaque psoriasis, psoriatic arthritis, and ulcerative colitis in adults. The manufacturer of Tremfya is seeking approval for Crohn's disease.
- **tildrakizumab (Ilumya)** has only one indication, plaque psoriasis in adults.

- **risankizumab (Skyrizi)** is indicated for plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease in adult patients. It is available as a prefilled pen, prefilled syringe, and prefilled cartridge for use in an on-body injector (OBI). The OBI is only approved for Crohn's disease and ulcerative colitis. In patients with inflammatory bowel disease (IBD), there is an associated risk of hepatotoxicity.
- **mirikizumab (Omvo)** is indicated for ulcerative colitis in adults. The manufacturer of Omvo is seeking approval for Crohn's disease. For safety, hepatotoxicity is a concern.

Plaque Psoriasis (IL-17s and IL-23s)

- All agents approved for plaque psoriasis are equally recommended in the U.S. (American Academy of Dermatology) and European (European Dermatology Forum) guidelines.
- A 2023 Cochrane Review reported for efficacy the IL-17s provided the most robust class response, followed by the IL-23s, TNF inhibitors, and then oral small molecules (e.g., apremilast [Otezla]). In terms of reaching Psoriasis Area Sensitivity Index (PASI) 90 scores, Taltz, Skyrizi, Bimzelx and the TNF-inhibitor infliximab (Remicade) were tied for best response. For safety, there was no overall difference in serious adverse events. For any adverse event, there was a slight preference for IL-23s over IL-17s.
- In terms of clinical coverage, due to REMS requirements Siliq is not recommended as a step preferred agent due to safety concerns, and Ilumya and Siliq are limited by approval solely for plaque psoriasis. For the remaining IL-17 and IL-23 agents, there is no clear reason to prefer one over another in terms of safety or efficacy for plaque psoriasis.

Psoriatic Arthritis (IL-17s and IL-23s)

- Various guidelines for psoriatic arthritis recommend TNF-inhibitors, IL-23s and IL-17s as first-line.
- A 2024 Network Meta-analysis concluded Cosentyx and Taltz were the treatments with highest probability of reaching both PASI100 and American College of Rheumatology Score (ACR)70 for skin and peripheral arthritis.
- Overall, the drug choice is based on concurrent disease states. An IL-17 is recommended for disease manifestations that are difficult to treat (e.g., fingernails).

Spondyloarthritis (IL-17s)

- Guidelines from the European League Against Rheumatism (EULAR) recommend NSAIDs as first-line therapy. A biologic can be considered after failure of high-dose NSAIDs.
- A published matching-adjusted indirect comparison of the individual clinical trials for Cosentyx, Taltz and Bimzelx for ankylosing spondylitis did not show compelling differences in endpoints between these three drugs.

Inflammatory Bowel Disease – Crohn’s Disease (IL-23s)

- Guidelines recommend considering use of biologics early in the disease course. Failure of non-biologics (e.g., 5-aminosalicylates, low-dose oral methotrexate) should not be required before a biologic.
- Guideline-recommend therapies include the TNF inhibitors, vedolizumab (Entyvio) which is an integrin receptor antagonist initiated as an IV infusion, IL-23s and Janus kinase (JAK) inhibitors (e.g., upadacitinib [Rinvoq]).
- When compared in a head-to-head, Skyrizi and Stelara were comparable for week 24 clinical remission although Skyrizi performed better at week 48 endoscopic remission. A head-to-head trial between Stelara and Humira did not show a statistically significant difference in clinical remission at 52 weeks.

Inflammatory Bowel Disease – Ulcerative Colitis (IL-23s)

- Non-biologics still maintain a role in ulcerative colitis treatment per most guidelines.
- The TNF inhibitors, Stelara, Entyvio, and JAK inhibitors are recommended per guidelines. Stelara is currently recommended per the guidelines, other IL-23s are not discussed.
- Clinical trial data is available with Stelara, Skyrizi, Tremfya and Omvoh. No head-to-head trials are available to influence decision-making as to comparative efficacy and safety among the IL-23s.
- *Note that following the November P&T meeting updated ulcerative colitis guidelines were published and will be reviewed at a future meeting.*

Safety

- Published clinical practice guidelines do not make a distinction among individual IL-17 or IL-23 agents in terms of safety.
- Noted adverse events for all the products include hypersensitivity risk, increased risk of infections including tuberculosis, and warnings against concurrent use of live vaccines. Unique safety concerns were discussed above with the individual product summaries.
- A systematic review and meta-analysis of the adverse events with IL-17 and IL-23 inhibitors in plaque psoriasis and psoriatic arthritis found the following:
 - The most common adverse drug reactions across all therapies included infections, nasopharyngitis, and headaches.
 - In long-term (52 week) treatment trials, Taltz and Skyrizi had the lowest frequency of serious adverse events.
 - The proportion of patients with any adverse event was lower with the IL-23 inhibitors compared with IL-17 inhibitors
 - Overall, both classes appear well-tolerated with good safety profiles.

Other Factors

- Special populations:
 - Stelara has supported safety in the pregnancy population. There is no compelling evidence that alternative IL-17s or IL-23s should be preferred over another during pregnancy. TNF inhibitors are also considered safe and effective in pregnancy.
 - Pediatric patients are directed to secukinumab (Cosentyx), ixekizumab (Taltz), or ustekinumab (Stelara), based on FDA-labeling.
- Provider opinion:
 - Military Health System (MHS) dermatologists voiced that for plaque psoriasis the IL-17s and IL-23s are superior to Humira and have a quicker onset of action. They also stated a preference for Taltz and Skyrizi.
 - MHS gastroenterologists stated that for the IL-23s for Crohn's disease and ulcerative colitis Stelara is the first-choice due to current formulary status and cost, and that Skyrizi is reserved for cases of Stelara failure.
 - MHS rheumatologists relayed that Humira still has a place in the algorithm, and will have continued use, even if the step-preference is removed. They also recommended adding Taltz to the formulary. However, they recommend that patients well-controlled on Cosentyx should not be moved to Taltz.

Overall Conclusion

- Based on FDA indication and published guidelines it is reasonable to require a trial of Humira first for many immune-mediated diseases including plaque psoriasis. Network meta-analysis and provider preference recommend IL-17s or IL-23s as first-line treatment for plaque psoriasis.
- Biosimilars are interchangeable to the reference product. Market launch of Stelara biosimilars in 2025 provides an opportunity for contracting initiatives with other Federal agencies via a JNC.
- Within the two subclasses, when the agents are compared to one another, there do not appear to be overall compelling differences in efficacy and safety. Individual patients may show differences in response to individual agents.
- Provider feedback overwhelmingly supported increasing accessibility to the IL-23 and IL-17 agents.
- For clinical coverage, at least one IL-17 and one IL-23 are needed on the formulary to meet the needs of MHS beneficiaries. Additional options should

be considered to provide additional choices for providers based on individual patient characteristics.

Relative Cost Effectiveness Analysis and Conclusion—The 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 (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Interleukin-17s

- CMA results showed that the formulary placement of ixekizumab (Taltz) as UF and step-preferred was cost-effective.
- BIA and sensitivity results showed that overall expenditures would increase, however, designating Taltz as step-preferred and all the other IL-17s as non-step-preferred would generate potential cost avoidance in the future as new patients transition over to Taltz.

Interleukin-23s

- CMA showed that leaving space open on the formulary to select a UF and step-preferred IL-23 via a future JNC could lead to increased long-term use of a cost-effective agent. Potential cost avoidance of anticipated biosimilar entrants to Stelara in 2025 were discussed.
- All BIA scenarios demonstrated elevated expenditures regardless of formulary status. However, as other biosimilars come on the market, designating cost effective agents as step-preferred may offer expenditure relief. Additionally, for the IL-23s, a JNC opportunity in 2025 may provide cost effective biosimilars to ustekinumab.
- The P&T Committee recognized that there is increasing expenditures for the class as new therapies emerge. While TNF inhibitors continue to remain a guideline-recommended therapy, improving the patient experience with increased access to drugs with multiple mechanisms of action, longer dosing intervals, and alternative side effect profiles over traditional TNF-inhibitors was supported by the collective professional judgement of the P&T Committee.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended for the IL-17s (19 for, 0 opposed, 0 abstained, 1 absent) and for the IL-23s (18 for, 0 opposed, 1 abstained, 1 absent), the following.

IL-17s

- UF and step-preferred
 - ixekizumab (Taltz) moves from NF non-step-preferred
- UF and non-step-preferred
 - secukinumab (Cosentyx)

- NF and non-step-preferred
 - brodalumab (Siliq)
 - bimekizumab (Bimzelx)
- Completely Excluded – None
- Note, as part of this recommendation the requirement for a trial of Humira will be removed for the plaque psoriasis indication for the step-preferred agents, but Humira will remain for the other agents and indications.

IL-23s

- UF and step-preferred
 - No agent selected, leaving option open for a future JNC IL-23 originator/biosimilar products (anticipated 2025)
- UF and non-step-preferred
 - ustekinumab (Stelara)
 - guselkumab (Tremfya) *moves from NF non-step-preferred*
 - risankizumab (Skyrizi) *moves from NF non-step-preferred*
 - tildrakizumab (Ilumya) *moves from NF non-step-preferred*
- NF and non-step-preferred
 - mirikizumab (Omvoh) *moves from UF non-step-preferred*
- Completely Excluded – None
- Note a trial of Humira is still preferred for some indications.

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 1 absent) updated manual PA criteria for the IL-17 and IL-23 products in new users as outlined below. See Appendix C for the full criteria.

- *General Changes:*
 - Updating the step therapy requirements as outlined in the formulary recommendation and adding new indications as necessary.
 - Refining the current statement regarding non-biologic systemic therapy for plaque psoriasis and ulcerative colitis to only include intolerance or contraindication and not inadequate response.
 - Updating all ankylosing spondylitis and non-radiographic ankylosing spondyloarthritis criteria to remove the requirement for non-biologic systemic therapy and retaining the requirement for using NSAIDs first, based on the EULAR guidelines.

- Removing the requirement to try non-biologic systemic therapy first for Crohn's disease.
- Removing the criteria regarding a negative tuberculosis test prior to starting therapy.
- Streamlining the list medications with which to avoid concurrent use to classes rather than individual agents (new medications, biosimilars).
- *IL-17s*: Current PA criteria for the IL-17s require a trial of Humira first for all indications. The recommended PA changes for the IL-17s include the following:
 - For Taltz, which is now the step-preferred IL-17, removing the requirement for a trial of Humira first for the plaque psoriasis indication. A trial of Humira is required for the indications of psoriatic arthritis, ankylosing spondylitis, and non-radiographic ankylosing spondylitis, unless the patient has had an inadequate response, contraindication or adverse reaction to Humira. Additionally, an automated look back for Cosentyx and Humira will allow bypass of the PA in new users. Automated specialist bypass will be added for dermatologists, so that no PA will be required.
 - For Cosentyx, removing the current automation, but maintaining the trial of Humira and adding a trial of Taltz first in new users, unless the patient has had an inadequate response, contraindication or cannot tolerate Humira and Taltz. A trial of Taltz is not required for the indications of generalized pustular psoriasis, enthesitis-related arthritis, HS or pediatric psoriatic arthritis.
 - For Siliq and Bimzelx, requiring a trial of Humira, Taltz and Cosentyx in new users, unless the patient has had an inadequate response, contraindication or cannot tolerate Humira, Taltz and Cosentyx.
- *IL-23s*: For the IL-23 agents, currently Humira is required first for all indications. The recommended PA changes include the following:
 - Maintaining the requirement for a trial of Humira for all the IL-23 products.
 - For Stelara removing the requirement for a trial of Humira first if the patient is stable on IV therapy for infliximab for ulcerative colitis, since Stelara will move to UF, non-step-preferred status and the other IL-23 products do not have this criteria. Removing the requirement for other treatments (immunomodulators, corticosteroids, Humira) first for Crohn's disease.
 - For Tremfya and Skyrizi, removing the previous step requirement for Cosentyx and Stelara; the Humira step will remain.
 - For Ilumya, the Humira requirement will remain, but automated specialist bypass will be added for dermatologists.

- For Omvoh, requiring a trial of Humira, Stelara, Tremfya and Skyrizi in all new users, unless the patient has had an inadequate response, contraindication or cannot tolerate Humira, Stelara, Tremfya and Skyrizi.
- Biosimilars for the IL-23 ustekinumab are expected to launch in 2025. This provides a potential option for a JNC. This subclass conditions set is open to allow the JNC selection to be placed as the step-preferred UF IL-23.

3. COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) MN criteria for the NF IL-17s, Siliq and Bimzelx, and for the IL-23 product Omvoh. See Appendix B for the full criteria.

4. COMMITTEE ACTION: QUANTITY LIMITS—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QLs for all agents of a 60-day supply at all three points of service (POS). See Appendix D for the full QLs.

5. COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the IL-17 subclass and IL-23 subclass on the TRICARE Maintenance Drug List and on the non-formulary to mail requirement.

6. COMMITTEE ACTION: UF, PA, MN, QL, TRICARE MAINTENANCE DRUG LIST, and IMPLEMENTATION PERIOD—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- **IL-17s:** an effective date of the first Wednesday 90-days after signing of the minutes in all points of service, and
- **IL-23s:** 1) an effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and that 2) DHA send letters to the patients affected by the formulary change for Omvoh. See Appendix G for the actual implementation date.

B. Migraine Agents: Calcitonin Gene-Related Peptide (CGRP) Antagonists Oral Agents Subclass

*Background—*The P&T Committee evaluated the relative clinical effectiveness of the oral CGRP antagonists. The subclass was previously reviewed in May 2022.

The drugs in the subclass differ in their FDA-approved indications. Ubrogapant (Ubrelvy) is approved for the acute treatment of migraine, rimegepant orally dissolving tablet (Nurtec ODT) is approved for both acute treatment of migraine and

prevention of episodic migraine, and atogepant (Qulipta) is labeled for prevention of episodic and chronic migraine. The evidence review focused on new information published since 2022.

The injectable CGRP products [erenumab (Emgality), fremanezumab (Ajovy) and galcanezumab (Aimovig)] which are solely indicated for prevention of migraine headache and were reviewed in November 2023, are not discussed here.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

Professional Treatment Recommendations

- *Acute migraine headache treatment:* According to the 2024 International Headache Society, medications with established efficacy for acute migraine treatment should be considered prior to initiating the oral CGRP agents. Specifically, oral CGRP agents may be considered after a trial of three or more triptans, or in patients with a contraindication to or intolerability to triptans.
- *Preventive migraine headache treatment:* The oral CGRP medications may be considered along with other standard treatment options, including antiepileptics (e.g., valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol) antidepressants (e.g., amitriptyline, nortriptyline) and injectable CGRP agents as first-line treatment options for episodic migraine prevention. This recommendation is supported by the 2024 American Headache Society regarding preventive treatment of episodic migraine management.

Efficacy

- *Acute treatment:* A 2024 British Medical Journal (BMJ) network meta-analysis concludes that the oral CGRP antagonists (Ubrovelvy, Nurtec ODT) are less efficacious than triptans when assessing pain freedom at 2 hours and sustained pain freedom from 2 to 24 hours post-dose when compared to placebo.
- *Preventive treatment:* There are no head-to-head trials comparing Nurtec ODT and Qulipta to other standard migraine preventive treatments or to their injectable CGRPs counterparts. Recent network meta-analysis shows superior efficacy of the injectable CGRPs over the oral preventive medications.

Safety

- *Acute treatment:* A 2024 BMJ network meta-analysis concludes that Ubrovelvy showed a statistically significantly increased risk of nausea compared with placebo; the risk of Nurtec ODT was not significant. For other adverse event outcomes where comparative data was available (e.g., chest pain, dizziness, vomiting, paresthesia, and diarrhea), both Nurtec ODT and Ubrovelvy were no different when compared to placebo.

- *Preventive treatment:* A 2023 Journal of Headache and Pain network meta-analysis concludes that based on moderate certainty evidence, the injectable CGRPs and oral CGRPs are not significantly different from placebo when assessing adverse events leading to discontinuation.

When comparing the oral CGRPs, Qulipta was associated with a statistically significant higher odds of treatment-emergent adverse events when compared to placebo, while Nurtec ODT was not statistically different from placebo. Both Qulipta and Nurtec ODT were no different than placebo when assessing adverse events leading to discontinuation and serious adverse events (2023 Cephalgia network meta-analysis.)

Other Factors

- *ubrogepant (Ubrelvy)* allows for multiple repeated doses in a 24-hour period. It is available in multiple strengths and can be dose-adjusted in patients with hepatic failure.
- *rimegepant (Nurtec ODT)* is available as a single strength. For acute treatment, a single dose may be used in a 24-hour period. For preventive treatment, the dosing regimen is taken every other day.
- *atogepant (Qulipta)* is indicated for preventive treatment for both chronic and episodic migraine types. It is available in multiple strengths and is dosed once daily.

Overall Conclusions

- In terms of efficacy and safety, there is a high degree of interchangeability between the oral CGRP agents, when compared across the same clinical indication.
- In order to meet the needs of MHS beneficiaries, at least one oral CGRP agent is required for treatment of each indication, acute migraine treatment and episodic migraine prevention.

Relative Cost Effectiveness Analysis and Conclusion—CMA, BIA and sensitivity analysis were performed. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that Ubrelvy was the most cost-effective oral CGRP antagonist, followed by Qulipta, and then Nurtec ODT.
- BIA results found that designating Ubrelvy and Qulipta as UF step-preferred and Nurtec ODT as NF non-step-preferred demonstrated significant cost avoidance for the MHS.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (17 for, 2 opposed, 0 abstained, 1 absent) the following:

- UF step-preferred
 - atogepant (Qulipta) *moves from UF to UF step-preferred*
 - ubrogepant (Ubrelvy) *moves from UF to UF step-preferred*
- NF non-step-preferred
 - rimegepant (Nurtec ODT) *moves from UF to NF non-step-preferred*
- Complete exclusion – None
- Note that step-therapy will require a trial of Qulipta or Ubrelvy in new and current users of Nurtec ODT

2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA criteria were originally recommended when the individual oral CGRP medications were first evaluated as new drugs in 2020. The PA criteria will follow the International Headache Society recommendations for first-line therapies. Additionally, use of the step-preferred oral CGRPs (Ubrelvy for preventive use and Qulipta for acute use) will be required first before Nurtec ODT. The P&T Committee recommended (18 for, 1 opposed, 0 abstained, 1 absent) the following as outlined below. See Appendix C for the full criteria.

- For Ubrelvy for acute use, in new users, an automated drug lookback for Nurtec ODT or a triptan in the previous 180 days will apply. If the patient has not previously received Nurtec ODT, then the current criteria for a trial of at least two triptans will be maintained. The current 6-month renewal criteria will be removed therefore the PA won't expire.
- For Nurtec ODT, the manual PA criteria will apply to new and current users.
 - For acute use, a trial of Ubrelvy and two triptans [e.g., sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), or eletriptan (Relpax)] is required, unless the patient has a contraindication to, intolerability to or has failed treatment with triptans and Ubrelvy.
 - For preventive use, a trial of Qulipta is required first in addition to the current requirements for a trial of one standard preventive drug (e.g., beta-blocker, anti-epileptic or antidepressant) and one injectable CGRP (Aimovig, Ajovy, Emgality) unless the patient has a contraindication to, intolerability to or has failed these treatments.

For patients currently using Nurtec ODT for migraine headache prevention who are stable on therapy, a trial of Qulipta is not required if a new PA is submitted. Additionally, in patients who have an approved PA (identified as those currently using 16 tablets monthly), if a new prescription is written for Qulipta, a corresponding PA will be approved for Qulipta.

- For Qulipta, for preventive use in new users, an automated drug lookback for an injectable CGRP in the past 720 days will apply. If the patient has not previously received an injectable CGRP, then the current manual PA criteria will be maintained, requiring a trial of one standard preventive drug (e.g., beta-blocker) and one injectable CGRP.

3. **COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Nurtec ODT. See Appendix B for the full criteria.
4. **COMMITTEE ACTION: QLs**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current quantity limits for Ubrelvy, Nurtec ODT, and Qulipta. See Appendix D for the full QLs.
5. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) excluding all three oral CGRPs due to the acute use exception. See Appendix F.
6. **COMMITTEE ACTION: UF, PA, MN, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following 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 receiving Nurtec ODT who will be affected by the formulary status change and PA. See Appendix G for the implementation date.

C. Insulins: Rapid-Acting Insulin Analogs Subclass and Short-Acting, Intermediate-Acting and Combination Insulin Analogs Subclass

Background—The Rapid Acting Insulin (RAI) subclass was last reviewed at the November 2019 DoD P&T Committee meeting, and branded insulin aspart (Novolog) and branded insulin lispro (Humalog) were designated as step-preferred. Since the last review, several biosimilars and unbranded biologics are now marketed. There are currently shortages in the class. Additionally, termination of pricing agreements along with other U.S. market forces, including the American Rescue Plan Act and Inflation Reduction Act, warranted a clinical effectiveness review in preparation for participation in a JNC in June 2025 with other Federal partners. The short-acting, intermediate-acting and combination insulins were also included in the review.

The DoD P&T Committee concluded in November 2022 and reaffirmed in at the August 2024 meeting (“Process for Evaluating Biosimilars and Biologics”) that by FDA approval and definition, biosimilars are equally safe and efficacious, which provides strong competition within products for drug classes with biosimilars. Not all biosimilars are cost effective when compared to their reference product.

Note that the inhaled insulin product Afrezza is now classified as a miscellaneous insulin and will not be reviewed here; it will remain NF with PA.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded for the RAIs (19 for, 0 opposed, 0 abstained, 1 absent) and for the short-acting, intermediate-acting and combinations (18 for, 0 opposed, 0 abstained, 2 absent the following:

RAIs

Professional Treatment Recommendations

- There were no major updates to the P&T Committee clinical conclusions from 2019 that showed there are no clinically relevant differences between the RAIs in lowering hemoglobin A1c. Since the last class review, biosimilar formulations of insulin lispro (Lyumjev and an unbranded lispro), and insulin aspart (unbranded) were reviewed as new drugs.
- Numerous clinical practice guidelines are available (e.g., American Diabetes Associate, American Association of Clinical Endocrinologists, American College of Endocrinology) and none give preference to one RAI (insulin aspart, insulin lispro and insulin glulisine) over another.
- For special populations, guidelines to include the American College of Obstetrics and Gynecology and International Society for Pediatric and Adolescent Diabetes acknowledged that RAIs are safe in pregnancy and pediatrics and no preferences were given regarding use of one RAI over another.
- Although there are subtle differences between RAIs in pharmacokinetic profiles in terms of onset and duration of action, there do not appear to be compelling clinically relevant difference between the products.

Safety

- With regard to adverse events, there was no new data to change the previous conclusion that there is no evidence suggesting a clinically relevant difference in the number, type or severity of adverse reactions between insulin aspart or lispro.

Individual Product Characteristics

- *Insulin aspart (Novolog)* is approved for use in insulin pumps and is suitable for children as young as 2 years of age. Other advantages include availability in various dosage forms, including pens, vials, and cartridges.

- *Insulin lispro (Humalog)* advantages include approval for insulin pumps and in pediatric patients down to age 3 years, and availability in all dosage forms (pen, vials, and cartridges). It is also available in a U-200 formulation. The Humalog Junior KwikPen formulation allows half-unit dosing for pediatrics.
- *Insulin glulisine (Apidra)* may be used in insulin pumps and in pediatric patients down to 4 years. Disadvantages of Apidra include a greater susceptibility to precipitation and catheter occlusions in insulin pumps, and the association with significantly elevated hypoglycemia rates.
- *Insulin lispro (Admelog)* is an insulin lispro formulation that does not show clinically relevant differences in hemoglobin A1c or post-prandial blood glucose versus Humalog. It is approved in pumps and in children as young as 3 years of age.
- *Fiasp* is a formulation of insulin aspart that contains niacinamide, a form of vitamin B3. There is no data to show that Fiasp is superior to other rapid-acting insulins, and it has been completely excluded from the formulary since November 2019.
- *Biosimilar RAIs:* Biosimilar RAI formulations include insulin lispro-aabc (Lyumjev) which is also available in a U-200 formulation, unbranded insulin lispro and unbranded insulin aspart. Lyumjev is not compatible in insulin pumps.

MHS Provider Feedback

- Provider feedback concluded that Humalog and Novolog are considered bioequivalent. The U-200 formulations are not routinely used clinically. Admelog and Apidra were rarely used. Providers related that having an RAI that was compatible with insulin pumps was essential. Additionally, products with half-unit pens available with the Humalog Junior is preferred for pediatrics.

Therapeutic Interchangeability and Clinical coverage

- Overall, there is a high degree of interchangeability among the RAIs, and one product is needed on the formulary to meet the needs of the majority of MHS patients.

Short-Acting, Intermediate-Acting and Combination Insulins

- For the short-acting products, Humulin R and Novolin R provide the same active ingredient, onset, peak, and duration of action. Differences may exist in packaging or brand names, but the core function and effectiveness of regular insulin are consistent across brands.
- For the intermediate-acting products, Humulin N and Novolin N are both neutral protamine Hagedorn (NPH) insulin with the same active ingredient.

- Premixed insulins are beneficial for patients who have difficulty drawing insulin from two separate vials. The short-acting/intermediate-acting analog mix pens are therapeutically interchangeable with each other.
- American Diabetes Association guidelines do not state a preference for one product over another within the categories.
- During emergency conditions, the FDA allows substitution of one regular insulin (e.g., Humulin R, Novolin R) for another brand of regular insulin, and allows substitution of one intermediate-acting insulin (e.g., Humulin N, Novolin N) for another intermediate-acting insulin product on a unit-per-unit basis.
- MHS provider feedback stated that within the short-acting, intermediate-acting and combinations space, the products are the same.
- Overall utilization of this subclass is much lower in the MHS than the RAIs.

Overall Conclusions

- The RAI reference biologics and their biosimilars are interchangeable; the RAI analogs (e.g., lispro, aspart, and glulisine) are interchangeable; and the RAI analog reference products are interchangeable to other RAI analog biosimilars (e.g., lispro reference to aspart biosimilar). The DoD P&T Committee accepts this review as the clinical review for rapid-acting insulins.
- The injectable short-acting, intermediate-acting and combination insulin reference products and their biosimilars are interchangeable. The MHS will continue to participate in the JNC process and will designate the JNC selected-product as the UF step-preferred product for all new patients.

Relative Cost Effectiveness Analysis and Conclusion—Given clinical interchangeability, cost can be the defining factor for selecting a rapid-acting, short-acting, intermediate-acting, and combination insulin product for inclusion on the UF, given the clinical conclusions above. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- The cost analysis for the RAIs included the influence of shortages and termination of pricing agreement on current pricing.
- For both the RAIs and the short-acting, intermediate-acting and combination insulins, the JNC processes meet the requirements for determining the relative cost effectiveness for biosimilar agents.
- The P&T Committee supports participation in future JNCs to secure optimal pricing for biosimilars.

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following.
 - The JNC selected rapid-acting, short-acting, intermediate-acting, and combination insulins will be designated as UF and step-preferred on the JNC effective date.
 - The rapid-acting, short-acting, intermediate-acting, and combination insulins that are not selected for the JNC will be designated as non-step-preferred on the JNC effective date.
 - The formulary status of the non-step-preferred/completely excluded RAIs will not change unless reviewed by the DoD P&T Committee and the Beneficiary Advisory Panel.
 - Step therapy will require a trial of the JNC preferred product in all new users for all the non-step-preferred products.
 - The P&T Committee will recommend that MTFs should consider implementing an auto-substitution policy for the preferred agent.
 - Until the JNC effective date for the RAIs, the current formulary status will apply.
 - UF and step-preferred
 - insulin aspart (Novolog Flex Pen)
 - insulin lispro (Humalog Kwikpen and authorized generic insulin lispro)
 - Lyumjev Kwikpen
 - UF and non-step-preferred
 - insulin aspart authorized generic
 - NF and non-step-preferred
 - insulin lispro (Admelog)
 - insulin glulisine (Apidra)
 - Completely Excluded
 - insulin aspart/niacinamide (Fiasp)
2. **COMMITTEE ACTION: MANUAL PA CRITERIA**—PA will not be required for the JNC preferred agent however, PA criteria have applied to the non-step-preferred products since the 2019 class review. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the following:
 - Maintaining the current step therapy for Admelog and Apidra until the JNC effective date, requiring a trial of insulin aspart (Novolog)

and insulin lispro (Humalog or authorized generic lispro) in new users, unless the patient is on an insulin pump or if the patient is currently stabilized on Admelog or Apidra. (See Appendix C)

- A general PA form for future non-step-preferred products in new users was created and will launch on the JNC effective date. The general PA form will acknowledge the JNC step-preferred agent does not require a PA, will require a diabetes diagnosis, require a trial and failure of the JNC-selected step-preferred product unless there is a contraindication or adverse events, and allow for coverage if the non-preferred product has an indication that is lacking with the JNC step-preferred product.

3. COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) maintaining the current MN criteria for Admelog and Apidra. See Appendix B for the full criteria. Upon the JNC effective date, the formulary alternatives will be the JNC selected preferred product and products designated as UF and step-preferred.

4. COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS—

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) maintaining all rapid-acting, short-acting intermediate-acting and combination insulins on the list. See Appendix F.

5. COMMITTEE ACTION: RAPID RESPONSE PROGRAM—

The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the RAIs on the rapid response (safety net program) maintained by Express Scripts. Upon the JNC effective date, the short-acting, intermediate-acting, and combination insulins will be added to the rapid response program.

6. COMMITTEE ACTION: UF, PA, MN, TRICARE MAINTENANCE DRUG LIST, RAPID RESPONSE PROGRAM and

IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) the following:

- The implementation plan will be based on the JNC effective date, taking into consideration the implementation timeline for P&T Committee recommendations.
- Implementation of step-preferred agent for new and current patients will occur on the JNC effective date or no more than 2 weeks after JNC effective date.
- Implementation of non-step-preferred agents for new patients will occur 60 days after the JNC effective date to allow for updating the PA forms.

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

The products were divided into two groups when presented at the DoD P&T Committee meeting. The generic names are presented below. Group 1 included Tryvio, Crexont, clobetasol ophthalmic, Onyda XR, Ebglyss, Nemluvio, Femlyv, Yorvipath, Livdelzi, Sofdra, Zepbound vials, Vafseo, Vigafyde, and Voranigo; Group 2 included Ohtuvayre, Neffy, Lazcluze, Aqneursa, and Cobenfy.

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

1. **COMMITTEE ACTION: UF RECOMMENDATION**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) the following:

- UF
 - carbidopa/levodopa extended release (ER) capsules (Crexont) – Parkinson’s Agents
 - epinephrine 2 mg/0.1 mL nasal spray (Neffy) – Miscellaneous Respiratory Agents
 - lazertinib (Lazcluze) – Oncological Agents: Epidermal Growth Factor Receptor (EGFR) plus Non-Small Cell Lung Cancer (NSCLC)
 - lebrikizumab-lbkz injection (Ebglyss) – Atopy Agent for atopic dermatitis
 - levacetylleucine (Aqneursa) – Miscellaneous Neurological Agent for Niemann Pick disease
 - nemolizumab-ilto injection (Nemluvio) – TIBs: Miscellaneous Interleukins for prurigo nodularis
 - palopegteriparatide injection (Yorvipath) – Osteoporosis Agents
 - seladelpar (Livdelzi) – Gastrointestinal-2 Agent for primary biliary cholangitis
 - vigabatrin 100 mg/mL oral solution (Vigafyde) – Anticonvulsants – Antimania Agents
 - vorasidenib (Voranigo) – Oncological Agent
- NF

- aprocitentan (Tryvio) – Antihypertensive Agent – Endothelin Receptor Antagonists
- clonidine (ER) 0.1 mg/mL oral suspension (Onyda XR) – Attention Deficit Hyperactivity Disorder (ADHD) Agents: Non-Stimulants
- ensifentrine nebulized inhalation suspension (Ohtuvayre) – Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease
- norethindrone acetate/ ethinyl estradiol orally dissolving tablet (ODT) (Femlyv) – Contraceptive Agents: Monophasics with 20 mcg estrogen
- sofipironium 12.45% topical gel pump (Sofdra) – Antiperspirants
- vadadustat (Vafseo) – Hematological Agents: RBC Stimulants Erythropoietin Agents
- xanomeline/ trospium (Cobenfy) – Antipsychotic Agents: Atypical
- Complete Exclusion
 - clobetasol 0.05% ophthalmic emulsion (no brand name) – Miscellaneous Ophthalmic
 - Clobetasol ophthalmic emulsion was recommended for complete exclusion status as it offers little to no additional clinical effectiveness compared to the other ophthalmic steroids, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include dexamethasone 0.01% ophthalmic suspension, loteprednol 0.5% ophthalmic suspension and prednisolone 1% ophthalmic suspension.
 - tirzepatide vials (Zepbound vials) – Weight Loss Agents; this formulation is not available to TRICARE beneficiaries and the manufacturer has limited access to the vials to patient self-pay only. Formulary alternatives include liraglutide (Saxenda), semaglutide (Mounjaro) and tirzepatide pens (Zepbound pens).

2. **COMMITTEE ACTION: MN CRITERIA**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) MN criteria for Tryvio, Onyda XR, Ohtuvayre, Femlyv, Sofdra, Vafseo, and Cobenfy. See Appendix B for the full criteria.

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

- Applying manual PA criteria to new users of, Crexont, Lazcluze, Nemluvio, Aqneursa, Yorvipath, Vafseo, and Voranigo, consistent with the current PA requirements for the respective drug classes.
 - Applying manual PA criteria to new users of Tryvio, requiring use of guideline-supported drugs for resistant hypertension first.
 - Applying manual PA criteria to new users of Onyda XR, Ohtuvayre, Ebglyss, Femlyv, Livdelzi, and Sofdra, requiring a trial of other formulary alternatives first.
 - Applying manual PA criteria to new users of Cobenfy requiring a trial of a first- and second-generation antipsychotic first.
4. **COMMITTEE ACTION: QUANTITY LIMITS (QLs)**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) QLs for Ohtuvayre, Neffy, Lazcluze, Ebglyss, Aqneursa, Nemluvio, Yorvipath, Livdelzi, Vafseo, Vigafyde and Voranigo. See Appendix D for the QLs.
5. **COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List 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 TRICARE Maintenance Drug List which includes the NF medications subject to the mail requirement.
6. **COMMITTEE ACTION: UF, MN, PA, QL, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD**—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 1 abstained, 1 absent and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) adding an effective date of the following:
- **New Drugs Recommended for UF and 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 Completely Excluded 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 for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5)

Manual PA criteria were recommended for three recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. 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. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

- a) **Oncological Agents: Renal Cell Carcinoma—everolimus tablet (Torpenz)**—Other versions of everolimus tablets in the same strengths are available, including Afinitor and generics, that are more cost-effective than this version made by a sole manufacturer. Additionally, Torpenz will be added to the rapid response program.
- b) **Skeletal Muscle Relaxants and Combinations—methocarbamol 1,000 mg tablet (generic, Tanlor)**—Numerous other more cost-effective methocarbamol tablets are available including methocarbamol 500 mg and 750 mg.
- c) **Antiemetic-Antivertigo Agents—ondansetron 16 mg ODT**—Numerous other more cost-effective ondansetron formulations are available including ondansetron tablets and ODTs in 4 mg and 8 mg strengths.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) manual PA criteria for everolimus tablet (Torpenz), methocarbamol 1,000 mg tablet (generic, Tanlor), and ondansetron 16 mg ODT in new and current users, due to the significant cost differences compared with other available alternative agents. 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. Everolimus (Torpenz) will be added to the Rapid Response Program. See Appendix C for the full criteria.

2. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

- a) **Oncological Agents**—Efforts to standardize and streamline the PAs for oncology drugs are ongoing. Edits were made to four oncology PAs (Retevmo, Augtyro, Krazati, and Lynparza). As part of this standardization effort, the following actions were taken: editing the NCCN guideline question to cite specific guideline version and page number to ease approvals for new indications, updating indications to more closely

match FDA label language, and removing lengthy clinical monitoring and counseling questions based on provider feedback.

- **Oncological Agents—repotrectinib (Augtyro)**—Augtyro is now approved for a subset of patients with solid tumors who have a neurotrophic receptor tyrosine kinase gene fusion. The manual PA criteria were also updated to reflect this new indication.
 - **Oncological Agents: Lung Cancer—adagrasib (Krazati)**—The manual PA criteria were also updated to allow use of Krazati in combination with cetuximab for the treatment of KRAS G12C-mutated locally advanced or metastatic colorectal cancer in adults who have received prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy.
 - **Oncological Agents: Lung Cancer—selpercatinib (Retevmo)**—The manual PA criteria were also expanded to include patients two years of age and older with one of the following cancers:
 - Advanced or metastatic medullary thyroid cancer with a rearranged during transfection (RET) mutation
 - Advanced or metastatic thyroid cancer with a RET gene fusion who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)
 - Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
 - **Oncologic Agents: Ovarian Cancer—olaparib (Lynparza)**—The Lynparza PA was updated with the aforementioned oncology standardization edits.
- b) **Psoriasis Agents: roflumilast 0.15% cream (Zoryve)**—Zoryve received a new indication for treating mild to moderate atopic dermatitis in patients six years of age or older. For this indication, Zoryve requirements include specialist prescribing or consultation with a specialist, and a trial of at least two weeks of both a topical corticosteroid and a topical calcineurin inhibitor, unless the patient has failed therapy, has a contraindication or has had an adverse reaction to the corticosteroid and calcineurin inhibitor.
- c) **Atopy: dupilumab (Dupixent)**—The manual PA criteria were expanded to include patients 12 years of age or older with chronic rhinosinusitis with nasal polyposis.
- d) **Atopy: benralizumab (Fasenra Pen)**—The manual PA criteria were updated to allow for treatment of adults with eosinophilic granulomatosis with polyangiitis.
- e) **TIBs: Non-TNFs—apremilast (Otezla)**—Otezla received an expanded age indication for moderate to severe plaque psoriasis in children six years of age or

older who weigh 20 kg or greater. The manual PA criteria were updated to require a trial of Humira and non-biologic systemic therapy for this indication.

- f) **TIBs: TNFs—certolizumab (Cimzia)**—Cimzia received a new indication for active polyarticular juvenile idiopathic arthritis in patients two years of age or older. The manual PA criteria were updated and require a trial of Humira and non-biologic systemic therapy.
- g) **Anticonvulsant Antimania Agents—lacosamide ER (Motpoly XR)**—The manual PA criteria were updated to allow for adjunctive use in treatment of primary generalized tonic-clonic seizures in patients weighing 50 kg or greater.
- h) **Immunological Miscellaneous Agents—peanut (Arachis hypogaea) allergen powder-dnfp (Palforzia)**—The manual PA criteria were expanded to include patients one through three years of age with a confirmed diagnosis of peanut allergy.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the manual PA criteria for Retevmo, Augtyro, Krazati, Lynparza, Zoryve, Dupixent, Fasenra, Otezla, Cimzia, Motpoly XR, and Palforzia 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.

3. Updated PA and MN Criteria for Reasons other than New Indications

- a) **Antipsychotic Agents: Atypical—pimavanserin (Nuplazid)**—The manual PA was edited to remove the requirement for a baseline Mini-Mental Status Examination score based on provider feedback.
- b) **Antifungals—oteseconazole (Vivjoa)**—The Vivjoa PA criteria were updated to allow for prescribing by infectious disease specialists in addition to gynecologists, based on specialist feedback.
- c) **Hematological Agents—iptacopan (Fabhalta)**—Fabhalta was reviewed as an innovator drug at the May 2024 P&T meeting and was designated NF with a PA, allowing use for paroxysmal nocturnal hemoglobinuria. In August 2024, the Fabhalta label was expanded to include the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. Currently, two other drugs are also approved for IgAN, sparsentan (Filspari), designated as UF, and budesonide delayed-release (Tarpeyo), which is completely excluded from the formulary. Filspari recently gained an expanded approval to slow the decline in kidney function in patients with IgAN.

A review of the clinical trial data for the three drugs, draft IgAN clinical practice guidelines, and cost effectiveness supported requiring a trial of Filspari before Fabhalta for IgAN. The updated PA criteria for Fabhalta also mirror the inclusion and exclusion criteria from the approval trial.

- d) **Osteoporosis Agents: Parathyroid Hormone (PTH) Analogs—teriparatide (Forteo, Bonsity)**—The manual PA criteria for the teriparatide products were updated due to a change in the FDA label and provider feedback. Previous labeling did not recommend use beyond two years of therapy due to concerns for osteosarcoma, based on rodent studies. Subsequent human observational studies have not shown an increased osteosarcoma risk, and the FDA label now allows use beyond two years in patients at high risk for fracture. The PA criteria were updated to remove the two-year limitation and to add renewal criteria where the provider acknowledges there is limited data regarding the risk of osteosarcoma.
- e) **Gynecological Agents Miscellaneous—fezolinetant (Veozah)**—Veozah was reviewed as an innovator drug at the August 2023 P&T meeting. In September of this year, the FDA released a drug safety communication stating that Veozah can cause rare but serious liver injury, based on one case report. This updated in package labeling necessitated a change in the Veozah PA criteria for hepatic monitoring.
- f) **Pancreatic Enzyme Replacement Therapy (PERT)—pancrelipase (Zenpep)**—For the PERT class, Creon is UF step-preferred, available without a PA, and available at the lowest (generic) co-pay. Viokace is UF non-step-preferred, while Pancreaze, Pertzye, and Zenpep are NF non-step-preferred. For Zenpep, a trial of Creon, Viokace, Pancreaze and Pertzye are required first, based on cost effectiveness from the February 2019 review.

Based on continual drug class surveillance, it was advantageous to the government to update the Zenpep PA and remove the additional requirements to trial Viokace, Pancreaze and Pertzye before Zenpep.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the manual PA criteria for Nuplazid, Vivjoa, Fabhalta, Forteo, Bonsity, Veozah, and Zenpep in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix C for the full criteria.

B. Antilipidemic-1s Class: Non-statins and Combinations and proprotein convertase subtilisin/kexin type-9 (PCSK-9) Inhibitors Subclasses—Updated PA criteria

The non-statins and combinations subclasses, which included bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) were reviewed for formulary status at the August 2024 DoD P&T Committee meeting. Nexletol and Nexlizet were both recommended to move to UF status, and the PA criteria were revised to require a trial of PCSK-9 inhibitor first, and to include the new FDA-approved indication for primary prevention in high-risk patients. Updates were also made at that time to the PCSK-9 inhibitors PA criteria for alirocumab (Praluent) and evolocumab (Repatha) to

expand the allowable uses to the primary prevention population. Implementation of these changes is set to occur on January 29, 2025.

DHA contracting provided clarifying information to the P&T Committee regarding Nexletol, Nexlizet and Repatha, prompting the P&T Committee to recommend changes to the PA criteria. For Nexletol and Nexlizet, the requirement for a trial of PCSK-9 inhibitor and the automated lookback for a PCSK-9 inhibitor will not be implemented.

For Repatha, no PA will be required if the prescription is written by a cardiologist, endocrinologist or cardiac transplant physician (specialist bypass). Additionally, for prescriptions initially written by a specialist, an automated drug lookback for Repatha will allow PA approval if the patient has received the drug in the past 180 days, to allow continuation of therapy for prescriptions subsequently written by non-specialists. Lastly, an automated drug look back will apply for prescriptions filled for a high intensity statin, ezetimibe, or ezetimibe/simvastatin in the past 180 days to allow bypass of the PA.

***COMMITTEE ACTION: NEXLETOL, NEXLIZET and REPATHA
UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION***

PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) updates to the PA criteria in new users for Nexletol, Nexlizet and Repatha. Nexletol and Nexlizet will be removed from TRICARE Maintenance Drug List, due to flat-pricing across all POS. The formulary status from the August 2024 P&T meeting (UF) will remain. The requirement for a PCSK-9 trial before Nexletol and Nexlizet from the August 2024 P&T meeting will not be implemented. Implementation of the changes noted above will be effective on signing of the minutes. See Appendix C for the full criteria.

C. Line Extensions

The P&T Committee clarified the formulary status for five product line extensions by the original manufacturer. Line extensions have the same FDA indication(s) as the “parent” drug and retain the same formulary and copayment status as the “parent” drug.

1. **Atopy**—designating **tralokinumab-ldrm (Adbry) autoinjector** with the same formulary status (NF), PA, QL, MN, Specialty and TRICARE Maintenance Drug List status as the parent Adbry prefilled syringe.
2. **Renin-Angiotensin Antihypertensives: Combinations**—designating **sacubitril/valsartan (Entresto Sprinkle)** with the same formulary status (UF) as the parent Entresto film-coated tablet.
3. **Self-Monitoring Blood Glucose Systems: Therapeutic Continuous Glucose Monitoring Systems**—designating **Freestyle Libre 3 Plus Sensor** with the same formulary status (UF) and PA as the parent FreeStyle Libre 3 Sensor. QLs will be updated from 28 to 30 days at retail, and from 84 to 90 days at MTF and Mail.

4. **Oncological Agents: Lung Cancer**—designating **selpercatinib (Retevmo) tablets** with the same formulary status (UF), PA, QL, Specialty, and TRICARE Maintenance Drug List status as the parent Retevmo capsules.
5. **TIBs: TNFs**—designating **adalimumab-ryvk (unbranded Simlandi) syringe kit** with the same formulary status (NF), non-step preferred, PA, QL, MN, Specialty and TRICARE Maintenance Drug List status as the parent Simlandi autoinjector.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) the formulary, QL, PA, MN, Specialty status, and TRICARE Maintenance Drug List status for Adbry, Entresto Sprinkle, FreeStyle Libre 3 Plus Sensor, Retevmo, and unbranded Simlandi. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. RE-EVALUATION OF NF GENERICS—ACNE AGENTS: TOPICAL ACNE AND ROSACEA

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 needs to be readdressed. Refer to the November 2022 DoD 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 supply, for NF/Tier 3 Topical Acne and Rosacea agents (adapalene or clindamycin gel and combinations.)

COMMITTEE ACTION: FORMULARY STATUS AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) the following changes to formulary status and prior authorization criteria, effective the first Wednesday 30 days after signing of the minutes. (See Appendix G for implementation dates):

- Returning the following to UF status: adapalene/benzoyl peroxide 0.1/2.5% gel pump (Epiduo generics; GCN 31775) and adapalene/benzoyl peroxide 0.3/2.5% gel pump (Epiduo Forte generics; GCN 39163); these two agents are similar in terms of average cost per 30-day supply to the two current UF adapalene products.
- Removing the PA requirements for adapalene/benzoyl peroxide [BP] 0.1/2.5% gel pump (Epiduo generics; GCN 31775), adapalene/BP 0.3/2.5% gel pump (Epiduo Forte generics; GCN 39163), and clindamycin/BP 1.2/2.5% gel (Acanya generics; GCN 29418); the latter is very little used compared to the three other current clindamycin/benzoyl peroxide gel products on the UF.

There are no changes to the PA or MN criteria for the remaining NF, non-step-preferred acne agents (e.g., Ziana, Veltin, Onexton, Neuac Kit).

IX. TRICARE MAINTENANCE DRUG LIST UPDATES

Nonformulary medications are generally restricted to TMOP 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 TRICARE pharmacy contractor managed TMOP. Medications subject to either the nonformulary requirement or added to the EMMPI program are combined as the TRICARE Maintenance Drug List, formerly known as the Select Maintenance Drug List.

The P&T Committee reviewed a list of drugs previously added to the TRICARE Maintenance Drug List on a contingent basis that were implemented after the March 1, 2024 start date for specialty replenishment (see Appendix F, Table 2 for a list). The P&T Committee also noted that the LHRH agonist antagonist relugolix (Orgovyx), which is currently on the contingent list, is projected for addition in Jan 2025.

X. MHS GENESIS OVER-THE-COUNTER (OTC) LIST BORIC ACID VAGINAL SUPPOSITORIES AND DICLOFENAC 1% TOPICAL GEL

Background—The DoD P&T Committee reviewed an MTF request to add boric acid vaginal suppositories to the MHS GENESIS (MHSG) OTC List. In addition, the P&T Committee considered addition of diclofenac 1% topical gel to the MHSG OTC list due to market changes from prescription to OTC versions of this product, which is widely used at MTFs. OTC drugs included on the MHSG OTC list allows dispensing of the product at MTFs, but not Retail network pharmacies or TMOP. The P&T Committee noted that:

boric acid vaginal suppositories

- Boric acid vaginal suppositories promote an acidic environment in the vagina to help balance normal vaginal flora and are typically used on a nightly basis for 2-3 weeks.
- The 2021 sexually-transmitted infection guidelines from the Centers for Disease Control and Prevention (CDC) support the use of boric acid suppositories as an option for treatment of recurrent non-albicans vulvovaginal candidiasis and recurrent bacterial vaginosis. For recurrent trichomoniasis the guidelines state alternative regimens might be effective but not have been systematically evaluated, therefore consultation with an infectious disease specialist or urogynecologist is recommended.
- Feedback from urogynecology supports availability on the MHSG OTC List.
- The product is commercially available as Azo Boric Acid 600-mg vaginal suppository [I-Health; national drug code (NDC) 87651-07-6030; generic code number (GCN) 54689]. It is both listed in First DataBank (a requirement for adjudication through the Pharmacy Data Transaction Service) and available to

MTFs through the national prime vendor. Compounded versions are not covered by TRICARE.

- Boric acid vaginal suppositories are a cost-effective alternative compared to other second- or third-line options for these conditions

diclofenac 1% topical gel

- Diclofenac 1% gel first became available as an OTC product in February 2020; prescription versions (e.g., Voltaren gel) are now leaving the market.
- The Joint National Contract (JNC) product for diclofenac 1% gel (Exelan Pharma) has a new NDC for an OTC version (NDC 76282-0103-39; GCN 45680).
- Diclofenac 1% gel is an effective and widely used topical pain agent, particularly at MTFs, which fill about 25,000 prescriptions for the product per month. It is considerably more cost-effective than alternative topical pain agents, including 1.5% topical solution (e.g., Pennsaid) and lidocaine 5% patches.
- **COMMITTEE ACTION: MHS GENESIS OTC LIST AND IMPLEMENTATION**—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) boric acid 600 mg vaginal suppositories (GCN) 54689) and diclofenac 1% gel (GCN 45680) to the MHS GENESIS OTC list, and any current BCF legend diclofenac 1% gel formulations that are now available OTC will be removed from the BCF. Implementation will occur on or before the first Wednesday two weeks after signing of the minutes.

XII. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

- A. Explanation PA Expiration Dates**—For PAs where the PA does not expire, coverage will continue unless or until there is an action by the P&T Committee, including re-review of the drug or drug class and a corresponding change in PA criteria.
- B. Other Changes to the MHSG OTC List: CetaKlenz and Cetaphil Skin Cleansers**—The NDCs for CetaKlenz skin cleanser (GCN 78090) are not adjudicating through PDTS. NDC 00904584416 is obsolete in First DataBank (FDB) and NDC 20555001100 is not listed in FDB. A similar product, under GCN 53704 (Cetaphil Gentle Skin Cleanser), has been added as an alternative and is now included on the MHSG OTC list.

XIII. ADJOURNMENT

The meeting adjourned at 1600 hours on November 7th. The next meeting will be in February 2025.

Appendix A—Attendance: November 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—TRICARE Maintenance Drug List Status of Medications Designated
Formulary or Nonformulary during the November 2024 DoD P&T
Committee Meeting**

Appendix G—Implementation Dates

Appendix H—Completely Excluded Agents and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY:


DoD P&T Committee Chair

The Director, DHA:



concurs with all recommendations.



concurs with the recommendations, with the following modifications:



concurs with the recommendations, except for the following:


Acting Assistant Director, Health Care
Administration

27 January 2025
Date

Appendix A—Attendance

[illegible]

Appendix A—Attendance

[illegible]

Appendix A—Attendance

[REDACTED]

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
brodalumab (Siliq) TIBs: IL-17 Subclass	- Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure Formulary Alternatives: Humira, Taltz, Cosentyx
bimekizumab (Bimzelx) TIBs: IL-17 Subclass	- Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure Formulary Alternatives: Humira, Taltz, Cosentyx
mirikizumab (Omvoh) TIBs: IL-23 Subclass	- Use of all formulary agents is contraindicated - Patient has experienced significant adverse effects from all formulary agents - Formulary agents result in therapeutic failure Formulary Alternatives: Humira, Stelara, Tremfya, Skyrizi
rimegepant (Nurtec ODT) Migraine Agents: Oral CGRP Antagonists	- Use of formulary agents are contraindicated - Formulary agents resulted in therapeutic failure Formulary alternatives: For Acute migraine headache treatment: ubrogepant (Ubrovelvy), three formulary triptans (for example: rizatriptan, sumatriptan, zolmitriptan, eletriptan, naratriptan) For Preventive migraine headache: atogepant (Qulipta) AND one injectable CGRP (Aimovig, Emgality, Ajovy)
- insulin lispro (Admelog) - insulin glulisine (Apidra) Insulins: Rapid Acting	Note: no changes from the Nov 2024 meeting Use of insulin aspart (Novolog) and insulin lispro (Humalog or authorized unbranded biologics) have resulted in therapeutic failure Formulary Alternatives: insulin aspart (Novolog) and insulin lispro (Humalog or authorized unbranded biologics)
New Drugs MN Criteria	
aproцитentan (Tryvio) Antihypertensive Agent: Endothelin Receptor Antagonists	- 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: spironolactone, eplerenone, alpha blocker (ex. doxazosin), beta blocker (ex. metoprolol succinate, bisoprolol, carvedilol), amiloride, and hydralazine
clonidine ER caps (Onyda XR) ADHD Agents: Non-Stimulants	- Use of formulary agents is contraindicated - Formulary agents resulted in therapeutic failure - No alternative formulary agent: cannot swallow tablets Formulary alternatives: atomoxetine (Strattera, generic), clonidine ER (Kapvay, generic), guanfacine ER (Intuniv)

Appendix B—Table of Medical Necessity Criteria

ensifentrine (Ohtuvayre) Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease	- 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: Breztri, Trelegy
norethindrone acetate/ ethinyl estradiol ODT (Femlyv) Contraceptive Agents: Monophasics w/20 mcg Estrogen	No alternative formulary agent: patient requires Femlyv ODT due to established difficulties with chewing and swallowing, and inability to use non-oral dosage forms (e.g., ring, patch, injection). Submit documentation Formulary alternatives: norethindrone/EE (generic Loestrin, Aurovela, Microgestin, Junel, Larin or equivalent); etonogestrel/EE ring (generic NuvaRing); norelgestromin/EE patch (Xulane, Zafemy); and medroxyprogesterone acetate injection (generic Depo-Provera)
sofipironium topical gel (Sofdra) Antiperspirants	- 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: topical 20% or higher aluminum salt solution (e.g., Drysol), glycopyrronium (Qbrexza cloth), Botox
Vadadustat (Vafseo) Hematological Agents: RBC Stimulants Erythropoietin	- 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 (Procrit, Epogen, Retacrit), darbepoetin alfa (Aranesp)
xanomeline/ trospium (Cobenfy) Antipsychotic Agents: Atypical	- Use of formulary agents is contraindicated - Patient has experienced significant adverse effects from formulary agents - Use of formulary agents resulted in therapeutic failure - Patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk - No alternative formulary agent – patient has tried the 2 formulary alternatives AND has a history of schizophrenia with acute psychosis requiring hospitalization Formulary alternatives: one second generation antipsychotic (e.g., aripiprazole, lurasidone, olanzapine, ziprasidone), one first generation antipsychotic (e.g., haloperidol)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
ixekizumab (Taltz) TIBs: IL-17 Subclass	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to all new users of ixekizumab (Taltz) <u>Automated PA Criteria:</u> When prescribed by a dermatologist prior dermatologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. OR <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) or secukinumab (Cosentyx) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND <u>Manual PA Criteria:</u> If automated PA criteria are not met coverage is ~~Humira, Cosentyx, AND, Stelara Step:~~ ~~Contraindication/inadequate response exists to Humira, Cosentyx, AND, Stelara~~ ~~Adverse reactions to Humira, Cosentyx, AND, Stelara not expected with requested non-step preferred TIB~~ - Patients ≥ 18 years of age or older with: - Active psoriatic arthritis (PsA) - Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy (Note: Humira step requirement does not apply) - Active ankylosing spondylitis (AS) - Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation - Pediatric patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy (6 years of age or older) (Note: Humira step does not apply) Patient had an inadequate response to Humira OR had an adverse reaction to Humira that is not expected to occur with Taltz the requested agent OR has a contraindication to Humira (Note: Applies to PsA, AS, nr-axSpA) ~~Has the p~~ Patient had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosaliclates [e.g. sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine], etc.) (Note: AS and nr-axSpA 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 and nr-axSpA) ~~Negative TB test result in past 12 months (or TB adequately managed)~~ - Coverage is NOT provided for concomitant use with other TIBs including, but not limited to: ~~adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade)~~ TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA-approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

secukinumab (Cosentyx) TIBs: IL-17 Subclass	Updates from the November 2024 meeting are in bold and strikethrough. 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~~ <u>Manual PA Criteria:</u> ~~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 provider acknowledges that Taltz is the Department of Defense's preferred interleukin-17 (IL-17) agent. A trial of Humira and Taltz are required before Cosentyx. The patient must have tried Humira AND Taltz:~~ - The patient had an inadequate response to Humira and Taltz OR - The patient experienced an adverse reaction to Humira and Taltz that is not expected to occur with Cosentyx OR - The patient has a contraindication to Humira and Taltz Note that a trial of Taltz is not required for patients with a diagnosis of generalized pustular psoriasis (GPP), enthesitis-related arthritis (ERA), hidradenitis suppurative (HS) or for pediatric patients with psoriatic arthritis. - Coverage is approved for patients 18 years of age or older with one of the following diagnosis/indications: - Active psoriatic arthritis (PsA) - Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past - Moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy - Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation - Active ankylosing spondylitis (AS) - Moderate to severe hidradenitis suppurativa (HS) - OR Coverage approved for pediatric patients with one of the following diagnosis/indications: - Moderate to severe plaque psoriasis in patients 6 years of age or older who are candidates for systemic therapy or phototherapy - Enthesitis-related arthritis (ERA) in patients 4 years of age or older - Active psoriatic arthritis in patients 2 years of age or older - Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past in patients 12 years of age or older - The criteria below apply to all patients unless noted: For plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa, and generalized pustular psoriasis: Patient has had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], antibiotics, anti-androgens, etc.) (Note: does not apply to AS, nr-axSpA, or ERA indications)
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Appendix C—Table of Prior Authorization (PA) Criteria

	▪ For ankylosing spondylitis and non-radiographic axial spondyloarthritis: Patient has had an inadequate response to at least two NSAIDs over a period of at least two months • Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Otezla, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA-approved uses are not approved, except as noted above Prior Authorization does not expire
• brodalumab (Siliq) TIBs: IL-17 Subclass	Updates from the November 2024 meeting are in bold and strikethrough. PA criteria apply to all new users of brodalumab (Siliq) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • The provider acknowledges that Taltz is the Department of Defense's preferred interleukin-17 (IL-17) agent. A trial of Humira, Taltz and Cosentyx are required before Siliq • ~~The patient must have tried Humira, Cosentyx, Stelara, Tremfya, Ilumya AND Taltz first~~ are required steps: ▪ Patient had an inadequate response to Humira, Cosentyx, ~~Stelara, Tremfya, Ilumya~~ AND Taltz OR ▪ Patient had an adverse reaction to Humira, Cosentyx, ~~Stelara, Tremfya, Ilumya~~ AND Taltz that is not expected to occur with the requested agent OR ▪ Patient has a contraindication to Humira, Cosentyx, ~~Stelara, Tremfya, Ilumya~~ AND Taltz AND • Patient is 18 years of age or older • Patient has moderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy • ~~Patient does not currently have or has not had a history of Crohn's disease~~ • Patient does not have suicidal ideation and behavior (~~SIB~~) • Patient had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosaliclates [e.g. sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine], 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 the requested agent, including but not limited to the following: ~~Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Otezla, Rinvoq ER, Rituxan, Siliq, Simponi, Skyrizi, Stelara, Taltz, Tremfya or Xeljanz/Xeljanz XR~~ TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA approved uses are not approved PA expires in 6 months, then approved indefinitely <u>Renewal criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for another year if all the criteria are met: • Patient has responded to therapy and has not had suicidal ideation

Appendix C—Table of Prior Authorization (PA) Criteria

bimekizumab (Bimzelx) TIBs: IL-17 Subclass	Updates from the November 2024 meeting are in bold and strikethrough. PA criteria apply to all new users of bimekizumab-bkzx (Bimzelx) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: The provider acknowledges that Taltz is the Department of Defense's preferred interleukin-17 agent. ~~Humira-Taltz is the Department of Defense's preferred targeted biologic where patient must try Taltz-Humira. The patient must have tried Taltz, Humira and Cosentyx.~~ - The patient had an inadequate response to Humira OR - The patient experienced an adverse reaction to Humira that is not expected to occur with Bimzelx OR - The patient has a contraindication to Humira and - Patient had inadequate response to Stelara Taltz OR had adverse reaction to Stelara Taltz that is not expected to occur Bimzelx OR has a contraindication to Stelara Taltz AND - Patient had an inadequate response to Cosentyx OR had an adverse reaction to Cosentyx that is not expected to occur with Bimzelx OR patient has a contraindication to Cosentyx AND - Patient is 18 years of age or older with: - Moderate to severe plaque psoriasis who is a candidate for systemic therapy or phototherapy Active psoriatic arthritis Active ankylosing spondylitis Active non-radiographic axial spondyloarthritis with objective signs of inflammation For plaque psoriasis and psoriatic arthritis: Patient had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) (Note: AS and nr-axSpA indications do not apply) ~~Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ For ankylosing spondylitis and non-radiographic axial spondyloarthritis: Patient has had an inadequate response to at least two NSAIDs over a period of at least two months - 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 TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
ustekinumab (Stelara) TIBs: IL-23 Subclass	Updates from the November 2024 meeting are in bold and strikethrough. PA criteria apply to all new users of ustekinumab (Stelara) ~~Note that Humira is the Department of Defense's preferred targeted biologic agent.~~ <u>Automated PA criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. <u>Manual PA criteria:</u> If automated PA criteria are not met, coverage is approved if all criteria are met:

Appendix C—Table of Prior Authorization (PA) Criteria

	• Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira ▪ The patient had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with Stelar OR ▪ The patient has a contraindication to Humira • Coverage approved for patients ~~≥18~~ 18 years of age or older with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ▪ Moderately to severely active Crohn's disease ~~who have failed or intolerant to immunomodulators, corticosteroids, or Humira.~~ ▪ Moderately to severely ulcerative colitis (UC); ~~infliximab may be used first in lieu of Humira~~ • Coverage approved for patients ages 6 to 17 years with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy • The criteria below apply to all patients unless noted: ▪ ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Crohn's Disease) ▪ Coverage is NOT provided for concomitant use with other TIBs including, but not limited to ~~adalimumab (Humira), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade)~~ TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA-approved uses are not approved PA does not expire
• guselkumab (Tremfya) TIBs: IL-23 Subclass	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to all new users of guselkumab (Tremfya) <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~~ • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira ▪ Patient had an inadequate response to Humira OR ▪ Patient had adverse reaction to Humira that is not expected to occur with Tremfya OR ▪ Patient has a contraindication to Humira ~~AND~~ • ~~Patient had inadequate response to Stelara OR had adverse reaction to Stelara that is not expected to occur with the requested agent OR has a contraindication to Stelara AND~~ • ~~Patient had inadequate response to Cosentyx OR had adverse reaction to Cosentyx that is not expected to occur with the requested agent OR has a contraindication to Cosentyx AND~~ • Patient is 18 years of age or older with the following diagnoses/indications:

Appendix C—Table of Prior Authorization (PA) Criteria

	- Active psoriatic arthritis (PsA) - Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy - Moderate to severely active ulcerative colitis (UC) (~~Note: Cosentyx stop not required~~) - Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosaliclates, (e.g. sulfasalazine, mesalamine), corticosteroids, immunosuppressants e.g., azathioprine). Note does not apply to Chron's disease) ~~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 concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors 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
tildrakizumab (Ilumya) TIBs: IL-23 Subclass	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to all new users of tildrakizumab (Ilumya) <u>Automated PA Criteria:</u> When prescribed by a dermatologist prior authorization is not required. Once therapy is initiated by a dermatologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. OR Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail pharmacies, or mail order) during the previous 180 days. <u>Manual PA criteria:</u> If automated criteria are not met, coverage is approved if all criteria are met: Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira ~~Humira is the Department of Defense's preferred targeted biologic agent where patient must try Humira~~ - Patient had an inadequate response to Humira OR - Patient had an adverse reaction to Humira that is not expected to occur with Ilumya OR - Patient has a contraindication to Humira AND ~~Patient had inadequate response to Stelara OR had adverse reaction to Stelara that is not expected to occur with the requested agent OR has a contraindication to Stelara AND~~ ~~Patient had inadequate response to Cosentyx OR had adverse reaction to Cosentyx that is not expected to occur with the requested agent OR has a contraindication to Cosentyx AND~~ - Patient is 18 years of age or older with the following diagnoses/indications: - Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy - Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosaliclates, corticosteroids, immunosuppressants etc.)

Appendix C—Table of Prior Authorization (PA) Criteria

	~~• 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 concurrently, including but not limited to the following: : TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors ~~Aeterna, 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
• risankizumab (Skyrizi) pens, syringes TIBs: IL-23 Subclass	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to all new users of risankizumab (Skyrizi) pens and syringes Manual PA Criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira ▪ The patient has had an inadequate response to Humira ~~Cosentyx, AND Stelara~~ OR ▪ The patient has had an adverse reaction to Humira ~~Cosentyx, AND Stelara~~ that is not expected with Skyrizi the requested ~~non-step preferred~~ TIB AND ▪ The patient has a contraindication to Humira, ~~Cosentyx AND Stelara~~ AND • Patient is 18 years or older with the following diagnosis/indication: ▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy • Patient has tried and had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (e.g., methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) • Coverage NOT provided for concomitant use with other TIBs, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors ~~• The patient has had a negative TB test result in past 12 months (or TB is adequately managed)~~ • For treatment of plaque psoriasis or psoriatic arthritis providers should fill out the PA for Skyrizi pen and syringes. Use of the on-body injector is limited to Crohn's disease or ulcerative colitis. Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

risankizumab (Skyrizi OBI), on-body injector TIBs: IL-23 Subclass	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to all new users of risankizumab (Skyrizi) On-Body Injector (Skyrizi OBI). <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: Provider acknowledges a trial of Humira is required before Skyrizi OBI - The patient has had an inadequate response to Humira ~~AND Stelara~~ OR - The patient has had an adverse reaction to Humira, ~~AND Stelara~~ that is not expected with Skyrizi ~~the requested non-step preferred TIB~~ OR - The patient has a contraindication or has had an inadequate response to Humira ~~AND Stelara~~ AND - Patient is 18 years of age or older ~~≥ 18~~-years old with the following diagnoses: - Moderately to severely active Crohn's disease - Moderately to severely active ulcerative colitis - Patient has tried and had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy (e.g., methotrexate, aminosaliclates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g. azathioprine]) (Note: does not apply to CD) - Coverage not provided for concomitant use with other TIBs, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors ~~The patient has had a negative TB test result in past 12 months (or TB is adequately managed)~~ Use of the on-body injector for non-FDA-approved indications including plaque psoriasis, or psoriatic arthritis is not approved. Providers should fill out the PA for Skyrizi pen and syringes for indications other than Crohn's disease or ulcerative colitis. Non-FDA approved uses are not approved PA does not expire
mirikizumab (Omvoh) TIBs: IL-23 Subclass	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to all new users of Omvoh <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: ~~Humira is the Department of Defense's preferred targeted biologic agent for ulcerative colitis~~ Provider acknowledges that a trial of Humira, Stelara, Tremfya AND Skyrizi are required before Omvoh - Patient had inadequate response to Humira, Stelara, Tremfya, and Skyrizi OR - Patient had adverse reaction to Humira, Stelara, Tremfya, and Skyrizi that is not expected to occur with Omvoh ~~the requested agent~~ OR - Patient has a contraindication to Humira, Stelara, Tremfya, and Skyrizi - Patient is 18 years of age or older with a diagnosis of: - Moderate to severely active ulcerative colitis - Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc.

Appendix C—Table of Prior Authorization (PA) Criteria

	• ~~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: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors 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
• atogepant (Qulipta) Migraine Agents: Oral CGRP Antagonists	Updates from the November 2024 meeting are in bold. PA criteria apply to all new users of Qulipta. <u>Automated PA Criteria:</u> The patient has filled a prescription for galcanezumab 120 mg (Emgality), erenumab (Aimovig), or fremanezumab (Ajovy) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE Mail Order Pharmacy) during the previous 720 days. <u>Manual PA criteria:</u> If automated criteria are not met, Qulipta is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrovelvy, Nurtec ODT or another gepant) is not allowed • Patient has a diagnosis of chronic migraine OR • Patient has Episodic Migraine as defined by the following: ▪ 4 to 7 migraine days per month for 3 months AND has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR ▪ 8 to 14 migraine days per month for 3 months • Patient has a contraindication to, intolerance to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: ▪ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate ▪ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol ▪ Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine • Patient has a contraindication to, intolerance to, or has failed a 2-month trial of one of these injectable CGRPs: ▪ erenumab-aooe (Aimovig) ▪ fremanezumab-vfrm (Ajovy) ▪ galcanezumab-gnlm (Emgality) Non-FDA-approved uses are not approved PA expires after 6 months

Appendix C—Table of Prior Authorization (PA) Criteria

	<u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal.) Coverage will be approved indefinitely for continuation of therapy if one of the following apply: - The patient has had a reduction in mean monthly headache days of $\geq 50\%$ relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR - The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: - Migraine Disability Assessment (MIDAS) - Reduction of ≥ 5 points when baseline score is 11–20 - Reduction of $\geq 30\%$ when baseline score is > 20 - Headache Impact Test (HIT-6): Reduction of ≥ 5 points - Migraine Physical Functional Impact Diary (MPFID): Reduction of ≥ 5 points
rimegepant (Nurtec ODT) Migraine Agents: Oral CGRP Antagonists	Changes from the November 2024 meeting are in bold and strikethrough PA apply to all new and current users of Nurtec ODT <u>Manual PA Criteria:</u> Nurtec ODT is approved if all criteria are met: <u>For Both Acute Treatment and Prevention</u> - The patient is 18 years of age or older - Medication is prescribed by or in consultation with neurologist - Concurrent use with any other small molecule CGRP targeted medication (i.e., Ubrelvy or another gepant) is not allowed <u>For Acute Treatment</u> - Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications - sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) AND Patient has a contraindication to, intolerability to, or has failed a trial of Ubrelvy <u>For Prevention of Episodic Migraine</u> - The patient has episodic migraine as defined by one of the following: - Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR - Patient has episodic migraine at a rate of at least 8 migraine days per month for 3 months - Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: - Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate - Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol - Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine - Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents - erenumab-aooe (Aimovig) - fremanezumab-vfrm (Ajovy)

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	▪ galcanezumab-gnlm (Emgality) • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of Qulipta. OR • It the patient is currently stable on Nurtec ODT for prevention of episodic migraine, then a trial of Qulipta is not required if a new PA is submitted • If approved for prevention: authorized quantity limit is 16 ODT for 30 days or 48 ODT for 90 days Non-FDA-approved uses are not approved. PA expires after 6 months. <u>Renewal Criteria:</u> (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply: <u>Acute Treatment</u> • Patient has a documented positive clinical response to therapy <u>Preventive Treatment</u> • The patient has had a reduction in mean monthly headache days of $\geq 50\%$ relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR • The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: ▪ Migraine Disability Assessment (MIDAS) - Reduction of ≥ 5 points when baseline score is 11–20 - Reduction of $\geq 30\%$ when baseline score is > 20 ▪ Headache Impact Test (HIT-6): Reduction of ≥ 5 points ▪ Migraine Physical Functional Impact Diary (MPFID): Reduction of ≥ 5 points
• ubrogepant (Ubrelvy) Migraine Agents: Oral CGRP Antagonists	Updates from the November 2024 meeting are in bold PA criteria apply to all new users of ubrogepant (Ubrelvy). <u>Automated PA criteria:</u> The patient has filled a prescription for rimegepant (Nurtec ODT) or any formulation of a triptan at any MHS point of service (MTFs, Retail pharmacies, or TRICARE Mail Order Pharmacy during the previous 180 days. <u>Manual PA criteria:</u> If automated criteria are not met, Ubrelvy is approved if all criteria are met: • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or another gepant) is not allowed • Patient has a contraindication to, intolerability to, or has failed a trial of at least TWO of the following medications ▪ sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), eletriptan (Relpax) Non-FDA-approved uses are not approved. ~~PA expires after 6 months~~ PA does not expire ~~Renewal Criteria: Coverage will be approved indefinitely for continuation of therapy if the following criteria is met (Note that initial TRICARE PA approval is required for renewal):~~ ~~Acute Treatment: Patient has a documented positive clinical response~~

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- insulin lispro (Admelog) - insulin glulisine (Apidra) Insulins: Rapid-Acting	Note: No changes from the Nov 2024 meeting <u>Automated PA Criteria:</u> The patient has filled a prescription for insulin aspart (Novolog) and insulin lispro (Humalog or authorized generic lispro) at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days <u>Manual PA criteria:</u> if automated criteria are not met, Apidra or Admelog is approved if all criteria are met: - Provider acknowledges Novolog, Humalog and the authorized generic insulin lispro are the DoD's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, prior authorization is not required. - The patient has diabetes AND - The patient has tried and failed insulin aspart (Novolog AND - The patient has tried and failed insulin lispro (Humalog or authorized generic insulin lispro) - OR - The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog) Non-FDA-approved uses are not approved PA does not expire
Newly Approved Drug PAs	
apocritentan (Tryvio) Antihypertensive Agents: Endothelin Receptor Agonists	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of Tryvio <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - The patient is 18 years of age or older - The drug is prescribed by a hypertension specialist (for example: internal medicine, cardiologist, nephrologist, or prescriber with certification from the American Society of Hypertension) - Patient has systolic blood pressure of greater than 140 mmHg - Patient has tried at least three antihypertensive medications from the following classes one of which must be a diuretic, taken at maximally tolerated doses - diuretic - renin-angiotensin system blockers (e.g., ACE inhibitor or ARB blocker) - calcium channel blockers - mineralocorticoid receptor blocker (e.g., spironolactone) ~~If patient is a female or child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation~~ ~~If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation~~ Women of child-bearing age will be tested for pregnancy Provider is enrolled in the Risk Evaluation and Mitigation System (REMS) program Non-FDA approved uses are not approved, including for pulmonary arterial hypertension. ~~PA does not expire.~~ PA expires in one year

Appendix C—Table of Prior Authorization (PA) Criteria

	Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met • Tryvio treatment has controlled blood pressure within goal range • Provider continues to be enrolled in the Risk Evaluation and Mitigation Strategies program
• carbidopa-levodopa XR (Crexont) Parkinson's Agents	Manual PA criteria apply to all new users of Crexont <u>Manual PA criteria:</u> Crexont is approved if: • Patient has tried and failed generic controlled release formulation of carbidopa/levodopa Non-FDA-approved uses are not approved PA does not expire
• clonidine XR oral suspension (Onyda XR) ADHD Agents: Non-stimulants	Manual PA criteria apply to all new users of Onyda XR <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 6 years of age or older • Patient has diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) • Patient has tried and failed, had an inadequate response, OR contraindication to all of the following: ▪ amphetamine salts XR (Adderall XR, generic) or other long-acting amphetamine or derivative drug ▪ methylphenidate OROS (Concerta, generic) or other long-acting methylphenidate or derivative drug ▪ non-stimulant ADHD medication (generic formulation of Strattera or Intuniv) ▪ generic clonidine HCL extended-release tablet OR • A trial of a non-stimulant medication is not required if the patient cannot swallow due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis, autism spectrum disorder, etc). Non-FDA approved uses are not approved PA does not expire
• ensifentrine nebulized inhalation suspension (Ohtuvayre) Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of ensifentrine (Ohtuvayre) <u>Manual PA criteria:</u> Coverage 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 pulmonologist • Patient has moderate to severe COPD (i.e., ~~GOLD 2 [moderate]~~ or ~~GOLD 3 [severe]~~ airflow obstruction as demonstrated by Forced Expiratory Volume 1 second (FEV1) ranging between 30% to 80% • ~~Prescriber affirms that ensifentrine is only to be used as add on therapy to one of the following inhaler: LAMA, LABA, LAMA/LABA, or LAMA/LABA/ICS~~ • Patient has tried and failed, defined as uncontrolled symptoms, with either of the following treatments: ▪ LAMA/LABA (Bevespi Aerosphere, Stiolto Respimat, Anoro Ellipta) or ▪ LAMA/LABA/ICS (Breztri Aerosphere, Trelegy Ellipta) AND

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	• Ensifentrine will only be used as add on therapy to LAMA, LABA LAMA/LABA or LAMA/LABA/ICS Non-FDA approved uses are not approved PA does not expire. PA expires in 12 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• lazertinib (Lazcluze) Epidermal Growth Factor Receptor (EGFR) plus Non-small Cell Lung Cancer (NSCLC)	Manual PA criteria apply to all new users of lazertinib (Lazcluze) <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 a hematologist/oncologist • Patient has a diagnosis of locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutation • The medication will be prescribed in combination with amivantamab (Rybrevant) • The patient will be given prophylaxis for the prevention of venous thromboembolism during the first four months 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. To facilitate approval, please list the diagnosis, guideline version and page number: _____. Non-FDA approved uses are not approved except as noted above PA does not expire
• lebrikizumab-lbkz (Ebglyss) Atopy Agents	Manual PA criteria apply to all new users of lebrikizumab-lbkz (Ebglyss) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 12 years of age or older • Patient's weight is 40 kg or greater • The drug is prescribed by a dermatologist, allergist or immunologist • Patient has diagnosis of moderate to severe atopic dermatitis • Patient has contraindication to, intolerance 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) or - For patients 12 to 17 years of age: any topical corticosteroid ▪ topical calcineurin inhibitors (i.e., tacrolimus, pimecrolimus) • Patient has contraindication to, intolerance to, inability to access treatment, or patient failed treatment with Narrowband UVB phototherapy • For all indications the patient is not currently receiving another immunobiologic therapy Non-FDA approved uses are not approved. PA expires after 12 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:

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	• Patient's disease severity has improved and stabilized to warrant continued therapy
• levacetylleucine (Aqneursa) Neurological Agents Miscellaneous	Manual PA criteria apply to all new users of levacetylleucine (Aqneursa) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient weighs 15 kilograms or greater • Prescribed by a physician who specializes in the treatment of Niemann-Pick disease type C • Patient has a genetically confirmed diagnosis of Niemann-Pick disease type C • Patient has one or more neurologic symptoms (e.g., loss of motor function, difficulty swallowing, and speech and cognitive impairment) • Concomitant use of this medication with arimoclomol (Miplyffa) is not allowed Non-FDA approved uses are not approved PA does not expire
• norethindrone acetate/ethinyl estradiol ODT (Femlyv) Contraceptive Agents: Monophasics with 20mcg Estrogen	Manual PA criteria apply to all new users of norethindrone acetate and ethinyl estradiol orally disintegrating tablets (Femlyv) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that other formulations of ethinyl estradiol (EE) 20 mcg/ norethindrone 1 mg (e.g., Loestrin, Aurovela, Microgestin, Junel, Larin or equivalent) are on the formulary and do not require prior authorization • Provider acknowledges that there are chewable contraceptive tablets (norethindrone 1 mg/EE 20 mcg/iron (e.g., Charlotte 24 Fe, Finzala, Mibelas 24 Fe); norethindrone 0.8mg/EE 25 mcg (e.g., Kaitlib Fe, Layolis Fe); norethindrone 0.4mg/EE 35 mcg/iron (e.g., Wymzya Fe)) and alternate dosage forms (etonogestrel/EE ring (generic NuvaRing); norelgestromin/EE patch (Xulane, Zafemy); and medroxyprogesterone acetate injection (generic Depo-Provera) on the formulary that do not require prior authorization • Patient has tried and failed or has a relative contraindication to a contraceptive from one of the following classes: chewable, patch, ring, injection, or IUD • Patient requires oral disintegrating tablets and can neither chew nor swallow due to some documented medical condition (e.g., developmental disability, muscular weakness, etc.) and not due to convenience Non-FDA approved uses are not approved PA does not expire
• nemolizumab-ilto (Nemluvio) TIBs: Miscellaneous Interleukins	Manual PA criteria apply to all new users of nemolizumab (Nemluvio) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Nemluvio is prescribed by an allergist, immunologist, or dermatologist • Patient has a diagnosis of prurigo nodularis • Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk • Patient has experienced pruritus for 6 weeks or longer • Patient's prurigo nodularis is not medication-induced or secondary to a nondermatologic condition OR the patient has a secondary

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	cause of prurigo nodularis that has been identified and adequately managed - The patient has a contraindication to, intolerance to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) - The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with phototherapy Non-FDA approved uses are not approved. PA does not expire.
palopegteriparatide (Yorvipath) Osteoporosis Agents	Manual PA criteria apply to all new users of palopegteriparatide (Yorvipath) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed or in consultation with endocrinologist - Patient has a diagnosis of chronic hypoparathyroidism; based on hypocalcemia in the setting of inappropriately low serum PTH levels - Patient cannot be well-controlled on calcium supplements and active forms of vitamin D - Patient has an albumin-corrected serum calcium concentration greater than or equal to 7.8 mg/dL at baseline OR ionized serum calcium greater than or equal to 4.4 mg/dL at baseline - Patient does not have acute post-surgical hypoparathyroidism Non-FDA approved uses are not approved PA does not expire
seladelpar (Livdelzi) Gastrointestinal-2 Agents	Manual PA criteria apply to all new users of seladelpar (Livdelzi) <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 a gastroenterologist, hepatologist or liver transplant physician - Patient has a diagnosis of primary biliary cholangitis (PBC) - Diagnosis has been confirmed by at least TWO of the following: - alkaline phosphatase (ALP) elevated above the upper limit of normal (ULN) as defined by normal laboratory reference values - positive anti-mitochondrial antibodies (AMAs) - histologic evidence of PBC from a liver biopsy - Patient does not have decompensated cirrhosis - Patient has been receiving ursodiol therapy for one year or greater and has had an inadequate response OR has been unable to tolerate ursodiol therapy - Patient has a contraindication to, intolerance to, or has failed a trial of obeticholic acid (Ocaliva) Non-FDA approved uses are not approved PA expires after 6 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: - Patient has responded to the requested medication as determined by the prescribing physician (for example, improved biochemical markers of PBC: alkaline phosphatase, bilirubin, gamma-glutamyl

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	transpeptidase, aspartate aminotransferase, alanine aminotransferase)
sofipironium topical gel (Sofdra) Antiperspirants	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of sofipironium (Sofdra) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 9 years of age or older - Patient has diagnosis of primary axillary hyperhidrosis for greater than or equal to 6 months - The drug is prescribed by a dermatologist - Patient has tried and failed at least one topical 20% or higher aluminum salt antiperspirant (either OTC or prescription; e.g., Drysol) - Patient has tried and failed at least ~~one~~ two additional options (e.g. Botox, MiraDry, iontophoresis, oral anticholinergics [glycopyrrolate, oxybutynin, propantheline], propranolol, clonidine or diltiazem) Non-FDA approved uses are not approved, including for palmar, plantar, facial, or other forms of hyperhidrosis PA does not expire
vadadustat (Vafseo) Hematological Agents Red Blood Cell (RBC) Stimulants: Erythropoietin	Manual PA criteria apply to all new users of vadadustat (Vafseo) <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 agents (ESA) for TRICARE and is available without prior authorization - 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 experienced an inadequate response or adverse reaction to Retacrit - Patient has been receiving dialysis for at least 3 months - Provider is aware of the warnings, screening and monitoring precautions for Vafseo Non-FDA approved uses are not approved PA expires in 6 months <u>Renewal Criteria:</u> Note that initial Tricare PA approval is required for renewal. After six months, PA must be resubmitted. Continued use of Vafseo will be approved indefinitely for the following: - The patient has had a positive response to therapy (i.e., increase or stabilization in hemoglobin levels or a reduction or absence in red blood cell transfusions.
vorasidenib (Vorango) Oncological Agents	Manual PA criteria apply to all new users of vorasidenib (Voanigo) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 12 years of age or older - Prescribed by or in consultation with an oncologist - Patient has diagnosis of Grade 2 astrocytoma or oligodendroglioma and had surgery, including biopsy, sub-total resection, or gross total resection - Patient has IDH1 or IDH2 mutations as demonstrated by an FDA-approved test - 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. To facilitate approval, please list the diagnosis, guideline version, and page number: _____

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	Non-FDA approved uses are not approved, except as noted above. PA does not expire.
xanomeline/trospium chloride (Cobenfy) Antipsychotic Agents: Atypical	Updates from the current PA criteria are in bold and strikethrough Manual PA criteria apply to all new users of xanomeline/trospium chloride (Cobenfy) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient is 18 years of age or older - Prescribed by a psychiatrist - Patient has an established, primary diagnosis of schizophrenia - Patient has a history of acute exacerbations OR relapses of psychotic symptoms which have failed to respond to ONE SECOND generation antipsychotic at maximally tolerated doses - Patient has a history of acute exacerbations OR relapses of psychotic symptoms which have failed to respond to ONE FIRST generation antipsychotic at maximally tolerated doses - Patient is being treated for an acute exacerbation or relapse of psychotic symptoms ~~Patient has Positive and Negative Syndrome Scale (PANSS) total score between 80 and 120~~ Non-FDA approved uses are not approved. PA does not expire
Utilization Management PAs	
everolimus (Torpenz) Oncological Agents: Renal Cell Carcinoma	Manual PA criteria apply to all new & current users of everolimus tablets (Torpenz). <u>Manual PA criteria:</u> everolimus (Torpenz) is approved if all criteria are met: - Provider acknowledges that this drug has been identified as having cost-effective alternatives and everolimus (Afinitor, generics) is available without prior authorization - Provider must explain why the patient cannot use everolimus (Afinitor, generics) - Acceptable responses include if the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in everolimus (Afinitor, generics) Non-FDA approved uses are not approved PA does not expire
methocarbamol 1,000 mg tablet Skeletal Muscle Relaxants and Combinations	Updates from the November 2024 meeting are in bold and strikeout. Manual PA criteria apply to all new and current users of methocarbamol 1,000 mg tablets (generics, Tanlor) <u>Manual PA criteria:</u> methocarbamol 1,000 mg tablet is approved if all criteria are met: - Provider acknowledges that this drug has been identified as having cost-effective alternatives including methocarbamol 500 mg or 750 mg. These agents are available without a PA. - The provider must explain why this agent is required and the patient cannot use methocarbamol 500 mg or 750 mg ~~take the formulary alternatives formulations of methocarbamol.~~ - Acceptable responses include the patient has trialed and failed methocarbamol 500 mg or 750 mg AND cyclobenzaprine 5 mg or 10 mg Non-FDA-approved uses are not approved. Prior authorization does not expire

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ondansetron 16 mg ODT Antiemetic-Antivertigo Agents	Manual PA criteria apply to all new and current users of ondansetron 16 mg ODT. <u>Manual PA criteria:</u> ondansetron 16 mg ODT is approved if <u>ALL</u> criteria are met: - Provider acknowledges that this drug has been identified as having cost-effective alternatives and ondansetron 4 mg and 8 mg tablets and ODTs are available without prior authorization - Provider must explain why the patient cannot use preferred formulations of ondansetron - Acceptable responses include if the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in preferred formulations of ondansetron Non-FDA approved uses are NOT approved PA does not expire
adagrasib (Krazati) Oncological Agents: Lung Cancer	Updates from the November 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of adagrasib (Krazati) <u>Manual PA criteria:</u> 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 - The patient has a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) ~~as determined by an FDA-approved test~~ OR To drug is used to treat KRAS G12C-mutated locally advanced or metastatic CRC in combination with cetuximab, in patients who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy ~~The patient will be monitored for QTC prolongation, gastrointestinal adverse reactions, hepatotoxicity, and interstitial lung disease~~ ~~If patient is a female, the patient will avoid breastfeeding during treatment and for at least 1 week after 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.~~ To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire
olaparib (Lynparza) Oncologic Agents: Ovarian Cancer	Updates from the November 2024 meeting are in bold and strikethrough. Manual PA criteria applies to all new users of Lynparza <u>Manual PA Criteria:</u> Lynparza 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 hematologist/oncologist or urologist - Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test (see prostate diagnosis with HRR mutation below for exception) - Lynparza will be prescribed as treatment for one of the following diagnoses: - Recurrent or Stage IV Triple negative breast cancer

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	▪ 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 & – 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: ▪ 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, please list the diagnosis.~~ To facilitate approval, please list the diagnosis, guideline version and page number _____. ~~• 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 except as noted above PA does not expire
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repotrectinib (Augtyro) Oncological Agents	Updates from the November 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of repotrectinib (Augtyro) <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~~ is an adult with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) • Patient is 12 years of age or older with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative ~~• 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. ~~If so, please list the diagnosis:~~ To facilitate approval, please list the diagnosis, guideline version and page number _____. ~~• 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
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Appendix C—Table of Prior Authorization (PA) Criteria

• selpercatinib (Retevmo) Oncological Agents: Lung Cancer	Updates from the November 2024 meeting are in bold and strikethrough Manual PA apply to all new users of Retevmo <u>Manual PA Criteria:</u> Retevmo is approved if all criteria are met: • Retevmo is prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following indications: ▪ Adult patients with locally advanced or metastatic ~~RET fusion-positive~~ non-small cell lung cancer (NSCLC) ▪ Patients ~~12~~ two years of age and older with advanced or metastatic ~~RET-mutant~~ medullary thyroid cancer (MTC) with a RET mutation who require systemic therapy ▪ Patients ~~12~~ two years of age and older with advanced or metastatic ~~RET fusion-positive~~ thyroid cancer with a RET gene fusion who require systemic therapy and who are radioactive iodine refractory (if radioactive iodine is appropriate) • ~~Adult patients~~ Patients 2 years of age and older with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options • ~~Patient will be monitored for hepatotoxicity and QT prolongation~~ • ~~Patient does not have uncontrolled hypertension~~ • ~~Provider is aware and has counseled patient that Retevmo can cause life threatening hemorrhage and allergic reactions~~ • ~~Female patients of childbearing age are not pregnant confirmed by (–) HCG~~ • ~~Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~ • ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA approved uses are NOT approved except as noted above Prior authorization does not expire
• apremilast (Otezla) TIBs: Non-TNFs	Updates from the November 2024 meeting are in bold and strikethrough. <u>Automated PA Criteria:</u> The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. Manual PA criteria applies to new users of apremilast (Otezla) <u>Manual PA Criteria:</u> Coverage approved for patients: • Coverage approved for patients 18 years of age or older with a diagnosis of: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy ▪ Oral ulcers associated with Behçet's disease (Note: Humira not required for Behçet's disease)

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	▪ Mild plaque psoriasis in patients who are candidates for systemic therapy or phototherapy if the following criteria are met: (Note: Humira not required for mild plaque psoriasis) – The patient has a contraindication to, intolerance to, or has failed treatment with medications from at least TWO of these THREE categories: • Moderate to High Potency Topical Corticosteroids (class 1 – class 5) e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream, betamethasone dipropionate 0.05% cream/lotion/ointment, etc. • Steroid Sparing Agents: Vitamin D analogs (e.g. calcipotriene and calcitriol), tazarotene, or topical calcineurin inhibitors (e.g. tacrolimus and pimecrolimus) • Other Topicals: emollients, salicylic acid, anthralin, or coal tar AND – The patient has a contraindication to, intolerance to, inability to access treatment, or has failed treatment with phototherapy • Coverage approved for patients ages 6 to 17 years with: ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy and who also weigh at least 20 kg • The below criteria apply to all patients unless noted: ▪ 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 (Note: Does not apply to mild plaque psoriasis or Behçet's disease) ▪ Patient has had an inadequate response to nonbiologic systemic therapy (for example – methotrexate, aminosaliclates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine). (Note: Does not apply to Behçet's disease) ▪ Will Otezla be prescribed in combination with Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kevzara, Kineret, Olumiant, Orencia, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, or Xeljanz/Xeljanz XR? – If yes: Fill in the blank write-in referencing literature to support combination, and attest patient will be monitored closely for adverse effects. Non-FDA-approved uses are not approved. PA does not expire
• benralizumab (Fasenra) Atopy	Updates from the November 2024 meeting are in bold and strikethrough Manual PA is required for all new users of Fasenra Pen <u>Manual PA Criteria:</u> Fasenra Pen coverage will be approved for initial therapy for 12 months if all criteria are met: For Eosinophilic Granulomatosis with Polyangiitis (EGPA) • The patient has a diagnosis of EGPA • The patient is 18 years of age or older • The drug is prescribed by an allergist, immunologist, pulmonologist, rheumatologist, or hematologist

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	For severe persistent eosinophilic asthma • The patient has a diagnosis of severe persistent eosinophilic asthma • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist, or pulmonologist • The patient must have an eosinophilic phenotype asthma as defined as either ▪ Eosinophils $\geq$ 150 cells/mcL within past month while on oral corticosteroids OR ▪ Eosinophils $\geq$ 300 cells/mcL • The patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following: ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR ▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • The patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: ▪ Long-acting beta agonist LABA e.g., Serevent, Striverdi), ▪ Long-acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zflo) • The patient is not currently receiving another immunobiologic (e.g., mepolizumab [Nucala], dupilumab [Dupixent] or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires after 12 months. Renewal PA criteria will be approved indefinitely <u>Renewal Criteria</u>; (initial TRICARE PA approval is required for renewal) AND • For EGPA: The patient's disease severity has improved and stabilized to warrant continued therapy • For severe persistent eosinophilic asthma: The patient has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second (FEV1) or decrease in oral corticosteroid use
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certolizumab (Cimzia) TIBs: TNFs	Updates from the November 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Cimzia Manual PA Criteria: Coverage is approved for Cimzia if: Coverage approved for patients 2- 17 years of age with: Moderate to severe active polyarticular juvenile idiopathic arthritis - Coverage approved for patients 18 years of age and older with: - Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS). - Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. - Moderately to severely active Crohn's disease (CD). - Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation ~~with evidence of elevated CRP and/or MRI evidence of sacroiliitis and Ankylosing Spondylitis Disease Activity Score (ASDAS) ≥ 2.1~~ - The provider acknowledges Humira is the Department of Defense's preferred targeted biologic agent in adults and children. The patient has tried Humira. - The patient has a contraindication to Humira (adalimumab) OR - The patient had an inadequate response to Humira. OR - The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent. ~~Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Cimzia. Is the prescriber aware of this?~~ - The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) (Note: Does not apply to AS or nr-axSpA) - AS and nr-axSpA only: Has the patient had an inadequate response to at least two NSAIDs over a period of at least two months? ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ - Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: adalimumab (Humira), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), or tildrakizumab (Ilumya). Non-FDA-approved uses are not approved. Non-FDA-approved uses are not approved. Prior authorization does not expire
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• dupilumab (Dupixent) Atopy	Updates from the November 2024 meeting for chronic rhinosinusitis with nasal polyposis are in bold and strikethrough Note that there were no changes to the PA criteria for other indications Manual PA criteria apply to all new users of dupilumab (Dupixent) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: For Chronic rhinosinusitis with nasal polyposis (CRSwNP): • The patient is ~~12~~ 18 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: ▪ Presence of nasal polyposis is confirmed by imaging or direct visualization AND ▪ At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments: ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND ▪ The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength Non-FDA-approved uses are not approved Prior authorization expires after 12 months for CRSwNP <u>Renewal criteria:</u> (initial TRICARE PA approval is required for renewal). Dupixent will be approved indefinitely for CRSwNP if: • CRSwNP: There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score.
• lacosamide ER capsules (Motpoly XR) Anticonvulsant Antimania Agents	Updates from the November 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of lacosamide ER capsules (Motpoly XR) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient has a diagnosis of partial-onset seizures OR a diagnosis of primary generalized tonic-clonic seizures • Patient weighs at least 50 kg • Medication is prescribed by or in consultation with 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 tablets (fill in blank) • Acceptable responses include that the patient is having adherence problems 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. Other non-FDA approved uses are NOT approved. PA does not expire.

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fezolinetant (Veoza) Gynecological Agents Misc.	Updates from the November 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of fezolinetant (Veoza) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: - Patient has moderate to severe vasomotor symptoms due to menopause - Patient has a contraindication to menopausal hormone therapy (estrogens with or without progestins) OR - Patient has an intolerance to menopausal hormone therapy OR - Based on individual patient characteristics and risk factors, the provider has determined that the patient is not a candidate for menopausal hormone therapy - Patient has tried and failed or had an adverse reaction to at least one of the following non-hormonal treatments for vasomotor symptoms - an SSRI (i.e. paroxetine, escitalopram, or citalopram) - an SNRI (i.e. venlafaxine, desvenlafaxine, or duloxetine) - gabapentin AND - Patient does not have severe renal impairment (eGFR of 15 to 30 mL/min/1.73m²) or end-stage renal disease (eGFR less than 15 mL/min/1.73m²) - Patient does not have cirrhosis - Provider acknowledges that patient's baseline hepatic function will be evaluated via bloodwork prior to therapy, ~~at~~ monthly for the first 3 months, at 6 months, at 9 months and when symptoms suggest hepatic injury Provider has advised patient to stop taking Veoza immediately and seek medical attention if they experience signs or symptoms that may suggest liver injury (new onset fatigue, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or right upper quadrant pain) Non-FDA approved uses are not approved PA expires after 6 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if the following applies: - Patient has had a positive response to therapy as noted by a decrease in the number of moderate to severe hot flashes
iptacopan (Fabhalta) Hematological Agents	Updates from the November 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Fabhalta <u>Manual PA criteria:</u> Coverage is approved if all criteria are met All indications - Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements - Patient is not receiving C3 or C5 inhibitors with Fabhalta, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or pegcetacoplan (Empaveli) - Patient is 18 years of age or older Paroxysmal nocturnal hemoglobinuria (PNH) – no changes to current PA criteria except as noted above Immunoglobulin A nephropathy (IgAN) Prescribed by a nephrologist The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli

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	• Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gram • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m² • Patient is not currently receiving dialysis or has not undergone kidney transplant • Patient has not received immunosuppressants, including corticosteroids, or Filspari in the past 2 weeks • Patient is not expected to need immunosuppressants in the next 6 months • Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and an SGLT-2 inhibitor (e.g., empagliflozin, dapagliflozin) and is at high risk for disease progression • Patient has failed therapy with, or has a contraindication to, or has had intolerable adverse effects with Filspari • Patient will not use Fabhalta concomitantly with Filspari Non-FDA approved uses are NOT approved including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schoenlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires after 9 months <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all the following apply: • Patient has had a response to Fabhalta defined by ▪ reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR ▪ reduction in proteinuria from baseline • Patient's eGFR rate ≥ 30 mL/min/1.73 m²
• oteseconazole (Vivjoa) Antifungals	Updates from the November 2024 meeting are in bold Manual PA criteria apply to all new users of Vivjoa <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • The prescription is written by a gynecologist or an infectious diseases specialist • Patient is post-menopausal OR post-menarchal and not of reproductive potential (i.e., history of tubal ligation, salpingo-oophorectomy, or hysterectomy) • Patient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC) confirmed by microscopy, nucleic acid amplification testing (NAAT) testing, or culture. RVVC is defined as greater than or equal to four acute episodes of symptomatic vulvovaginal candidiasis within a one year period • Patient has experienced therapeutic failure, contraindication, or intolerance to a six month maintenance course of oral fluconazole Non FDA-approved uses are not approved PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA
• peanut (<i>Arachis hypogaea</i>) allergen powder-dnfp (Palforzia) Immunological Agents Miscellaneous	Updates from the November 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Palforzia <u>Manual PA Criteria:</u> Palforzia is approved if all criteria are met: • Palforzia is prescribed by an allergist or immunologist, or in consultation with an allergist or immunologist, and the provider has satisfied the requirements of the REMS program

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	- The patient is between the ages of ~~four~~ 1 to 17 years - The patient has a documented history of peanut allergy - The patient has a history of diagnostic evidence of peanut allergy, including either serum IgE to peanut of ≥ 0.35 kUA/L (serum testing) and/or positive skin prick test (SPT) for peanut ≥ 3 mm greater than negative control - The patient does not have uncontrolled asthma; eosinophilic esophagitis or other eosinophilic gastrointestinal diseases - The patient has not had severe or life-threatening anaphylaxis within the previous 60 days prior to starting therapy - Provider acknowledges that the patient will be counseled on the following: - Avoiding peanut ingestion - The need for access to an epinephrine injector - Palforzia is not intended to treat emergencies Non-FDA-approved uses are not approved PA does not expire
pimavanserin (Nuplazid) Antipsychotics: Atypicals	Updates from the November 2024 meeting are in strikethrough Manual PA criteria apply to all new users of pimavanserin <u>Manual PA Criteria:</u> Nuplazid is approved if the following criteria are met: - Patient is age 18 years of age or older - Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's disease psychosis - Nuplazid is being prescribed by or in consultation with a neurologist, psychiatrist, or gerontologist (i.e., geriatric medicine specialist) - Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin ~~The patient's baseline Mini-Mental State Examination (MMSE) score ≥ 24.~~ - Patient does NOT have history of known QT prolongation, cardiac arrhythmias, or other circumstances that would increase the risk of Torsade's de Pointes and/or sudden death - Patient is NOT taking additional antipsychotics Non-FDA approved uses are NOT approved Prior authorization does not expire
roflumilast 0.15% cream (Zoryve) Psoriasis Agents	Changes from the November 2024 meeting are for the new indication for atopic dermatitis Note that there were no changes to the PA criteria for the 0.3% formulation for plaque psoriasis Manual PA criteria apply to all new users of Zoryve 0.15% cream <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: Atopic Dermatitis Patient is 6 years of age or older The medication is being prescribed by or in consultation with a dermatologist, allergist, or immunologist The patient has mild to moderate atopic dermatitis 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:

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	- For patients 18 years of age or older: high potency class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) - For patients 6 to 17 years of age: any topical corticosteroid - Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) Non-FDA-approved uses are not approved PA expires in 1 year for Atopic Dermatitis; PA does not expire for plaque psoriasis Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely if the following applies: Atopic Dermatitis: The patient's disease severity has improved and stabilized to warrant continued therapy.
teriparatide 600 mcg (Forteo and generic) Osteoporosis Agents: PTH Analogs	Updates from the November 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Forteo <u>Manual PA criteria:</u> Coverage is 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 - Patient is greater than or equal to 18 years of age - Patient is a postmenopausal female with osteoporosis or is a male with primary or hypogonadal osteoporosis or is a male or female who has osteoporosis associated with sustained systemic glucocorticoid therapy (for example, greater than 6 months use of greater than 7.5 mg/day prednisone or equivalent) - Patient has one of the following: - The patient is at high risk for fracture, defined as one of the following: - history of osteoporotic fracture - multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) - documented bone mineral density (BMD) T-score of -2.5 or worse - has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND - The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND ~~Cumulative treatment with Forteo will not exceed 24 months during the patient's lifetime AND~~ Patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton)

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	Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. ~~Prior Authorization may not be renewed.~~ 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 • Provider acknowledges that there are limited data assessing the risk of osteosarcoma beyond 2 years of use with teriparatide
• teriparatide 620 mcg Osteoporosis Agents: PTH Analogs	Updates from the November 2024 meeting are in bold and strikethrough. Manual PA criteria apply to all new users of Bonsity. <u>Manual PA criteria:</u> Coverage is approved if all criteria are met • The provider acknowledges that Forteo is the Department of Defense's preferred osteoporosis parathyroid hormone (PTH) analog; the patient must try and fail Forteo • Patient is greater than or equal to 18 years of age • Patient is a postmenopausal female with osteoporosis or is a male with primary or hypogonadal osteoporosis or is a male or female who has osteoporosis associated with sustained systemic glucocorticoid therapy (for example, greater than 6 months use of greater than 7.5 mg/day prednisone or equivalent) • Patient has one of the following: ▪ The patient is at high risk for fracture, defined as one of the following: – history of osteoporotic fracture – multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) – documented bone mineral density (BMD) T-score of -2.5 or worse – has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND • The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND • ~~Cumulative treatment with Forteo will not exceed 24 months during the patient's lifetime AND~~ • Patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton) Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. ~~Prior Authorization may not be renewed.~~ 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:

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	- The patient has had a positive response to therapy - Provider acknowledges that there are limited data assessing the risk of osteosarcoma beyond 2 years of use with teriparatide
pancrelipase (Zenpep) Pancreatic Enzyme Replacement Therapy (PERT)	Updates from the November 2024 meeting are in bold and strikethrough Manual PA criteria apply to all new users of Zenpep. <u>Manual PA criteria:</u> Zenpep is approved if ALL of the following criteria are met: Provider acknowledges that Creon is the DoD's preferred Pancreatic Enzyme Replacement product and that Prior Authorization is not required for Creon - For patients 2 years of age or younger - The patient has had a sufficient trial of Creon and treatment was unsuccessful - For patients older than 2 years of age - The patient has failed an adequate trial of Creon, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND ~~The patient has failed an adequate trial of Pancreaze, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND~~ ~~The patient has failed an adequate trial of Pertzye, defined as at least 2 dose adjustments done over a period of at least 4 weeks; document the dates tried _____ AND~~ ~~The patient has failed an adequate trial of Viokace; defined as at least 2 dose adjustments done over a period of at least 4 week; document the dates tried _____. OR the patient is between 2 and 19 years of age and requires a dosage strength that is not available with Viokace.~~ Prior authorization does not expire.
- bempedoic acid (Nexletol) - bempedoic acid/ezetimibe (Nexlizet) Antilipidemic-1s: Non-statins and combinations	Updates from the November 2024 meeting are in bold and strikethrough PA criteria apply to new users of Nexletol and Nexlizet ~~Automated PA criteria: The patient has filled a prescription for Repatha or Praluent at any MHS pharmacy point of service (MTFs, retail pharmacies, or network TRICARE Mail Order Pharmacy) during the previous 720 days~~ <u>Manual PA Criteria:</u> ~~If automated PA criteria are not met~~ Nexletol or Nexlizet is approved if all criteria are met: - Prescribed by a cardiologist, endocrinologist, or lipidologist (e.g., provider is certified through the National Lipid Association or similar organization) - Patient has one of the following diagnoses: - Patient has established atherosclerotic cardiovascular disease (ASCVD) including one or more of the following: acute coronary syndrome (ACS), coronary artery disease (CAD), myocardial infarction (MI), stable or unstable angina, coronary or arterial revascularization, stroke, transient ischemic attack (TIA) or peripheral arterial disease (PAD), OR - Patient is at high risk for atherosclerotic cardiovascular disease (ASCVD) based on one of the following: - type 1 or type 2 diabetes or

Appendix C—Table of Prior Authorization (PA) Criteria

	○ 10-year ASCVD risk score (Pooled Cohort Equation – PCE) >20% or Reynolds Risk score > 30% or SCORE risk score >7.5% over 10 yrs or ○ Coronary calcium score >400 Agatston units at any time in the past ▪ Patient has Heterozygous Familial Hypercholesterolemia (HeFH) AND • For Nexletol: ▪ Patient is taking concurrent ezetimibe OR ▪ Patient was not able to tolerate an ezetimibe trial of at least 4-6 weeks AND ▪ Patient is on concurrent statin therapy at the maximum tolerated dose and dose hasn't reached LDL goals OR ▪ Patient is statin intolerant based on one of the following: ○ Patient has experienced intolerable and persistent (lasting longer than 2 weeks) muscle symptoms (muscle pain, muscle cramps), with at least 2 statins OR ○ History of creatine kinase (CK) levels greater than 10 x the upper limit of normal (ULN) unrelated to statin use OR ○ History of statin-associated rhabdomyolysis ⇨ Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) AND • ~~Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR~~ • ~~Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCSK-9 inhibitor~~ • For Nexlizet: ▪ Patient is taking concurrent ezetimibe, which will be discontinued once Nexlizet is started (Note that a history of intolerance to ezetimibe will not allow for a patient to try Nexlizet) AND ▪ Patient is on concurrent statin therapy at the maximum tolerated dose and hasn't reached LDL goal OR ▪ Patient is statin intolerant based on one of the following: ○ Patient has experienced intolerable (muscle pain, cramp) with at least 2 statins OR ○ History of creatine kinase (CK) levels greater than 10 times the upper limit of normal (ULN) unrelated to statin use OR ○ History of statin-associated rhabdomyolysis OR ○ Patient has a contraindication to statin therapy (e.g., active liver disease, including unexplained or persistent elevations in hepatic transaminase levels, hypersensitivity, pregnancy) AND • ~~Patient is taking concurrent PCSK-9 inhibitor evolocumab (Repatha) or alirocumab (Praluent) and hasn't reached LDL goal OR~~ • ~~Patient is unable to tolerate a PCSK-9 inhibitor or has a contraindication to a PCSK-9 inhibitor~~ Non-FDA-approved uses are not allowed Prior authorization does not expire
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Appendix C—Table of Prior Authorization (PA) Criteria

evolocumab (Repatha) PCSK-9 Inhibitors	Changes from November 2024 meeting are in BOLD Manual PA criteria apply to all new users of Repatha <u>Automated PA Criteria:</u> When prescribed by a cardiologist, endocrinologist or cardiac transplant specialist, prior authorization is not required. Once therapy is initiated by a specialist, an automated drug lookback will apply, allowing for continuation of coverage by any other prescriber if the patient has received the requested medication in the past 180 days. OR <u>Automated PA Criteria:</u> The patient has filled a prescription for atorvastatin, rosuvastatin, ezetimibe or ezetimibe/simvastatin at any MHS pharmacy point of service (MTFs, retail network pharmacies or TRICARE Mail Order Pharmacy) during the previous 180 days OR <u>Manual PA Criteria:</u> if automated criteria are not met, evolocumab (Repatha) is approved if all criteria are met - When prescribed by a cardiologist, endocrinologist or cardiac transplant specialist, prior authorization is not required. <i>For HoFH and HeFH</i> - For heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH), the patient is 10 years of age or older - The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol - The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses <i>For ASCVD</i> - The patient is at least 18 years of age for clinical atherosclerotic cardiovascular disease (ASCVD) - The patient has established ASCVD with the following LDLs, despite maximally tolerated statin doses: - Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions. <i>Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information</i>) OR - Not at very high risk of events: LDL > 70 mg/dL AND - The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR - The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR - If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND - The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy <i>For patients at high risk for ASCVD</i> - The patient has LDL >190 mg/dL or - Patient has diabetes and LDL <190 mg/dL or - Patients with LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD >7.5% or
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Appendix C—Table of Prior Authorization (PA) Criteria

	- Patients with LDL < 190 mg/dL and evidence of significant subclinical atherosclerosis defined as: - Significant atherosclerotic plaque observed in an asymptomatic patient on any of the following diagnostic studies: coronary artery calcification noted on computed tomography (CT) studies, including calcium scoring, cardiac CT coronary angiography, chest CT for ruling out pulmonary embolism, chest CT for lung cancer screening, or diagnostic chest CT; carotid plaque noted on carotid ultrasound or angiography; or abnormal ankle-brachial index or plaque noted on peripheral arterial angiography. AND - The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR - The patient must have tried any maximally tolerated statin in combination with ezetimibe, OR - If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND - The patient must have had a trial of at least 4-6 weeks of maximally tolerated therapy. <i>For all uses:</i> If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: - Intolerance - The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND - The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR - The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. - Contraindication to statin - The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) <i>For all indications</i> - Repatha is not approved for patients who are pregnant or lactating. - The dosage must be documented on the PA Form as either: 140 mg every 2 weeks, or 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. PA does not expire
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Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
TIBS (except Stelara)	No change to current QLs MTF/Mail/Retail 60 days supply
ustekinumab (Stelara)	- Retail: 1 syringe/vial per fill - MTF/Mail: 3 syringes/vials per fill
ubrogepant (Ubrelevy) Migraine Agents oral CGRPs	- Retail: 16 tabs/30 days - MTF/Mail: 48 tabs/90 days
rimegepant (Nurtec ODT) Migraine Agents oral CGRPs	For Acute Migraine Indication: - Retail: 8 ODT/30 days - MTF/Mail: 24 ODT/90 days For Migraine Prevention Indication, approved through PA process: - Retail: 16 ODT/30 days - MTF/Mail: 48 ODT/90 days Note that Nurtec ODT is only available as 8 ODT per pack
atogepant (Qulipta) Migraine Agents oral CGRPs	- Retail: 30 tabs/30 days - MTF/Mail: 90 tabs/90 days
ensifentrine (Ohtuvayre) Pulmonary 2 Agents: COPD	MTF/TMOP/Retail: 60-day supply
epinephrine nasal spray (Neffy) Respiratory Agents Miscellaneous	MTF/TMOP/Retail: 4 packages per fill
Freestyle Libre 3 Plus Self-Monitoring Blood Glucose Systems: Therapeutic Continuous Glucose Monitoring Systems	- Retail: 30 days - MTF/Mail: 90 days Note – The FreeStyle Libre 3 Plus sensor is replaced every 15 days, compared with the FreeStyle Libre 3 (November 2022) where the sensor is replaced every 14 days
lazertinib (Lazcluze) Oncological Agents: Epidermal Growth Factor Receptor (EGFR) plus Non-small Cell Lung Cancer (NSCLC)	MTF/TMOP/Retail: 60-day supply
lebrikizumab-lbkz (Ebglyss) Atopy Agents	Retail/MTF/TMOP: 60-day supply

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
levacetylleucine (Aqneursa) Neurological Agents Miscellaneous	MTF/TMOP/Retail: 60-day supply
nemolizumab-ilto (Nemluvio) TIBS: Miscellaneous Interleukins	MTF/TMOP/Retail: 60-day supply
palopegteriparatide (Yorvipath) Endocrine Agents Miscellaneous	MTF/TMOP/Retail: 60-day supply
seladelpar (Livdelzi) Gastrointestinal 2 Agents	MTF/TMOP/Retail: 60-day supply
vadadustat (Vafseo) Hematological Agents	MTF/TMOP/Retail: 60-day supply
vigabatrin (Vigafyde) Anticonvulsants-Antimania Agents	MTF/TMOP/Retail: 30-day supply
vorasidenib (Voranigo) Oncological Agent	Retail/MTF/TMOP: 60-day supply

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
aprocitentan (Tryvio) Anti-hypertensive Agents: Endothelin Receptor Agonist	- spironolactone (Aldactone) - metoprolol succinate (Toprol XL) - hydralazine (Apresoline) - macitentan (Opsumit)	- Tablet: 12.5 mg - Dosing: 12.5 mg orally once daily	Treatment of hypertension (HTN) in combo with other antihypertensive drugs in adults who are not adequately controlled on other drugs	ADRs ($\geq 2\%$): - edema/fluid retention - anemia	- Although Tryvio has a new MOA (endothelin receptor antagonist), current HTN guidelines recommend a mineralocorticoid receptor antagonist (spironolactone) for resistant HTN - Requires a REMS program due to increased LFTs, risk of hepatotoxicity, fluid retention, peripheral edema, fetal toxicity, and decreases in HCT/Hgb - The current place in therapy and long-term safety remains to be determined - More established therapies should be tried first as add-in therapy for resistant HTN	- NF - PA - MN
carbidopa/levodopa XR capsules (Crexont) Parkinson's Agents	carbidopa/levodopa XR cap (Rytary)	- XR Capsule: 35/140 mg, 52.5/210 mg, 70/280 mg, 87.5/250 mg - Dosing: Treatment naïve: (C/L: 35/140 mg) cap BID x3d, then increase gradually up to max daily dose: (C/L: 525/2100 mg)	- Treatment of Parkinson's Disease - Post-encephalitic parkinsonism - Parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults.	ADRs ($>3\%$): - nausea - Anxiety	- Approval based on single trial of Crexont demonstrating statistically significant improvement in mean change in daily "good on-time" from baseline, compared to IR carbidopa and levodopa - No head-to-head trials between Crexont and other extended or controlled release carbidopa levodopa - Crexont provides no compelling clinical advantage over existing agents	- UF - PA
clobetasol 0.05% ophthalmic suspension (no brand name) Ophthalmic Miscellaneous	- dexamethasone ophth suspension - loteprednol ophth suspension - prednisolone ophth susp	One drop into the affected eye BID beginning the day after surgery and continuing throughout the first 2 weeks of the post-operative period	Treatment of post-operative inflammation and pain following ocular surgery	ADR ($\geq 1\%$) - eye inflammation - corneal edema - anterior chamber inflammation - cystoid macular edema - intraocular pressure elevation - photophobia - vitreous detachment	- New formulation of ophthalmic corticosteroid - Phase 3 study demonstrated favorable efficacy over vehicle at reducing pain and anterior chamber cell count during the short-term study - Guidelines do not prefer one ophthalmic corticosteroid over another - Other than the fact it does not require tapering at the end of therapy, it provides no compelling clinical advantage over existing agents	Completely Excluded

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
clonidine XR 0.1 mg/mL oral suspension (Onyda XR) ADHD Agents: Non-Stimulants	- clonidine XR tabs - guanfacine ER tabs - Intuniv tabs	0.1 mg/mL ER suspension Dosing: 0.1 mg QHS - May increase 0.1 mg/ day at weekly intervals to max dose 0.4 mg per day	Treatment of ADHD as monotherapy or as adjunctive therapy to CNS stimulant medications in patients ≥6 years of age	ADR (≥5%) - irritability - nightmare - insomnia - constipation - dry mouth	- New ER oral solution of clonidine - No new clinical data; FDA approved via 505(b)(2) pathway - Offers another formulation of extended-release clonidine for ADHD treatment, but has no compelling clinical advantages over other ADHD non-stimulants	- NF - PA - MN - TRICARE Maintenance Drug List
ensifentrine nebulizer inhalation solution (Ohtuvayre) Pulmonary-2 Agents: COPD	- Daliresp - Spiriva - Anoro Ellpita - Trelegy - Breztri	- Inhalation suspension: 3 mg/2.5 mL aqueous suspension in unit-dose ampules Dosing: 1 ampule BID	The maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult s	ADR (1%) - back pain - Hypertension - urinary tract infection - diarrhea	- New selective, dual phosphodiesterase (PDE)3 and PDE4 inhibitor with bronchodilator and anti-inflammatory effects - Two phase III trials demonstrated significantly improved lung function when added on to maintenance COPD therapy; no data on whether this therapy will reduce COPD exacerbations - Generally well tolerated in both trials, with a similar incidence of AEs between ensifentrine and placebo - Has not been studied in all possible combinations of medications that could be used to currently treat COPD - Trials excluded patients receiving concurrent dual LAMA/LABA or triple therapy - Provides another alternative maintenance treatment for patients with COPD	- NF - PA - MN - QL - Specialty

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
epinephrine nasal spray (Neffy) Respiratory Agents	EpiPen	- Nasal spray: 2 mg/0.1 mL - Dosing: 1 spray administered into one nostril	Emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater	ADR ($\geq 2\%$) - throat irritation - nasal discomfort - nasal pruritus - feeling jittery - rhinorrhea - sneezing - dizziness - nausea/vomiting	- First FDA-approved nasal epinephrine product - Limited use for pediatric patients due to weight (≥ 30 kg) - Approval based on pharmacokinetic data; limited clinical data - Neffy has a longer shelf life and can withstand greater temperature excursions than other epinephrine formulations - Offers an alternative to injectable epinephrine products	- UF - QL
lazertinib (Lazcluze) Oncological Agents: Epidermal Growth Factor (EGFR) + Non-Small Cell Lung Cancer (NSCLC)	Iressa	- Tablets: 80mg, 240 mg - Dosing: 240mg QD	Kinase inhibitor indicated in combination with amivantamab for 1st line treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations	ADR ($\geq 20\%$) - rash - nail toxicity - infusion-related reaction - musculoskeletal pain - edema - stomatitis - VTE - paresthesia - fatigue - hemorrhage - pruritus - nausea	- Novel kinase inhibitor - Category 1 recommendation from the NCCN for treatment of this disease state - Shows increased clinical efficacy compared to its alternative, osimertinib - Associated with a higher side effect profile - Requires administered with prophylaxis during the first four months of administration to prevent venous thromboembolism (VTE) - The FDA is requiring a comprehensive safety analysis to further characterize the risk of VTE associated with treatment - lazertinib offers an additional treatment option for the treatment of locally advanced/metastatic NSCLC	- UF - PA - QL - Specialty - TRICARE Maintenance Drug List
lebrikizumab-lbkz (Ebglyss) Atopy Agents	- Adbry - Dupixent	250 mg/2 mL single-dose prefilled pen or syringe - Dosing: 500 mg SC at week 0 and Week 2 followed by 250 mg SC Q2W; Maintenance Dose: 250 mg SQ Q4 W	Treatment of adults and pediatrics ≥ 12 years weighing at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	ADRs ($>1\%$) - conjunctivitis - Injection site reactions - Herpes zoster	- Second IL-13 antagonist - Phase 3 study demonstrated significantly larger proportions of patients achieving an IGA response with Ebglyss vs. placebo - Ebglyss and Adbry both approved for children down to age 12, while Dupixent may be used in patients ≥ 6 months of age - Ebglyss therapy resulted in similar proportions of patients achieving a clinical response as were noted in the Dupixent pivotal studies and numerically slightly larger proportions than were observed with Adbry - Dupixent has several other indications including	- UF - PA - QL

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
					asthma and chronic rhinosinusitis with nasal polyposis; conditions that are common among patients with atopic dermatitis • Ebglyss is an alternative to Adbry and Dupixent but provides no compelling clinical advantage over existing agents	
levacetyl-leucine (Aqneursa) Neurological Agents	Myplyffa (FDA-approved in Nov 2024)	- Capsule: 100 mg - Dosing: based on body weight PO daily	Treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥ 15 kg	ADR ($\geq 5\%$) - abdominal pain - dysphagia - upper respiratory tract infections - vomiting	- A Phase 3 study demonstrated a statistically significant impact on the Scale for the Assessment and Rating of Ataxia (SARA) score compared to placebo in patients, most of whom were on miglustat - Safety profile was overall well tolerated - Aqneursa is an option for the treatment of this rare condition	- UF - PA - QL - TRICARE Maintenance Drug List
nemolizumab-ilto (Nemluvio) TIBS: Misc Interleukins	Dupixent	- Single-dose prefilled dual chamber pen: 30 mg - Dosing: < 90 kg: loading dose 60 mg (two 30 mg injections) then 30 mg SUBQ Q4W ≥ 90 kg: loading dose 60 mg (two 30 mg injections) then 60 mg SUBQ Q4W	Treatment of adults with prurigo nodularis	ADR ($\geq 1\%$) - headache - dermatitis atopic - eczema - eczema nummular	- IL-31 receptor antagonist - Two randomized trials demonstrated statistically significantly achievement of improvement in Investigator's Global Assessment for disease severity and a reduction in Peak Pruritus Numeric Rating Scale compared with placebo - The safety profile is generally well tolerated with mild adverse events - Nemluvio offers an additional treatment option for this chronic, intractable disease	- UF - PA - QL - Specialty

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
norethindrone acetate/ ethinyl estradiol ODT (Femlyv) Contraceptive Agents: Monophasics with 20mcg estrogen	- norethindrone/ EE (generic Loestrin, Aurovela, Microgestin, Junel, Larin or equivalent) - etonogestrel/EE ring (generic NuvaRing) - norelge-/EE patch (Xulane, Zafemy) - medroxyprogesterone acetate injection (generic Depo-Provera)	24 ODTs each with 1 mg norethindrone acetate and 20 mcg ethinyl estradiol and 4 inert ODTs - Dosing: Place 1 ODT on the tongue, allow to disintegrate, and then follow with 8 ounces of water	Use by females of reproductive potential to prevent pregnancy	ADR ($\geq 2\%$) - headache - vaginal candidiasis - nausea - menstrual cramps - breast tenderness - bacterial vaginitis - abnormal cervical smear - acne - mood swings - weight gain	- First orally disintegrating tablet (ODT) contraceptive formulation - No new clinical data - Femlyv is an alternative contraceptive for patients who have swallowing difficulties; however, there are numerous available contraceptives on the UF including multiple norethindrone 1 mg/ethinyl estradiol 0.02 mg tablets, chewable tablets, and alternative dosage forms (patch, ring, injection, etc.)	- NF - PA - MN
palopeg-teriparatide (Yorvipath) Osteoporosis Agents	parathyroid hormone (Natpara)-discontinued	- Prefilled syringe: 60 mg 168 mcg/0.56 mL 294 mcg/0.98 mL 420 mcg/1.4 mL - Dosing: Starting dose is 18 mcg SC QD and titrated in 3 mcg increments/decrements	Treatment of hypoparathyroidism in adults. Not for acute post surgical hypoparathyroidism.	ADRs ($>5\%$) - injection site reactions - vasodilatory signs and symptoms - headache - diarrhea - back pain - hypercalcemia - oropharyngeal pain	- PTH analog - Phase 3 study demonstrated significantly more patients were able to achieve the composite efficacy endpoint vs. placebo in patients with chronic hypoparathyroidism who had not adequately responded to conventional therapy - Guidelines currently recommend conventional therapy with oral calcium supplementation and active vitamin D as first-line therapy - PTH replacement is recommended in patients who are not able to be adequately managed with conventional therapy - Natpara is similarly indicated in patients with chronic hypoparathyroidism. However, Natpara is associated with serious safety concerns regarding the risk of osteosarcoma and will no longer be available end of 2024; due to supply issues - Yorvipath provides an option for those who cannot be managed with conventional therapy	- UF - PA - QL - Specialty

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
seladelpar (Livdelzi) Gastro-intestinal-2 Agents	- Iqirvo - Ocaliva	10 mg Capsules: - Dosing: 10 mg PO QD	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA	ADRs ($\geq 5\%$) - headache - abdominal pain - nausea - abdominal distension - dizziness	- Second PPAR agonist approved for the treatment of PBC - Phase 3 studies demonstrated Livdelzi improved biochemical markers of disease progression compared with placebo - Livdelzi demonstrated similar biochemical efficacy as Iqirvo and Ocaliva over 52 weeks; however, maintenance of biochemical response at Year 5 was demonstrated in an open-label extension study with Ocaliva - Over a 6-year period, Ocaliva-treated patients experienced a reduced risk of liver transplantation and death vs. comparable external controls - No head-to-head studies with Ocaliva or Iqirvo - Livdelzi is an alternative to Iqirvo and Ocaliva for PBC; however Ocaliva has real world outcomes data suggesting improvement in a clinical endpoint of transplant-free survival	- UF - PA - QL - Specialty
sofpironium 12.45% topical gel pump (Sofdra) Antiperspirant	Qbrexza	- topical gel: 12.45% (60 pumps/bottle) - Dosing: 1 pump per underarm QHS dose 0.7	Treatment of primary axillary hyperhidrosis in patients 9 years of age and older	ADRs ($\geq 2\%$) - dry mouth - blurred vision - site pain irritation - Mydriasis - urinary retention	- Two phase 3 studies achieved a ≥ 2-point improvement in the Hyperhidrosis Disease Severity Measure-Axilla score and reduced Gravimetric Sweat Production results compared to vehicle - No head to head trials vs other hyperhidrosis treatments - Adverse events were overall well tolerated and reversible, and mostly consistent with anticholinergic effects, as well as local site pain and skin irritation - Sofdra provides no compelling clinical advantage over existing agents	- NF - PA - MN - TRICARE Maintenance Drug 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
tirzepatide vial (Zepbound) Weight Loss Agents	- Zepbound pen - Wegovy - Saxenda	- Vial: 2.5mg/ml, 5mg/ml - Dosing: 2.5 mg injected subcutaneously once weekly	Chronic weight management in adults	ADRs ($\geq 5\%$): - nausea - diarrhea - vomiting - constipation - abdominal pain - dyspepsia - injection site reactions - hypersensitivity reactions - eructation - hair loss, - gastroesophageal reflux	- The VIAL is another formulation of Zepbound, only available for cash paying patient - Only available through LillyDirect - Currently only available in 2.5 mg and 5 mg strength - No changes to the formulary placement and - PAs for the Zepbound autoinjectors	Completely Excluded
vadadustat (Vafseo) Hematological Agents: RBC Stimulants Erythropoietin Agents	- Jesduvroq - Procrit - Epogen - Retacrit	- Tablets: 150 mg 300 mg 450 mg - Dosing: 300 mg PO QD	Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months	ADRs ($\geq 10\%$): - hypertension - diarrhea	- Second approved oral HIF-PH inhibitor - Two phase 3 studies demonstrated noninferiority to ESA therapy regarding effects of hemoglobin levels and CV outcomes - Vafseo has a Boxed Warning like Jesduvroq and ESAs regarding increased risks of death, MI, stroke, VTE and thrombosis of vascular access - Vafseo should not be utilized in pediatrics or for treating of anemia in CKD among patients who are not on dialysis - Hepatotoxicity has been reported; and liver function testing is required - Provides no compelling clinical advantage over existing agents	- NF - PA - MN - Specialty - TRICARE Maintenance Drug List
vigabatrin 100 mg/mL oral solution (Vigafyde) Anticonvulsant and Antimania Agents	- vigabatrin (Sabril) - vigabatrin (Viagadrone) - vigabatrin (Vigoder) - vigabatrin generic	- Oral solution: 100 mg/ml - Dosing: Initiate 25 mg/kg BID; may increase every 3 days, max: 75 mg/kg BID	Monotherapy for treatment of infantile spasms in patients 1 month to 2 years of age, for whom the benefits outweigh the potential risk of vision loss	ADRs ($\geq 5\%$): - somnolence - bronchitis - ear infection - acute otitis media	- Another oral formulation of vigabatrin - Available in a concentrated solution that is ready to use, compared to alternative vigabatrin packets that require reconstitution - No new clinical data - Provides no compelling clinical advantage over existing agents	- UF - QL - Specialty - Add to Rapid Response (Safety net) program

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
vorasidenib (Vorango) Oncological Agents	N/A	- Tablet: 10 mg 40 mg - Dosing: ≥ 40 kg: 40 mg QD < 40 kg: 20 mg QD	Treatment of patients ≥ 12 years Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection	ADRs ($\geq 15\%$): - fatigue - headache - musculoskeletal pain - diarrhea - nausea - seizure	- A single phase 3 study demonstrated statistically significant improvement in progression-free survival as compared to placebo - The safety profile is overall well tolerated, however there is a notable warning for hepatotoxicity requiring regular monitoring of liver function tests - Vorango provides an FDA approved option these rare, incurable CNS malignancies	- UF - PA - Specialty - TRICARE Maintenance Drug List
xanomeline/trospium (Cobenfy) Antipsychotic Agents: Atypical	N/A	- Capsule: 50/20 mg 100/20 mg 125/30 mg - Dosing: Start: 50/20 mg BID x 2 days, then 100/20 mg BID x 5 days max: 125/30 BID	Treatment of schizophrenia in adults	ADRs ($\geq 5\%$): - rash - nausea - vomiting - diarrhea - abdominal pain - dyspepsia - constipation - hypertension - tachycardia - dizziness - gastrointestinal reflux disease	- Two identical phase 3 studies demonstrated a statistically significant reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo at 5 weeks - Long term extension data is lacking at this time - Adverse events were predominantly GI related and transient - Cobenfy provides an additional treatment option for patients with an established diagnosis of schizophrenia and a history of inadequate response to prior therapies	- NF - PA - MN

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary*

Table 1: TRICARE Maintenance Drug List 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 TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from TMOP Requirement)
November 2024	Drug Class Reviews Targeted Immunomodulatory Biologics: IL-17 and IL-23 subclasses Designated UF Retain current status for all agents on the TRICARE Maintenance Drug List - guselkumab (Tremfya) - ixekizumab (Taltz) - risankizumab (Skyrizi) - secukinumab (Cosentyx) - tildrakizumab (Ilumya) - ustekinumab (Stelara) Designated NF Retain current status for all TIBs on the TRICARE Maintenance Drug List (no reason to exempt from NF requirement) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated NF (no reason to exempt from NF requirement) - clonidine extended-release oral suspension (Onyda XR) - sofipirionium gel (Sofdra) * 10 USC 1074g(a)(9) requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or TMOP. Medications subject to these requirements are listed on the TRICARE Maintenance Drug List	Drug Class Reviews (August 2024) Antilipidemics-1s – Non-statins and Combinations <i>Do not add – not cost advantageous to Government</i> - nebivolol (Nexletol) - nebivolol/ezetimibe (Nexlizet) Calcitonin Gene-Related Peptide (CGRP) Oral Agents Designated UF <i>Do not add</i> - atogepant (Qulipta) - ubrogepant (Ubrelevy) Designated NF <i>Exempt from NF requirement (acute use)</i> - rimegepant (Nurtec) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF <i>Do not add– not cost advantageous to government</i> - carbidopa-levodopa extended release (Crexont) - lebrikizumab-lbkz (Ebglyss) - nemolizumab-ilto (Nemluvio) - palopeg teriparatide (Yorvipath) - seladelpar (Livdelzi) <i>Do not add– acute use</i> - epinephrine nasal spray (Neffy) <i>Do not add– REMS, limited duration of use</i> - vigabatrin oral solution (Vigafyde) Designated NF <i>Exempt from NF requirement (REMS and limited distribution requirements)</i> - aprocitentan (Tryvio) <i>Exempt from NF requirement (antipsychotic exception applies)</i> - xanomeline/trospium (Cobenfy) <i>Exempt from NF requirement (contraceptive exception applies)</i> - norethindrone acetate/ethinyl estradiol orally disintegrating tablet (Femlyv) <i>Exempt from NF requirement (not cost advantageous to government)</i> - ensifentrine (Ohtuvayre)

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

Table 2: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with an Implementation Date Contingent on Cost Effectiveness & Operational Considerations

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from TMOP Requirement)	Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from TMOP Requirement)
November 2024	Drug Class Reviews Targeted Immunomodulatory Biologics: IL-17 and IL-23 subclasses – maintain TIBs class as generally suitable for inclusion on the contingent list; retain/add any agent not already on the TRICARE Maintenance Drug list to the contingent list Designated NF No reason to exempt from NF-2-Mail requirement - bimekizumab (Bimzelx) - brodalumab (Siliq) - mirikizumab (Omvoh) Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5) Designated UF - lazertinib (Lazcluze) - levacetylleucine (Aqneursa) - vorasidenib (Voranigo) Designated NF No reason to exempt from NF-2-Mail requirement - vadadustat (Vafseo)	
Added April 2024–September 2024	Medications previously on the contingent list that were added to the TRICARE Maintenance Drug List after March 24, by class and subclass (see May 2024 minutes, Appendix F, for medications added in March 24) - Antihemophilic Factors – emicizumab-kxwh (Hemlibra) - Antineoplastic and Premalignant Lung Cancer Lesion Agents – repotrectinib (Augtyro) - Endocrine agents Misc – pegvisomant (Somavert) - Neurological Agents: Movement Disorders – deutetrabenazine (Austedo XR), valbenazine tosylate (Ingrezza) - Oncological Agents - No subclass – selpercatinib (Retevmo), alpelisib (Vijoice) - PARP inhibitors – talazoparib tosylate (Talzenna) - Targeted Immunomodulatory Biologics - Non-Tumor Necrosis Factor Inhibitors – vedolizumab (Entyvio Pen), ustekinumab (Stelara vial) - Tumor Necrosis Factor Inhibitors – adalimumab-ryvk (Simlandi), infliximab-dyyb (Zymfentra)	
May 2023 – August 2024	Drug Classes or Subclasses Designated by the P&T Committee at prior meetings as generally suitable for inclusion on the contingent list - Atopy - Breast Cancer: Cyclin Dependent Kinase Inhibitors - LHRH agonists/antagonists - Multiple Sclerosis agents - Oncological agents 2nd Generation Antiandrogens - Acute Myelogenous Leukemia - Breast Cancer	

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary Minutes & Recommendations of the DoD P&T Committee Meeting November 6-7, 2024

Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary

	○ Chronic Myelogenous Leukemia ○ Colorectal Cancer ○ CYP-17 Inhibitors ○ EGFR+ Non-Small Cell Lung Cancer ○ Lung Cancer ○ Melanoma ○ Multiple Myeloma ○ Myelofibrosis ○ Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors ○ Renal Cell Carcinoma • Neurological Misc: Movement Disorders • Targeted Immunomodulatory Biologics (TIBs)
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Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: January 27, 2025

Repatha, Nexletol and Nexlizet: January 29, 2025

Two weeks after signing: February 12, 2025

30 days after Signing: February 26, 2025

60 days after signing: April 2, 2025

90 days after signing: April 30, 2025

120 days after signing: May 28, 2025

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

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
November 2024	Ophthalmic Miscellaneous	clobetasol 0.05% ophthalmic emulsion	- dexamethasone 0.01% ophthalmic suspension - loteprednol 0.5% ophthalmic suspension - prednisolone 1% ophthalmic suspension	120 days
November 2024	Weight Loss Agents	tirzepatide vials (Zepbound)	- liraglutide (Saxenda) - semaglutide (Wegovy) - tirzepatide pens (Zepbound)	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 TMOP 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 health.mil website.