**DEPARTMENT OF WAR**
**PHARMACY AND THERAPEUTICS COMMITTEE**

**MINUTES AND RECOMMENDATIONS**

**May 2026**

## I. CONVENING

The Department of War (DoW) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 6th and 7th, 2026.

## II. ATTENDANCE

The attendance roster is listed in Appendix A.

**A. Approval of February, May, August, November 2025 and February 2026 Meeting Minutes—**On March 10, 2025, the Secretary of Defense directed a pause of all DoD Advisory Committees, including the Uniform Formulary Beneficiary Advisory Panel meeting (UF BAP). As a result, the UF BAP meeting is delayed, and the signing of the February, May, August, November 2025, and February 2026 P&T Committee meeting minutes will also be delayed.

**B. Clarification of previous meeting minutes**

- **February 2026**
  - **Miscellaneous Metabolic Agents for Barth Syndrome: elamipretide injection (Forzinity)—**Forzinity does not have other formally FDA-approved alternatives, however supportive measures are widely used. The medical necessity (MN) criteria were clarified to state "No alternative therapies, the patient has failed supportive therapies for managing symptoms."
  - **Oncological Agents—tazemetostat (Tazverik) PA criteria—**PA updates were recommended at the February 2026 meeting for two new FDA approved indications. In March 2026, the manufacturer announced Tazverik will be discontinued from the market due to safety concerns regarding the risk of secondary hematologic malignancies.
- **November 2025**
  - **Rapid Acting Insulins: lispro-aabc (Lyumjev) TEMPO pen—**This formulation of Lyumjev was recommended for complete exclusion status. Prior authorization (PA) criteria currently apply and will remain in place until implementation occurs, 120 days after signing of the minutes.
- **August 2025**
  - **Benign Prostatic Hypertrophy (BPH) Agents: terazosin 1 mg/mL oral solution (Tezruly)—**Tezruly was designated as nonformulary (NF) with PA and MN criteria at the August 2025 P&T Committee meeting. In February 2026 Tezruly was voluntarily discontinued from the market. If this product does return, it will retain the same formulary status as was recommended in August 2025.

## 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 pharmaceutical agents selected for complete exclusion status were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All pharmaceutical agents recommended for uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and complete exclusion status 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) requires beneficiaries to 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 formerly known as the Select Maintenance Drug List.

## IV. UF DRUG CLASS REVIEWS

### A. Antihemophilic Agents: Non-Factor Agents Subclass

*Background*—The P&T Committee evaluated the relative clinical effectiveness of the Antihemophilic Agents class, Non-Factor Agents subclass. This subclass has not previously been reviewed and consists of four drugs that were previously reviewed as innovators and designated as UF: emicizumab-kxwh (Hemlibra) marstacimab-hncq (Hympavzi), concizumab-mtci (Alhemo), and fitusiran (Qfitlia).

*Relative Clinical Effectiveness Conclusion*— The following clinical review focuses on non-factor agents for hemophilia A or hemophilia B, with or without inhibitors. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

*Indications and Mechanisms of Action*

- **emicizumab-kxwh (Hemlibra)** is only indicated for hemophilia A with or without inhibitors. It is the only non-factor agent currently approved for use in newborns and young children. As a factor VIIIa mimetic, it mimics the action of factor VIIIa while retaining efficacy even in the presence of factor VIII inhibitors.
- **marstacimab-hncq (Hympavzi)** is indicated for patients 12 years and older with hemophilia A and B without inhibitors. The manufacturer is seeking approval for an expanded indication in patients as young as six years old and in patients with hemophilia A and B with inhibitors. Hympavzi is a

monoclonal antibody that antagonizes tissue factor pathway inhibitor (TFPI), which is a primary inhibitor of the extrinsic coagulation cascade.

- **concizumab-mtci (Alhemo)** is indicated for patients 12 years and older with hemophilia A and B with or without inhibitors. Like Hympavzi, it is a TFPI antagonist.
- **fitusiran (Qfitlia)** is also indicated for patients 12 years and older with hemophilia A and B with or without inhibitors, like Alhemo. Unlike the others, it is a non-biologic. Qfitlia is a small interfering RNA molecule that targets and lowers antithrombin.

*Efficacy*

- There are no published head-to-head trials that directly compare the non-factor agents against each other. Available data analyzed for the clinical review included pivotal trials, systematic reviews, and meta-analyses.
- The Annualized Bleeding Rate (ABR) for treated bleeds was the primary efficacy measure evaluated. The lower the ABR score, the better the outcome, and the optimal ABR is zero, representing zero bleeds. Additionally, quality of life measures including the total Health-related Quality of Life of Adults with Hemophilia questionnaire (Haem-A-QoL) score were evaluated.
- Although indirect efficacy comparisons are difficult due to differences in study design, the FDA-approved dosing of Qfitlia appears to result in slightly higher ABRs than the other non-factor agents in patients with or without inhibitors. More long-term data is needed to confirm if Qfitlia is less efficacious than the other agents.
- One meta-analysis included six trials for Hemlibra, Alhemo, and Qfitlia. Compared to on-demand therapy with factor agents, non-factor prophylaxis significantly decreased ABR and increased quality of life in patients. No significant differences in ABR were noted between Hemlibra, Alhemo, or Qfitlia; however, this analysis was exploratory and included a Qfitlia dose that was higher than the FDA-approved dose.
- Data on Hympavzi was not included in any of the meta-analyses reviewed, but the pivotal Hympavzi trial for patients without inhibitors showed non-inferiority when compared to factor prophylaxis in terms of ABR.

*Safety*

- Injection site reactions are the most common adverse reaction for all four non-factor agents

- All four non-factor agents have concerns with hypercoagulability when used concomitantly with clotting factor concentrates or bypassing agents in situations of active bleeds or surgical management.
- Thrombotic events were reported with all four non-factor products in clinical trials. Studies with Alhemo and Qfitlia were paused, and dose modification strategies were required to mitigate this risk.
- Hemlibra has a black box warning for thrombotic microangiopathy and thromboembolism. These complications were observed in patients who received on average a cumulative amount of >100 U/kg/24 hours of activated prothrombin complex concentrate (aPCC) while receiving Hemlibra prophylaxis. Qfitlia has a black box warning for thrombotic events and for acute and recurrent gallbladder disease, with some patients requiring cholecystectomy.
- Hemlibra interferes with partial thromboplastin time (PTT) and PTT-based clinical coagulation assays, artificially normalizing results. Alhemo can increase lab values of fibrin D-dimer and prothrombin fragment 1.2.
- There is more long-term safety data for Hemlibra than there is for Hympavzi, Alhemo, and Qfitlia. Additional long-term safety data is needed to clarify thromboembolic risk with these newer agents.

*Other Factors*

- Hemlibra is administered every one to four weeks, Hympavzi once weekly, Alhemo once daily, and Qfitlia once every one to two months.
- Hemlibra and Hympavzi do not require routine lab monitoring, while Alhemo requires drug plasma-level lab monitoring and Qfitlia requires regular monitoring of antithrombin activity and liver enzymes.
- Unlike the other non-factor agents which have a pen formulation, Hemlibra is only available in a vial.
- Qfitlia is the only non-factor agent that has an antidote, antithrombin infusion.
- For Hemlibra and Alhemo, there were rare instances of anti-drug antibodies that decreased drug efficacy. In clinical trials, Hympavzi and Qfitlia did not have any anti-drug antibodies that had clinically significant effect on efficacy or safety.
- There is limited data on using Hemlibra concurrently with immune tolerance induction (ITI) therapy and no data for concomitant use of Hympavzi, Alhemo, and Qfitlia with ITI.

*Overall Clinical Conclusion*

- In terms of efficacy, all four agents have a high degree of therapeutic interchangeability for their approved indications; however, Hemlibra is required on the formulary for the youngest hemophilia patients.
- Based on available safety data, all agents have a moderate degree of therapeutic interchangeability; some uncertainty remains with the rebalancing agents (Hympavzi, Alhemo, and Qfitlia) concerning long-term safety, given lack of data.
- At least one agent is required for each clinical indication (e.g., Hemophilia A with inhibitors, Hemophilia B without inhibitors, etc.) to meet the vast majority of Military Health System (MHS) beneficiary treatment needs.

- *Relative Cost Effectiveness Analysis and Conclusion*—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA) and budget impact analysis (BIA). The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) that 1) Hemlibra represents 99% of current use and is the least costly agent overall; 2) given current utilization, it is difficult to predict future use of Hympavzi, Alhemo, and Qfitlia; and 3) for the Hemophilia B without inhibitors indication, Alhemo and Hympavzi are less costly than Qfitlia.

    1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the formulary recommendations as outlined below.
        - UF
            - emicizumab-kxwh (Hemlibra)
            - marstacimab-hncq (Hympavzi)
            - concizumab-mtci (Alhemo)
        - NF
            - fitusiran (Qfitlia)
        - Complete Exclusion
            - None
    2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA currently applies to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria as discussed below in new users. See Appendix C for the full criteria.
        - Removing the PA for emicizumab-kxwh (Hemlibra), based on provider input and cost-effectiveness.
        - For Alhemo, Hympavzi and Qfitlia, criteria were added to prevent use with immune tolerance induction, due to the lack of supporting data for combination therapy.

- Qfitlia will require step-therapy with Hemlibra for patients with Hemophilia A, and with either Hympavzi or Alhemo for patients with hemophilia B, based on specialist feedback. The step-therapy will apply to new users.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Qfitlia. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QL of a 60-day supply at MTF and TMOP and a 30-day supply at Retail pharmacies for Hemlibra and a 60-day supply at MTF and TMOP and a 60-day supply at Retail pharmacies for Qfitlia (since it can be dosed once every two months). The QLs for Hympavzi and Alhemo were adjusted to match the QLs for Hemlibra. See Appendix D.

5. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LIST***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) all four non-factor products remain on the TRICARE Maintenance Drug List (Hemlibra) contingent list (Alhemo, Hympavzi, Qfitlia). See Appendix F.

6. ***COMMITTEE ACTION: UF, PA, QLs, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service .and 2) DHA send letters to patients affected by the formulary change for Qfitlia. See Appendix G.

**B. Leukemia and Lymphoma Agents: Breakpoint cluster (BCR)-Ableson (ABL) Tyrosine Kinase Inhibitors (TKIs) Subclass**

*Background*—The P&T Committee evaluated the relative clinical effectiveness of the Leukemia and Lymphoma class, BCR-ABL Tyrosine Kinase Inhibitors (TKI) subclass. The class was last reviewed in August 2015 and included the following drugs: imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna), bosutinib tablet (Bosulif), and ponatinib (Iclusig). Since the last class review, new entrants include asciminib (Scemblix), and alternative formulations for nilotinib, dasatinib and imatinib. Imatinib is considered a first generation BCR-ABL TKI; while dasatinib, nilotinib, and bosutinib are considered second generation; asciminib and ponatinib are third generation products. Generic formulations are available for imatinib, bosutinib and nilotinib. The clinical review focused on frontline treatment with these agents for Chronic Myeloid Leukemia.

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

*Professional Treatment Guidelines*

- The BCR-ABL TKIs are all recommended for the treatment of Chronic Myeloid Leukemia (CML) in the National Comprehensive Cancer Network (NCCN) guidelines.
    - The following agents are preferred with Category 1 recommendation for low-risk Chronic Phase-CML: imatinib, dasatinib, nilotinib, bosutinib, and asciminib.
    - The following agents are preferred with Category 1 recommendation for intermediate or high-risk Chronic Phase-CML: dasatinib, nilotinib, bosutinib, and asciminib. Imatinib is considered an "other recommended treatment" for these risk categories.
    - Ponatinib is a later line therapy for CML, which is recommended after use of two other TKIs or for accelerated or blast phase disease.

*Efficacy*

- For low, intermediate, and high-risk chronic phase-CML, NCCN categorizes imatinib and asciminib with an efficacy level 4 or "very effective." Dasatinib, nilotinib, bosutinib are ranked with an efficacy level 5 or "highly effective."
- Indirect comparison between agents is challenging due to the varying treatment arms, study designs, and inclusion criteria in the clinical trial data.
- Where available, comparative studies demonstrate that second generation TKIs (dasatinib, nilotinib, bosutinib) and the third generation TKI (asciminib) demonstrate a more rapid and deeper molecular response for newly diagnosed CML patients, compared to imatinib.
- To date, the newer generation TKIs, compared to imatinib, do not improve overall survival or maintenance of treatment-free remission for frontline treatment of chronic phase-CML.

*Safety*

- Adverse events that are commonly associated with these agents include gastrointestinal (GI) symptoms, myelosuppression, rash, edema, musculoskeletal pain, and fatigue.
- Similar warnings for all the products include cardiovascular concerns, hepatic toxicity, fetal toxicity, growth failure, and fatigue.
    - Imatinib has fewer cardiovascular warnings compared to other agents.
    - Dasatinib carries a higher risk of pleural effusion.
    - Nilotinib has a black box warning for QT interval prolongation and sudden death.

- Bosutinib carries a high risk for GI toxicity.
- Asciminib carries a warning for hypersensitivity reactions.

*Other Factors*

- Imatinib (Gleevec) is administered once daily. The tablets may be dispersed in water or apple juice for patients with swallowing difficulties. Generic formulations are available. It is approved in children as young as one year of age.
- Imatinib oral solution (Imkeldi) provides an alternative dosage formulation with the same indications as Gleevec. It was approved using bioavailability data, and clinical trials are not available. The labeling includes children as young as 10 months of age.
- Dasatinib is available in two different tablet formulations and is administered once daily without regard to food intake. Both formulations are approved for children.
    - Sprycel was the original dasatinib product and now has generic availability. Drug levels are highly dependent on gastric pH.
    - Phyrago is a branded dasatinib formulation that can be administered with H2 blockers and proton pump inhibitors. It was approved via the 505(b)(2) pathway using data from Sprycel. Absorption is independent of pH, however the mechanism by which this is accomplished is not publicly available.
- Nilotinib monohydrochloride monohydrate (Tasigna) is formulated as a sprinkle cap and is available as a generic. It was the first TKI to include information in the package insert regarding eligibility of certain patients to discontinue treatment after three years of therapy. Another advantage is approval in the pediatric population. It requires administration on an empty stomach to limit cardiotoxicity.
- Nilotinib tartrate (Danziten) is a branded product that can be administered without mealtime restrictions. No new clinical trials were conducted, and it lacks pediatric approval. Danziten has improved bioavailability allowing for a lower dose while achieving similar blood levels as Tasigna.
- Nilotinib d-tartrate (Nilceya) contains the dextro isomer of tartaric acid. It was approved via the 505(b)(2) pathway using data from Tasigna; clinical efficacy trials were not conducted. It does not provide compelling clinical advantages over Tasigna.
- Bosutinib is available under the brand name Bosulif. The tablets must be swallowed whole and are now generic. The capsules may be opened and

sprinkled and mixed with applesauce or yogurt. Both formulations are approved for the pediatric population.

- Asciminib (Scemblix) is only available as a tablet administered once daily. It provides a treatment option for later stage CML.
- Ponatinib (Iclusig) is an option for more aggressive (e.g., accelerated phase) CML disease or for those who have failed treatment with two or more TKIs.

*Overall Clinical Conclusion*

- In terms of clinical effectiveness for reviewed indication, all agents have a high degree of therapeutic interchangeability.
- In terms of safety for reviewed indication, there is a moderate degree of therapeutic interchangeability.
- To meet the needs of the beneficiaries, at least one agent should remain on the formulary.

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

- Generic imatinib and dasatinib were the most cost-effective TKIs.
- A BIA was performed to evaluate the potential impact of designating selected agents as formulary or non-formulary. BIA results showed that designating all agents as UF except for Danziten and Nilceya generated cost avoidance for the Military Health System (MHS).

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following.
    - UF
        - asciminib (Scemblix)
        - bosutinib tablets (Bosulif)
        - bosutinib capsules (Bosulif), *moves from NF to UF*
        - dasatinib (Sprycel, generic)
        - dasatinib (Phyrago), *moves from NF to UF*
        - imatinib (Gleevec, generic)
        - imatinib solution (Imkeldi), *moves from NF to UF*
        - nilotinib monohydrochloride monohydrate (Tasigna, generic)
        - ponatinib (Iclusig)
    - NF

- nilotinib tartrate (Danziten)

- Complete Exclusion
  - nilotinib d-tartrate 50, 150, 200 mg capsules (Nilceya new brand name)

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria currently apply to the newer agents, Scemblix, Bosulif capsule, Phyrago, Imkeldi, Danziten, and Nilceya. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria as outlined below, including standardizing the wording regarding labeling, safety and NCCN guideline references. The PA updates will only apply to new users. See Appendix C for the full criteria.
   - No PA is required for the generic imatinib tablets (Gleevec, generic), dasatinib (Sprycel generic), nilotinib monohydrochloride monohydrate (Tasigna), and ponatinib (Iclusig).
   - The current PA for Imkeldi oral solution was updated to include the full list of FDA-approved indications.
   - A trial of one generic TKI will now be required for new users of Phyrago, Danziten, Bosulif caps, and Scemblix. Iclusig will now require a PA and will include a trial of two TKIs. An automated lookback for generic imatinib or dasatinib will apply for Phyrago, Bosulif tablets and capsules and Scemblix.
   - Temporary manual PA criteria will apply to Nilceya until implementation of complete exclusion status.
3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Danziten. See Appendix B for the full criteria.
4. ***COMMITTEE ACTION: QLs***—QLs currently apply to the class. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the QLs for all drugs and updating to a 60-day supply at all three points of service for Scemblix. See Appendix D.
5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining Gleevec, Sprycel, Tasigna, Bosulif on the TRICARE Maintenance Drug List and maintaining Iclusig, Scemblix, Phyrago, Imkeldi, Danziten on the contingent list. See Appendix F.
6. ***COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT***—Although generic formulations of Tasigna are available, they are not cost-effective, and currently the branded Tasigna formulations are required instead of the generics. The P&T Committee recommended (19 for, 0 opposed, 0

abstained, 0 absent) maintaining the nilotinib (Tasigna) brand over generic requirement. Tasigna will also be maintained at the Tier 1 copay.

7. ***COMMITTEE ACTION: UF, PA, QLs, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service for the products moving to UF, the NF change for Danziten and the PA changes, 2) an effective date of the first Wednesday 120 days after signing of the minutes for the nilotinib d-tartrate (Nilceya) complete exclusion change, and 3) DHA mail letters to patients affected by the NF change for Danziten and the complete exclusion change for Nilceya. See Appendix G.

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

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions*—The P&T Committee agreed (18 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 2026 DoW 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 Maintenance Drug List.

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

   - UF
     - aficamten (Myqorzo) – Miscellaneous Cardiovascular Agent for obstructive hypertrophic cardiomyopathy (HCM)
     - copper histidinate injection (Zycubo) – Electrolyte-Mineral-Trace Element for Menkes Disease
     - doxecitine /doxribtimine 2 gram packet for oral solution (Kygevvi) – Miscellaneous Metabolic Agent replacement enzyme for thymidine kinase 2 deficiency
     - navepegritide powder for injection (Yuviwel) – Growth Stimulating Agent for achondroplasia
     - orforglipron (Foundayo) – Metabolic Dysfunction Agents: Weight Loss
     - pegzilarginase-nbln injection (Loargys) – Miscellaneous Metabolic Agent for hyperargininemia
     - pivmecillinam (Pivya)– Beta Lactam Antibiotic for urinary tract infections
   - NF

        - desmopressin acetate 0.05 mg/mL oral solution (Desmoda) – Miscellaneous Endocrine Agent for Diabetes Insipidus
        - etripamil nasal spray (Cardamyst) – Calcium Channel Blocker
        - icotrokinra (Icotyde) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitor for plaque psoriasis
        - lerodalcibep-liga injection (Lerochol) – Antilipidemic-1 Agent; Protein convertase subtilisin/kexin type 9 (PCSK9) inhibitor
        - lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta) – Attention Deficit Hyperactivity Disorder (ADHD) Agent Stimulant
        - methocarbamol 750 mg/5 mL oral suspension (Atmeksi) – Skeletal Muscle Relaxants and Combinations
        - tizanidine 2 mg/5 mL oral solution (Ontralfy) – Skeletal Muscle Relaxants and Combinations
        - tocilizumab-anoh injection syringe (Avtozma) – Targeted Immunomodulatory Biologics (TIBs), Interleukin-6 (IL-6) inhibitor; Actemra biosimilar (Note that the vials are available under the TRICARE Medical benefit)
    - Complete Exclusion: See Appendix H for additional detail regarding complete exclusion agents and formulary alternatives.
        - amlodipine powder for oral solution (Sdamlo) – Calcium Channel Blocking Agents
            - Sdamlo powder for oral solution was recommended for complete exclusion status as it has little to no clinical benefit relative to the other amlodipine formulations, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include amlodipine tablets, amlodipine 1 mg/mL oral suspension (Katerzia) and amlodipine 1 mg/mL oral solution (Norliqva)

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Desmoda, Cardamyst, Icotyde, Lerochol, Arynta, Atmeksi, Ontralfy, and Avtozma. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (18 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 Foundayo, requiring a trial of generic phentermine first, similar to what is in place for the weight loss agents Wegovy and Zepbound.

- Applying manual PA criteria to new and current users of Icotyde, as is currently in place for the other non-step-preferred TIBs. Patients must first try adalimumab (Humira), ustekinumab-aauz (Otulfi) and ixekizumab (Taltz).
- Applying manual PA criteria to new and current users of Avtozma requiring a trial of the tocilizumab biosimilar Tyenne first, as is currently in place for Actemra.
- Applying temporary PA criteria to new and current users of Sdamlo until implementation of Complete Exclusion status.
- Applying manual PA criteria to new users of Myqorzo. Accordingly, updates were made to the other drug used for HCM, mavacamten (Camzyos); (see the utilization management section on page 18).
- Applying manual PA criteria to new users of Arynta, Cardamyst, Lerochol and the specialty drugs Zycubo, Kygevvi, Yuviwel, and Loargys.
- Applying manual PA criteria to Atmeksi, Desmoda, and Ontralfy, requiring a trial of other formulary agents first.
- Applying manual PA criteria to Pivya, similar to what is required for the other antibiotics used to treat urinary tract infections, Orlynvah, and Blujepa.

4. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) QLs for Atmeksi, Avtozma, Cardamyst, Foundayo, Icotyde, Lerochol, Ontralfy, Pivya, and Yuviwel. See Appendix D for the QLs.
5. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS*** —The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 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 TMOP requirement. Drugs recommended for addition to the Specialty Drug List are found in Appendix E.
6. ***COMMITTEE ACTION: UF, MN, PA, QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, and IMPLEMENTATION PERIOD***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) 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 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 status 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 seven 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 under this authority. Numerous cost-effective formulary alternatives are available that do not require prior authorization. All of the below PAs will require a provider to write-in clinical rationale explaining the need for the medication.

a) **Antihistamine-1: Second Generation and Combinations—desloratadine solution**—Desloratadine solution was previously available on the market before it was discontinued by its manufacturer for business reasons. It has now been brought back to the market and is NF. Compared to other antihistamines, including alternate dosage forms, this desloratadine solution is not cost-effective.

b) **Corticosteroids-Immune Modulators: Low Potency—hydrocortisone rectal suppository (Anusol HC, Proctocort)—**These hydrocortisone rectal suppositories are much less cost-effective than other hydrocortisone rectal suppositories available in the same strengths.

c) **Diabetes Non-Insulin: Biguanides—metformin 625 mg IR tablet**—Numerous other metformin IR (500 mg and 850 mg) and ER (750 mg and 1000 mg) formulations are more cost-effective than this 625 mg IR formulation. This drug will be added to the same PA as other non-cost-effective metformin 625 mg formulations.

d) **Histamine 2 (H2) Blockers and Other Antiulcer Agents—ranitidine—**In April 2020, the FDA requested removal of all ranitidine products from the market due to N-nitrosodimethylamine (NDMA) contamination. In November 2025, the FDA approved a reformulated ranitidine tablet that addressed the previous NDMA concern. This reformulated ranitidine is much less cost-effective than all other H2-blockers.

e) **Pain: Non-Steroidal Anti-inflammatory Drugs (NSAIDs)**

i. **ibuprofen 300 mg tablet**—Ibuprofen is available in a variety of strengths and formulations including 200 mg and 400 mg tablets. There are numerous other more cost-effective NSAIDs on the formulary that can meet the needs of the beneficiaries.

ii. **ketoprofen (Orudis) 75 mg capsule**—Numerous other more cost effective NSAIDs are available including ketoprofen 50 mg capsule

f) **Skeletal Muscle Relaxants and Combinations—tizanidine 8 mg capsule—** This tizanidine 8 mg capsule made by a sole manufacturer is less cost-effective than tizanidine 2 mg and 4 mg tablets. This drug will be added to the same PA as other non-cost-effective tizanidine capsule formulations.

***COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD*** —The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for ibuprofen 300 mg, metformin IR 625 mg, tizanidine 8 mg, ketoprofen 75 mg, ranitidine, desloratadine 0.5 mg/mL solution, and hydrocortisone rectal suppositories in new and current users, due to the significant cost differences compared with other 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.

2. **New Manual PA Criteria**

a) **New PA criteria for drugs approved under New Drug Applications (NDA) pathways:** The P&T Committee reviewed two medications that contain active ingredients widely found in cost-effective generic formulations. These two products were approved via the NDA pathway, but do not have proprietary names. The drugs will default to UF status, with the PA criteria detailed below. New and current users will be affected.

1) **Skeletal Muscle Relaxants and Combinations—metaxalone 640 mg tablet—**This formulation of metaxalone is less cost-effective than alternatives including metaxalone 400 mg and 800 mg. Additionally, there are many other more cost-effective muscle relaxants on the formulary. The P&T committee recommended a write-in PA for new and current users of metaxalone 640 mg tablets. Providers must explain why the patient requires this drug and cannot take cost effective alternatives.

2) **Beta Blockers and hydrochlorothiazide (HCTZ) Combinations—metoprolol tartrate 12.5 mg IR tablet—**This formulation of metoprolol is less cost-effective than other versions of metoprolol. Of note, metoprolol tartrate 25 mg IR tablets can be split, and many are available pre-scored. Cardiologist feedback supported addition of a write-in PA for new and current users of metoprolol tartrate 12.5 mg IR tablets. Providers must explain why the patient requires this drug and cannot take cost effective alternatives.

b) **Gastrointestinal-2 Agents—sodium phenylbutyrate packets for oral suspension (Olpruva), sodium phenylbutyrate oral pellets (Pheburane), and glycerol phenylbutyrate oral liquid (Ravicti)**—Olpruva, Pheburane, Ravicti, and generic sodium phenylbutyrate powder and tablets are approved for treating

urea cycle disorders in combination with dietary management. They are all designated as UF.

Olpruva recently gained an expanded age indication, which prompted a review of whether PA should apply to these drugs. Generic sodium phenylbutyrate is the most cost-effective agent but has been associated with poor palatability. Olpruva, Pheburane, and Ravicti are formulated to either mask the unpleasant taste or are tasteless or odorless. In addition, Ravicti is available as a preparation without sodium content for those who require sodium restriction.

Many commercial plans require PA for these products. Provider outreach determined it was reasonable to require a trial of generic sodium phenylbutyrate first in most patients. The P&T committee recommended PA criteria in new users for Olpruva, Pheburane, and Ravicti, restricting use to the FDA-approved indication, requiring specialist prescribing, and a trial of generic sodium phenylbutyrate. Additionally, the PA allows patients with dietary sodium restrictions access to Ravicti. Generic sodium phenylbutyrate will continue to be available without a PA. Olpruva, Pheburane, and Ravicti will be added to the Rapid Response/Safety Net Program.

c) **Pulmonary-1 Agents: Short-acting Beta Agonists—budesonide/albuterol (Airsupra)**—Airsupra is a metered dose inhaler containing budesonide, an inhaled corticosteroid (ICS), and albuterol, a short-acting beta agonist (SABA). It is approved as an as-needed rescue inhaler to treat or prevent asthma symptoms. At the November 2023 P&T meeting, the committee reviewed Airsupra as an innovator drug and it was designated with NF status at the November 2023 P&T Committee meeting. Increasing utilization and spend have been noted, prompting a rereview for addition of a PA.

In the 2025 Global Initiative for Asthma guidelines, ICS-formoterol is listed as the preferred reliever therapy, and ICS-SABA or SABA alone are listed as alternative options. MHS specialist feedback relayed that generic budesonide/formoterol (Symbicort) is used first-line, and Airsupra has a limited role. The VA and several commercial health plans require a PA for Airsupra. Airsupra is significantly less cost-effective than budesonide and albuterol taken as separate inhalers and generic ICS-formoterol combination product Symbicort.

For the reasons above, PA criteria were recommended, restricting Airsupra use to the FDA-approved indication and requiring a trial of or contraindication to other inhalers. Due to its approval as a rescue inhaler, Airsupra will be added to the Rapid Response/Safety Net Program.

***COMMITTEE ACTION: NEW PA CRITERIA, RAPID RESPONSE PROGRAM AND IMPLEMENTATION PERIOD***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for metaxalone 640 mg and metoprolol tartrate 12.5 mg IR tablet in new and current users, and Airsupra, Olpruva, Pheburane, and Ravicti in new users, due to provider feedback, clinical guidelines, and the significant cost differences compared with generic alternatives. Airsupra, Olpruva,

Pheburane, and Ravicti will be added to the Rapid Response/Safety Net program. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes. DHA will mail letters to the patients affected by the new PA requirements for metaxalone 640 mg and metoprolol tartrate 12.5 mg IR. See Appendix C for the full criteria.

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

The P&T Committee recommended (19 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) **Antibiotics—gepotidacin (Blujepa)--**The manual PA criteria for Blujepa were updated to include its use in the treatment of *Neisseria gonorrhoeae* in patients 12 years of age or older who have limited or no alternative options.

b) **Atopy: IL-13, IL-31—dupilumab (Dupixent)—**The manual PA criteria for Dupixent were updated to allow for the new indication of allergic fungal rhinosinusitis in patients six years of age or older. The updated PA criteria require specialist prescribing and a trial of other therapies.

c) **Breast Cancer Agents: PARP Inhibitors—rucaparib (Rubraca)—**The P&T committee recommended updates to the Rubraca PA to allow for earlier treatment of prostate cancer based on the latest FDA label. Rubraca is now indicated for the treatment of metastatic castration-resistant prostate cancer (mCRPC) associated with a deleterious BRCA mutation (germline and/or somatic) in adults who have been treated with androgen receptor-directed therapy. Additionally, oncology standardization edits were incorporated.

d) **Electrolyte-Mineral-Trace Element Replacement—ferric maltol (Accrufer)—**The manual PA criteria for Accrufer were updated to allow use in patients 10 years of age and older. Previously, Accrufer had only been approved for use in adults.

e) **Gynecological Agents Miscellaneous—flibanserin (Addyi)—**The FDA updated the Addyi label to include postmenopausal women less than 65 years old. Previously, Addyi was only approved in premenopausal women for hypoactive sexual desire disorder. The manual PA criteria were updated accordingly.

f) **Lung Cancer: HER2+—zongertinib (Hernexeos)—**Hernexeos is now indicated for treatment naïve patients who have non-squamous metastatic non-small cell lung cancer (mNSCLC) with a HER2 (ERBB2) mutation in the tyrosine kinase domain. The P&T committee recommended updates to the manual PA criteria to remove the requirement for prior systemic therapy.

g) **Metabolic Agents Miscellaneous—pegvaliase-pqpz (Palynziq)—**The manual PA criteria for Palynziq were updated to allow for the expanded age indication for phenylketonuria to include pediatric patients 12 to 17 years of

age. Additionally, the renewal criteria were updated to align with other agents in the class.

h) **Oncological Agents—niraparib/abiraterone acetate (Akeega)—**The manual PA criteria for Akeega were updated to include a new indication for the treatment of deleterious or suspected deleterious BRCA2-mutated (BRCA2m) metastatic castration-sensitive prostate cancer (mCSPC) in adults. In addition, oncology standardization edits were incorporated (i.e., revising the NCCN question and removing safety questions).

i) **Targeted Immunomodulatory Biologics (TIBs)—deucravacitinib (Sotyktu)—**Sotyktu received a new indication for the treatment of adults with active psoriatic arthritis. This new indication was added to the PA, and step-therapy for all indications were edited to require a trial of ustekinumab and to require Taltz instead of Cosentyx. The MN criteria were also updated.

***COMMITTEE ACTION: PA UPDATES, REMOVAL OF ESBRIET PA CRITERIA, CLARIFICATION OF AUTOMATED SPECIALIST BYPASS INTENT AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the PA updates for Blujepa, Dupixent, Rubraca, Accufer, Addyi, Hernexeos, Palynziq, Akeega, and Sotyktu. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after signing of the minutes.

**4. Updated PA Criteria for Reasons other than New Indications**

Updates to the PA criteria for several drugs were recommended, due to reasons other than new FDA-approved indications. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

a) **Endocrine Agents Miscellaneous—octreotide (Mycapssa)—**Mycapssa is an oral formulation of octreotide that is currently designated as NF with a PA. An MTF endocrinologist requested an update to the Mycapssa PA which currently requires a trial and failure of injectable octreotide. This requirement does not match the FDA labeling or available clinical trials and guidelines which state that oral octreotide should only be considered if a patient has had an adequate response to injectable octreotide. This question on the PA was updated, and an additional blank write in question was added requiring the provider to document the clinical rational for why the patient could not remain on injectable octreotide.

b) **Hematological Agents—avacopan (Tavneos)—**The FDA released a safety alert on Tavneos due to concerns regarding serious drug-induced liver injuries, some fatal, and vanishing bile duct syndrome. This warning language was added to the Tavneos PA. The P&T committee will continue to follow for any future FDA actions.

c) **Miscellaneous Cardiovascular Agents for obstructive hypertrophic cardiomyopathy (HCM)—mavacamten (Camzyos)—**The manual PA criteria was updated due to the recent approval of aficamten (Myqorzo), (see new drugs section on page 12). The PA was updated to include the prohibition of concomitant use with Myqorzo, and to remove some of the safety criteria.

d) **Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis and Progressive Pulmonary Fibrosis**

Several changes were made to the PAs for the drugs approved for treating idiopathic pulmonary fibrosis, including pirfenidone (Esbriet), nintedanib (Ofev) and nerandomilast (Jascayd). There is step-therapy in the class, where a trial of generic Esbriet is required first. The details are discussed below, with new users affected. See Appendix C for full criteria.

1) **PA update for nerandomilast (Jascayd)—**Jascayd received a new indication for progressive pulmonary fibrosis (PPF) in adults. The P&T committee recommended allowing this indication and requiring step therapy with nintedanib (Ofev) first, based on current guidelines.

2) **PA update for nintedanib (Ofev)—**Ofev is approved for treating idiopathic pulmonary fibrosis, along with Esbriet and Jascayd. The renewal criteria for Ofev were updated to align with the renewal criteria for Jascayd. Additionally, concurrent use of Esbriet and Ofev will now be allowed, based on clinical trial data.

3) **PA removal for pirfenidone (Esbriet)—**Currently, pirfenidone is designated as UF requiring a PA. It is available as a generic and is more cost effective than other agents used for idiopathic pulmonary fibrosis. For these reasons, it was recommended for PA removal.

e) **TIBs: Tumor Necrosis Factor Inhibitors—etanercept (Enbrel)—**The current step-therapy requirements for Enbrel were adjusted to include the preferred formulary alternatives (i.e., Humira, ustekinumab and Taltz) for all adult and pediatric indications, as appropriate. Currently Enbrel only requires step-therapy with Humira in adults and with ustekinumab for pediatric plaque psoriasis.

f) **TIBs: IL-1, IL-6, CTLA-4—anakinra (Kineret)—**An MTF rheumatologist requested that the P&T committee consider adding the off-label indications of gout and pseudogout to the Kineret PA. This recommendation was supported by the American College of Rheumatology 2020 Gout guidelines, which list an IL-1 inhibitor as an option for gout patients who cannot tolerate or have a contraindication to anti-inflammatory therapies. Additionally, Kineret is more cost-effective than some TRICARE medical benefit medications used for these indications. The off-label uses for gout and pseudogout are approved if Kineret is prescribed by or in consultation with a rheumatologist and the

patient has had an inadequate response, intolerance, or contraindication to other therapies.

g) **Updating Automated Specialist Bypass Implementation—** Automated specialist bypass is a process where physicians of certain specialties are allowed to bypass selected PAs if their National Provider Identifier (NPI) number corresponds with the preferred specialist taxonomy designated in the P&T Committee minutes.

Automated specialist bypass was first recommended for Humira in May 2023, allowing rheumatologists to bypass the PA. Since that time, automation has been recommended for over 20 drugs. Specialist bypass is reliant on accurate NPI taxonomy codes to automate the bypass. Previously, for PAs eligible for a specialist bypass, a question was added asking if the provider was the designated specialist type. If the provider answered in the affirmative, they would sign and date the form, and the PA would be approved. An audit of these drugs revealed that these PAs were not operationalized as intended; providers without the approved taxonomy were inappropriately bypassing the PA criteria.

To clarify, the P&T Committee will explicitly identify who may bypass the PA utilizing an automated specialist lookback. The P&T Committee will clearly identify which provider specialty types are allowed to bypass. The minutes will explicitly state the approved specialty types and any other physician specialists and mid-level providers (e.g., physician assistants, nurse practitioners, etc.) will not be able to bypass the PA criteria. These other providers are required to fill out the PA form and ensure the patient meets the P&T approved criteria. The self-attestation question allowing providers to manually bypass the PA will be removed to ensure compliance, and only the providers identified through the automated lookup will be allowed to bypass the PA.

This PA bypass question will be removed from the PAs for Humira, Repatha, Taltz, Ilumya, Brukinsa, Calquence, Zytiga 250 mg and 500 mg, Vosevi, Sovaldi, Harvoni, Zepatier, Epclusa, Sunosi, Restasis, Zymfentra, Entyvio, the Blood Glucose test strips, Ebglyss, Myrbetriq, Blujepa and Orlynvah. Moving forward specialty bypass will only trigger solely based on automation verifying against the approved list of NPI taxonomy codes (the provider is responsible for keeping this up to date); otherwise the full manual PA form will need to be completed.

***COMMITTEE ACTION: PA UPDATES, REMOVAL OF ESBRIET PA CRITERIA, CLARIFICATION OF AUTOMATED SPECIALIST BYPASS INTENT AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the PA updates for Enbrel, Tavneos, Kineret, Mycapssa, Jascayd and Ofev, removing the PA criteria for pirfenidone (Esbriet), and updating the automated specialist bypass implementation. Implementation for the PA changes for the drugs will be effective the first Wednesday 60 days after

signing of the minutes, while the PA removal for pirfenidone 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 eight 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. **Anticonvulsants-Antimania Agents**—designating the authorized generic formulation of **levetiracetam tablet for suspension** with the same formulary status (UF) as Spritam tablet for suspension.
2. **Electrolyte-Mineral-Trace Element Replacement**—designating **potassium chloride 10 mEq/15mL liquid (Pokonza)** with the same formulary status (UF), and PA as Pokonza packets. Refer to the February 2024 P&T minutes to see the PA applied to the Pokonza packets.
3. **Immunological Agents Miscellaneous—**designating **immune globulin (human) (Gammargard Liquid ERC**) with the same formulary status (UF, non-step-preferred), PA, QL, and Specialty status as the parent Gammagard liquid.
4. **Metabolic Dysfunction Agents: Weight Loss Agents**
    a. designating **semaglutide 7.2 mg pen (Wegovy HD)** with the same formulary status (UF), PA, and QL as the parent Wegovy pen.
    b. designating **tirzepatide multidose pen (Zepbound Kwikpen)** with the same formulary status (UF), PA, and QL as the parent Zepbound pen.
5. **Ophthalmic: Anti-infective**
    a. designating the authorized generic formulation of **besifloxacin eye drops** with the same formulary status (UF) as Besivance eye drops.
    b. designating the authorized generic formulation of **loteprednol etabonate/ tobramycin eye drops** with the same formulary status (UF) as Zylet eye drops.
6. **Thyroid and Antithyroid Agents**—designating the authorized generic formulation of **levothyroxine capsules** with the same formulary status (UF), PA, and TRICARE Maintenance Drug List status as Tirosint capsules.

***COMMITTEE ACTION: LINE EXTENSION AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, MN, Specialty and TRICARE Maintenance Drug Lists status for the eight products listed above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

## VII. THERAPEUTIC SUBSTITUTION BEST PRACTICES

*Background:* Previous P&T Committee approved conclusions and definitions regarding therapeutic substitution. concluded that therapeutic substitution is the practice of dispensing a

drug that is chemically different but therapeutically similar to the one prescribed, including biosimilars. Therapeutic substitution may apply to both prescriptions for the outpatient setting and medication orders for the inpatient and/or clinic setting.

For biosimilars, the P&T Committee determined that FDA approved biosimilar products, whether officially designated as interchangeable or not, are equally safe and efficacious when compared to the reference product. Similar to the U.S. FDA, European Medicines Agency, and the United Kingdom Medicines and Healthcare Regulatory Agency guidance, the DoW P&T Committee will consider all approved biosimilars as interchangeable to the reference product for both efficacy and safety.

The P&T Committee stance for therapeutic substitution is as follows:

- To ensure high quality, effective operation of the TRICARE Pharmacy benefit and to optimize drug selection and maximize cost avoidance, standardized therapeutic substitution will be utilized at the MTFs as directed by the DoW P&T Committee.
- Therapeutic substitution is a method of formulary management that streamlines administrative processes and improves compliance with formulary changes.
- Therapeutic substitution is a tool, used either alone or in combination with provisions including "grandfathering" (substitutions affecting only new to therapy patients) or "no grandfathering" (substitutions affecting both new and current users) and bulk prior authorization (PA) placement, to efficiently manage the benefit.
- While therapeutic substitution may be directed at the local level, DoW P&T Committee-directed processes can optimize these therapeutic substitutions for maximum efficacy across the enterprise.
- Therapeutic substitution approved at the national level will be applied to prescriptions and orders written by MTF providers for dispensing at MTF pharmacies. MTFs are encouraged to utilize local state laws regarding therapeutic substitution for providers external to the MTF.

*Conclusion:* MTF guidance for therapeutic substitution and ustekinumab-aauz (Otulfi) implementation:

The committee reviewed the recommended procedure for implementation of therapeutic substitution, along with specific recommendations for the therapeutic substitution to the JNC awardee ustekinumab-aauz (Otulfi).

- When a therapeutic substitution occurs, if the original prescription is written for the non-preferred ustekinumab medication and dispense as written (DAW) is not indicated, the pharmacist will perform the substitution to the preferred product (i.e., Otulfi).
- This process will occur automatically at the MTF pharmacy and streamlines the administrative process for the provider or patient.
- For prescriptions of non-preferred products that do not meet the criteria for therapeutic substitution, the current standard patient and provider notifications will still take place.

- Interagency approvals are in process.

The IL-23 subclass was reviewed at the November 2024 P&T Committee meeting. The JNC ustekinumab biosimilar (pending selection at that time) was chosen as the UF step-preferred IL-23 agent. At the February 2025, May 2025, August 2025, and February 2026 P&T Committee meetings, newly approved ustekinumab biosimilars were reviewed for formulary placement and considered therapeutically equivalent to the reference product and each other.

- The JNC for ustekinumab was awarded to ustekinumab-aauz (Otulfi) on May 4, 2026.
- A trial of the JNC-selected ustekinumab-aauz (Otulfi) will be required before use of any other ustekinumab in new and current users.
- The JNC-selected ustekinumab (Otulfi) will be required before the use of other IL-23 agents in new users. Current users will not be affected.
- Therapeutic substitution for ustekinumab medications filled at MTF pharmacies written by MTF providers will improve efficiency and facilitate cost avoidance by increasing patient movement to the DoW P&T Committee preferred product, Otulfi, while maintaining clinically appropriate care.
- The DoW P&T Committee will approve therapeutic substitution by determining clinically appropriate and cost-effective care and approving the specific substitution with location for application (e.g., outpatient, clinic, inpatient) and clearly noting if the substitution is approved for interagency utilization
- When approved by the Director, Pharmacy Operations Division will execute and monitor the implementation by notifying MTF providers and MTF pharmacies prior to implementation, providing education as appropriate and communicating to patients regarding no-grandfathering scenarios via notification letters

***COMMITTEE ACTION: RECOMMENDATION ON THE MTF GUIDANCE FOR MEDICATION THERAPEUTIC SUBSTITUTION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the guidance as presented for implementation of therapeutic substitution. Sufficient evidence was presented to move forward with therapeutic substitution as signed by the Director.

*Conclusion:* Interagency collaboration

To enhance the DoW's therapeutic substitution program, a position statement on therapeutic substitution best practices was developed in collaboration with the Department of Veterans Affairs (VA). This position statement details the process for therapeutic substitution using a collaborative, evidence-based approach that prioritizes patient safety, provider-approved protocols, communication, education, and ongoing safety monitoring.

This collaboration establishes the following interagency guidelines:

- Interagency Substitution Portability: This collaboration supports interagency therapeutic substitution. Once formal approval has been obtained from both DoW and VA P&T Committees, a prescription or order from an MTF provider may be therapeutically substituted by a VA pharmacy, and vice versa.
- Jurisdictional Boundaries: Unless otherwise indicated and explicitly approved by both agencies, specific therapeutic substitution protocols will only apply to orders/prescriptions written by MTF providers and filled/dispensed at an MTF pharmacy.
- When approved by the Director, Pharmacy Operations Division will execute therapeutic substitution and monitor the implementation by collaborating with the Department of Veterans Affairs on joint efforts regarding monitoring (i.e., patient safety reports).

***COMMITTEE ACTION: RECOMMENDATION ON THE JOINT STATEMENT ON THERAPEUTIC SUBSTITUTION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) accepting the Joint Statement on Therapeutic Substitution Best Practices in collaboration with the VA for interagency efficiency to improve portability of the benefit, improve transitions of care, and increase accessibility. Upon formal approval, this collaboration includes support for interagency therapeutic substitution (i.e., a prescription or order from an MTF provider may be therapeutically substituted by a VA pharmacy and vice versa).

## VIII. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

**A. Ustekinumab JNC Award Announcement**: On May 4, 2026, the ustekinumab JNC was awarded to ustekinumab-aauz (Otulfi), which will now be the UF, step-preferred product. Refer to the February 2026 P&T Committee meeting minutes for the formulary recommendations. Note that in the "JNC-Awarded Scenario" branded Otulfi is listed as NF and non step-preferred; this no longer applies. Additionally, all the information in the "JNC not awarded scenario" does not apply, since a JNC was awarded.

**B. Annual Utilization Management Review**: The P&T Committee reviewed a summary of approximately 140 UM actions from the four P&T Committee meetings held in FY2025 (November 2024 to August 2025). A focused review of actions showed that while there were more PA additions than removals, more patients were positively affected by PA removals than PA additions. The Committee reviewed detailed analysis of the effects of PAs on MHS utilization and spend. A review of previously implemented automated specialist bypass PAs showed a decrease in PA volume without a significant change in utilization of these drugs, indicating selection criteria were appropriate. Of note, many UM actions for FY2025 have not yet been implemented due to the UF BAP pause.

**C. Manufacturer brand name change for semaglutide (Rybelsus) to semaglutide (Ozempic) tablets:** Semaglutide tablets (Rybelsus) are approved for treating Type 2

diabetes mellitus (T2DM) and were designated as UF with a PA at the November 2019 P&T Committee meeting. The manufacturer has changed the semaglutide tablets brand name from Rybelsus to Ozempic, similar to the brand name for semaglutide injection for T2DM. The renamed Ozempic tablets will retain the same formulary status and PA criteria as the previous Rybelsus tablets. Beneficiary notification will occur via letters.

D. **Oncological Agents for epithelial sarcoma: tazemetostat (Tazverik) Market Withdrawal:** The manufacturer voluntarily withdrew Tazverik from the market for all its indications due to secondary hematologic malignancies. The TPharm5 contractor will notify affected beneficiaries.

E. **Standardization of concurrent immunomodulatory agents use wording:** PAs in multiple classes do not allow for concurrent use of two immunomodulatory agents. There is variation in how this PA question is phrased, with some PAs listing out classes of medication while others list out individual medications. To standardize this phrase across classes, the following language will be used moving forward, "Coverage is not provided for concomitant use with other targeted immunobiologics including but not limited to, TNF inhibitors, interleukins, JAK inhibitors".

F. **Administrative update to GLP-1 weight loss PAs:** The TPharm5 contractor identified that GLP-1 PA requests were resulting in unintended denials for patients resuming therapy after a break in treatment. To prevent unintended denials for patients restarting GLP-1 therapy, a new "interruption in therapy" option was added to the electronic PA continuation pathway. This option will correctly reroute prescribers to the initial "new start" evaluation criteria rather than a denial for not meeting the continuation pathway criteria.

G. **Phosphodiesterase-5 (PDE-5) Inhibitors—sildenafil oral film (Vibrique**) recently gained market approval and was originally slated for review as an innovator drug. The manufacturer is only intending the product for patient self-pay, and Vibrique will not be available for purchases by MTFs or at TMOP.

H. **Ophthalmic Agents for Presbyopia—carbachol 2.75%/brimonidine 0.1% ophthalmic solution:** Yuvezzi treats age-related blurred vision (presbyopia). The drug requires long-term administration due to the short duration of action and does not reverse the underlying problem. Yuvezzi is not medically necessary, and thus is not a covered TRICARE pharmacy benefit, similar to the other drugs for presbyopia, including pilocarpine 0.125% ophthalmic solution (Vuity), pilocarpine 0.4% ophthalmic solution (Qlosi) and aceclidine 1.44% ophthalmic (Vizz).

## IX. ADJOURNMENT

The meeting adjourned at 1200 hours on May 7th. The next meeting will be in August 2026.

**Appendix A—Attendance: May 2026 DoW 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 May 2026 DoW P&T Committee Meeting**
**Appendix G—Implementation Dates**
**Appendix H—Drugs with Complete Exclusion Status and Formulary Alternatives**

## DECISION ON RECOMMENDATIONS

**SUBMITTED BY**: Signed/Signature on file

John P. Kugler, M.D., MPH
DoW 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:

Signed/Signature on file

Bill A. Soliz
BG, USA
Acting Assistant Director
Health Care Administration and Operations

July 20, 2026
Date

**Appendix A—Attendance**

| **Voting Members Present** | |
|---|---|
| John Kugler, MD, COL (Ret.), USA | DoW 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.), USA | DHA, Family Medicine Physician |
| LTC Megan Donahue, MC | Army, Physician at Large |
| LTC Ryan Burkhart, MC | Army, Internal Medicine Physician |
| COL James Masterson, MSC | Army, Pharmacy Consultant |
| CDR Derek Larson, MC | Navy, Internal Medicine Physician |
| CDR Danielle Barnes, MC | Navy, Pediatrics |
| MAJ Loraine Baraki, MC | Army, OBGYN |
| CAPT Peter Cole, MC | Navy, Physician at Large |
| CAPT Katie Jaudon, MSC | Navy, Pharmacy Consultant |
| Maj Callie Cheatham, MC | Air Force, Internal Medicine Physician |
| Col Soo Sohn, BSC | Air Force, Pharmacy Consultant |
| Walter Downs, MD, CAPT (Ret.), USN | DHA, Physician at Large |
| Maj Rebecca Wetzel, MC | Army, Oncology Physician |
| David Nowinski, PharmD, BCOP | DHA, Oncology Pharmacist |
| CAPT Jackie Finocchio, USCG | Coast Guard, Pharmacy Consultant |
| Richard Ruck, MD, COL (Ret.), MC, USA | TRICARE Health Plan Chief Medical Officer |

**Appendix A—Attendance**

| **Nonvoting Members Present** | |
|---|---|
| Dennis Dyke, DHA | Attorney Advisor, Contract Law |
| Shannon Kilgore, MD | Department of Veteran's Affairs |
| Eric Dill, PharmD | Department of Veteran's Affairs |
| Marsha Peterson | DHA Contracting Officer |
| Eric Parsons, PharmD | TPharm5 Clinical COR, Pharmacy Benefit Integration Branch |
| Lt Col Josh Stallings, BSC, PharmD | Defense Logistics Agency, CPOC |
| **Guests** | |
| CDR Brett Whitehead | Indian Health Service |
| Hazel Richardson, PharmD | CDC World Trade Center Health Plan |
| LT Jacob Kocher | Indian Health Service pharmacy resident |
| **POD Staff Present** | |
| CAPT Tiffany Cline, PharmD USN | Deputy Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO |
| 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 |
| Lt Col Pansy Uberoi, MC | DHA POD Formulary Management Branch |
| Maj Angelina Escano, MC | DHA POD Formulary Management Branch |
| Heather Johnson, PharmD, BCCP | DHA POD Formulary Management Branch |
| Darrilyn Bihm, PharmD | DHA POD Formulary Management Branch |
| Thinh Ha, PharmD | DHA POD Formulary Management Branch |
| CPT Ji Yoon Kim | DHA POD Formulary Management Branch |
| Dean Valibhai, PharmD | TPharm5 Clinical ACOR, Pharmacy Benefit Integration Branch |
| Mike Lee, MBM, MPharm-Econ | DHA POD Formulary Management Branch |
| David Folmar, MS, MBA | DHA POD Formulary Management Branch |

**Appendix A—Attendance**

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|---|---|
| Helen Feinstein, PharmD, BCPS | DHA POD Formulary Management Branch |
| Mat Garber, PharmD, MA, PhD | DHA POD Formulary Management Branch |
| Maj Mark McGiffin | Air Force PhD Student |
| **DHA Contracting** | |
| Jules Canaley | DHA Contracting |
| Kirk Heyen | DHA Contracting |
| Keith Marasigan | DHA Contracting |
| Tracy Banks | DHA Contracting |
| Dwight Bonham | DHA Contracting |
| Julia Trang | DHA Contracting |
| Stephanie Erpelding | DHA Contracting |
| Patricia Legra | DHA Contracting |
| Viktoria Reed | DHA Contracting |
| Brooke Wolfe | DHA Contracting |

## Appendix B—Table of Medical Necessity Criteria

| Drug / Drug Class | Medical Necessity (MN) Criteria |
|---|---|
| **Drug Class Reviews MN Criteria** | |
| • fitusiran (Qfitlia)<br><br>**Antihemophilic Agents: Non-Factor Agents** | • Use of formulary agents is contraindicated<br>• Patient has experienced significant adverse effects from formulary alternatives which is not expected with the nonformulary product<br>• Formulary agents result or are likely to result in therapeutic failure<br><br>**Formulary alternatives:** For hemophilia A: Hemlibra, Alhemo, and Hympavzi; For hemophilia B: Alhemo and Hympavzi |
| • nilotinib tartrate (Danziten)<br><br>**Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | • Use of formulary agents is contraindicated<br><br>**Formulary alternatives**: nilotinib (Tasigna), imatinib, dasatinib |
| **New Drugs MN Criteria** | |
| • desmopressin acetate 0.05 mg/mL solution (Desmoda)<br><br>**Endocrine Agents Miscellaneous** | • Use of formulary agent is contraindicated<br><br>**Formulary alternatives**: desmopressin injection, desmopressin tablets, desmopressin (DDAVP) nasal spray |
| • etripamil (Cardamyst)<br><br>**Cardiovascular Agents: Calcium Channel Blockers** | • Formulary agents resulted in therapeutic failure<br><br>**Formulary alternatives**: Oral verapamil, oral diltiazem, metoprolol, propranolol (for maintenance) |
| • icotrokinra (Icotyde)<br><br>**TIBs: IL-23 Inhibitor** | • Use of formulary agents is contraindicated<br>• Patient has experienced significant adverse effects from formulary agents<br>• Formulary agents resulted in therapeutic failure<br><br>**Formulary alternatives**: adalimumab (Humira), ustekinumab-aauz (Otulfi), ixekizumab (Taltz), apremilast (Otezla) |
| • lerodalcibep-liga injection (Lerochol)<br><br>**Antilipidemic-1 Agent: PCSK9 Inhibitors** | • Patient has experienced significant adverse effects from formulary agents<br>• Formulary alternatives have resulted in therapeutic failure<br><br>**Formulary alternatives**: Repatha, Praluent |
| • lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)<br><br>**ADHD Agents** | • Use of formulary agent is contraindicated<br>• Patient has experienced significant adverse effects from formulary agents<br><br>**Formulary alternatives**: lisdexamfetamine capsules, lisdexamfetamine chewable tablets, methylphenidate (e.g., Concerta), amphetamine (e.g., Adderall) |

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|---|---|
| • methocarbamol 750 mg/5 mL oral suspension (Atmeksi)<br><br>**Skeletal Muscle Relaxants and Combinations** | • No alternative formulary agent; patient requires a liquid methocarbamol formulation due to a documented medical condition and not due to convenience<br><br>**Formulary alternatives**: methocarbamol tablets, baclofen tablets, and cyclobenzaprine tablets |
| • tizanidine 2 mg/5 mL oral solution (Ontralfy)<br><br>**Skeletal Muscle Relaxants and Combinations** | • No alternative formulary agent; patient requires a liquid tizanidine formulation due to a documented medical condition and not due to convenience<br><br>**Formulary alternatives:** tizanidine tablets, tizanidine capsules |
| • tocilizumab-anoh injection (Avtozma)<br><br>**TIBs: IL-6 Inhibitor** | • Use of formulary agents is contraindicated<br>• Patient has experienced significant adverse effects from formulary agents<br><br>• **Formulary alternatives**: adalimumab (Humira), tocilizumab-aazg (Tyenne) |
| **Utilization Management MN Criteria** | |
| • deucravacitinib (Sotyktu)<br><br>**Targeted Immunomodulatory Biologics** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>• Patient has experienced **~~or is likely to experience~~** significant adverse effects from formulary agents<br>• Formulary agents resulted **~~or are likely to result~~** in therapeutic failure<br><br>**Formulary alternatives:** apremilast (Otezla), secukinumab (Cosentyx), adalimumab (Humira), **ixekizumab (Taltz), ustekinumab-aauz (Otulfi)** |

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

| Drug / Drug Class | Prior Authorization Criteria |
|---|---|
| **Drug Class Review PAs** | |
| • concizumab-mtci (Alhemo)<br><br>**Antihemophilic Agents: Non-Factor Agents** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all new users of concizumab-mtci<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 12 years of age or older<br>• Prescribed by or in consultation with a hematologist<br>• Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors<br>• Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding<br>• **Medication is not being used in combination with Immune Tolerance Induction (ITI)**<br>Non-FDA approved uses are not approved.<br>PA does not expire |
| • fitusiran (Qfitlia)<br><br>**Antihemophilic Agents: Non-Factor Agents** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all new users of fitusiran (Qfitlia)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 12 years of age or older<br>• Prescribed by or in consultation with a hematologist<br>• Patient has hemophilia A with or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors<br>• Patient is not concurrently receiving factor VIII or factor IX therapy after initial transition period unless for the treatment of breakthrough bleeding<br>• For hemophilia A, the patient has had an inadequate response, intolerance, or contraindication to emicizumab-kxwh (Hemlibra)<br>• **For hemophilia B, the patient has had an inadequate response, intolerance, or contraindication to marstacimab-hncq (Hympavzi) or concizumab-mtci (Alhemo)**<br>• **Medication is not being used in combination with Immune Tolerance Induction (ITI)**<br>Non-FDA approved uses are not approved<br>PA does not expire |
| • marstacimab-hncq (Hympavzi)<br><br>**Antihemophilic Agents: Non-Factor Agents** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of Hympavzi.<br>Manual PA criteria: Hympavzi is approved if all criteria are met:<br>• Patient is 12 years of age or older<br>• Prescribed by or in consultation with a hematologist<br>• Patient has ~~**moderate to severe**~~ hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors<br>• Patient is not concurrently receiving Factor VIII or IX therapy unless for the treatment of breakthrough bleeding<br>• **Medication is not being used in combination with Immune Tolerance Induction (ITI)**<br>Non-FDA-approved uses are not approved.<br>PA does not expire. |

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

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| • asciminib (Scemblix)<br><br>**Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>**Automated PA Criteria: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days**<br>Manual PA criteria apply to all new users<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Prescribed by or in consultation with an ~~hematologist~~/oncologist<br>• The patient is being treated for the following:<br>▪ Philadelphia chromosome-positive chronic myeloid leukemia ~~in chronic phase~~ and<br>– **has tried and failed OR**<br>– **had an intolerance to OR**<br>– **has a risk stratification (i.e. low, advanced) OR**<br>– **has a contraindication (e.g. comorbidity, mutation, concomitant PPI) to at least one generic TKI (i.e. imatinib, dasatinib)**<br>• The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.<br>Non-FDA-approved uses are not approved except as noted above<br>Prior authorization does not expire |
| • bosutinib tablets and capsules ~~(~~Bosulif)<br><br>**Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>**Automated PA Criteria: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days**<br>Manual PA criteria apply to all new users<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Prescribed by or in consultation with an ~~hematologist/~~oncologist<br>• **Patient has Philadelphia chromosome-positive chronic myeloid leukemia and**<br>▪ **has tried and failed OR**<br>▪ **had an intolerance to OR**<br>▪ **has a risk stratification (i.e., low, advanced) OR**<br>▪ **has a contraindication (e.g., comorbidity, mutation, concomitant proton pump inhibitor use) to at least one generic TKI (i.e., imatinib, dasatinib)**<br>~~• 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~~<br>~~• Patient is 18 years of age or older with accelerated or blast phase Ph+ chronic myeloid leukemia with resistance or intolerance to prior therapy~~<br>~~• Patient cannot swallow tablets due to a documented medical condition (e.g. dysphagia)~~<br>~~• The provider is aware of all warnings, screening, and monitoring precautions for Bosulif~~<br>• The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval, please list the diagnosis, guideline version and page number _____.** |

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

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| | Other non-FDA approved uses are NOT approved except as noted above<br>PA does not expire |
| • dasatinib (Phyrago)<br><br>• **Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>**<u>Automated PA Criteria</u>: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days**<br>Manual PA criteria apply to all new users<br><u>Manual PA criteria:</u> Coverage is approved if all criteria are met:<br>• Prescribed by or in consultation with an oncologist<br>• **Patient is being treated for one of the following:**<br>▪ **Acute lymphoblastic leukemia**<br>▪ **Philadelphia chromosome-positive chronic myeloid leukemia and**<br>- **has tried and failed OR**<br>- **had an intolerance to OR**<br>- **has a risk stratification (i.e., low, or advanced) OR**<br>- **has a contraindication (e.g., comorbidity, mutation, concomitant proton pump inhibitor use) to at least one generic TKI (i.e., imatinib, dasatinib)**<br>~~• The patient has one of the following diagnoses:~~<br>~~▪ Adults 18 years or older with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase~~<br>~~▪ Adults 18 years or older with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib~~<br>~~▪ Adults 18 years or older with Ph+ acute lymphoblastic leukemia who no longer benefit from, or did not tolerate other treatment~~<br>~~▪ Pediatric patients 1 year of age and older with Ph+ CML in chronic phase~~<br>~~▪ Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.~~<br>~~• Patient is receiving concurrent H2 blockers (e.g., famotidine, ranitidine, cimetidine) or PPI (e.g., omeprazole esomeprazole, rabeprazole, lansoprazole).~~<br>~~▪ The provider must document the reason why the patient requires long-term concurrent H2 blockers or proton pump inhibitors. OR~~<br>~~▪ The patient has been referred to GI for additional work up (e.g., endoscopy)~~<br>• The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guideline version and page number._____<br>Other non-FDA approved uses are not approved except as noted above<br>**Prior authorization does not expire**<br>~~PA expires yearly. PA will be renewed for an additional year if : patient has a documented reason to remain on concurrent H2 blockers or PPIs~~ |
| • imatinib oral solution (Imkeldi)<br><br>**Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | **Updates from the Feb 2026 meeting are in bold and strikethrough**<br>Age edit: PA not required if patient is age 6 years or younger<br>Manual PA criteria apply to all new users of imatinib oral solution (Imkeldi)<br><u>Manual PA criteria</u>: Coverage is approved if all criteria are met:<br>• Provider acknowledges that generic imatinib tablets can be dissolved in water or juice and are available to **TRICARE** beneficiaries without requiring prior authorization |

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

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| | • Prescribed by or in consultation with an oncologist<br>• **Patient is being treated for one of the following:**<br>▪ **Philadelphia Chromosome-positive Chronic Myeloid Leukemia**<br>▪ **Acute Lymphoblastic Leukemia**<br>▪ **Myeloproliferative Disease**<br>▪ **Mastocytosis**<br>▪ **Hypereosinophilic Syndrome**<br>▪ **Chronic Eosinophilic Leukemia**<br>▪ **Dermatofibrosarcoma Protuberans**<br>▪ **Gastrointestinal Stromal Tumor**<br>• Patient has had an adverse reaction to an excipient in imatinib tablets that is unlikely to occur with Imkeldi **or patient has documented swallowing dysfunction requiring an alternative formulation for treatment**<br>• ~~Patient has tried and failed treatment with dissolving imatinib tablets in liquid~~<br>• **The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.**<br>Non-FDA-approved uses are not approved, except as noted above<br>PA does not expire |
| • nilotinib tartrate (Danziten)<br><br>**Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>**<u>Automated PA Criteria</u>: The patient has filled a prescription for generic imatinib or dasatinib at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days**<br>Manual PA criteria apply to all new users<br><u>Manual PA criteria</u>: Coverage is approved if all criteria are met:<br>• Provider acknowledges there is no PA with Tasigna<br>• Prescribed by or in consultation with an ~~hematologist or~~ oncologist<br>• Patient is 18 years of age or older<br>• **Patient has Philadelphia chromosome-positive chronic myeloid leukemia and**<br>▪ **has tried and failed OR**<br>▪ **had an intolerance to OR**<br>▪ **has a risk stratification (i.e., low, advanced) OR**<br>▪ **has a contraindication (e.g., comorbidity, mutation, concomitant proton pump inhibitor use) to at least one generic TKI (i.e., imatinib, dasatinib)**<br>• ~~Patient has a diagnosis of:~~<br>▪ ~~Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase~~<br>▪ ~~Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib~~<br>• ~~Patient has tried Tasigna and had an adverse reaction not expected to occur with Danziten OR~~<br>• ~~Patient cannot avoid food 2 hours before and one hour after taking Tasigna~~<br>• The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number._____<br>Other non-FDA approved uses are not approved except as noted above |

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

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| | PA does not expire |
| • ponatinib (Iclusig)<br><br>**Leukemia Lymphoma: BCR-ABL Tyrosine Kinase Inhibitors** | Manual PA criteria apply to all new users<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Prescribed by or in consultation with an oncologist<br>• Patient is being treated for one of the following:<br>▪ Acute lymphoblastic leukemia<br>▪ Patient has Philadelphia chromosome-positive chronic myeloid leukemia and<br>– has tried and failed OR<br>– had an intolerance to OR<br>– has a risk stratification (i.e., low, advanced) OR<br>– has a contraindication (e.g., comorbidity, mutation, concomitant proton pump inhibitor use) to at least one generic TKI (i.e., imatinib, dasatinib)<br>• The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____.<br>Non-FDA-approved uses are not approved except as noted above<br>Prior authorization does not expire |
| **Newly Approved Drug PAs** | |
| • aficamten (Myqorzo)<br><br>**Miscellaneous Cardiovascular Agents Miscellaneous** | Manual PA criteria apply to all new users of Myqorzo<br>Manual PA criteria: Myqorzo is approved if all criteria are met:<br>• The patient is 18 years of age and older<br>• Drug is prescribed by a cardiologist<br>• The patient has documented evidence of obstructive hypertrophic cardiomyopathy (HCM)<br>• Left ventricular outflow tract (LVOT) pressure gradient is greater than or equal to 30 mmHg at rest or greater than or equal to 50 mmHg after the Valsalva maneuver<br>• The patient has NYHA Class II to III obstructive HCM that is symptomatic (e.g., dyspnea, chest pain, lightheadedness, syncope, fatigue, reduced exercise capacity)<br>• The patient's left ventricular ejection fraction (LVEF) is greater than or equal to 55%<br>• Patient has failed therapy with at least one agent from both of the following classes:<br>▪ Beta blocker (non-vasodilating) – propranolol, metoprolol AND<br>▪ Calcium channel blockers (non-dihydropyridine) – verapamil, diltiazem<br>• Myqorzo will not be used concomitantly with Camzyos<br><br>Non-FDA-approved uses are not approved<br>PA expires in 1 year<br>Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be renewed indefinitely if the following applies:<br>The patient has responded to therapy, as evidenced by improvement in obstructive hypertrophic cardiomyopathy symptoms |

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

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| • amlodipine powder for oral solution (Sdamlo)<br><br>**Calcium Channel Blocker** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all new users of amlodipine powder for oral solution Sdamlo<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• **Provider acknowledges that Sdamlo will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T meeting minutes by the Director, DHA**<br>• Provider must document why the patient cannot take amlodipine tablets, amlodipine suspension (Katerzia), or amlodipine solution (Norliqva)<br>▪ Acceptable responses include that the patient requires a long-acting CCB and cannot swallow amlodipine tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience AND that they have failed and tried Katerzia AND Norliqva<br>Non-FDA approved uses are not approved<br>PA does not expire **until after implementation of complete exclusion status** |
| • copper histidinate injection (Zycubo)<br><br>**Electrolyte Mineral Trace Elements: Replacement Enzymes** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of copper histidinate (Zycubo)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 17 years of age or younger<br>• Prescribed by a physician who specializes in Menkes Disease treatment<br>• Patient has a confirmed diagnosis of Menkes Disease with a severe pathogenic variant of the ATP7A gene<br>• Patient does not have any of the following: mild phenotype, liver or kidney disease, participation in other investigational treatment, any disease which impacts gastrointestinal absorption<br>Non-FDA approved uses are not approved<br>**PA does not expire**<br>~~PA expires in 6 months~~<br>~~Renewal criteria: Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:~~<br>• ~~Patient had a positive response to therapy~~ |

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

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| • desmopressin acetate 0.05 mg/mL oral solution (Desmoda)<br><br>**Miscellaneous Endocrine Agent** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>**Age edit: PA does not apply to patients 6 years of age and younger**<br>Manual PA criteria apply to all new users of desmopressin oral solution (Desmoda)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient has a diagnosis of diabetes insipidus<br>• Prescription is written by an endocrinologist<br>• Provider must explain why patient requires desmopressin oral solution and cannot take desmopressin tablets and the DDAVP nasal spray<br>▪ Acceptable responses include:<br>– The patient requires desmopressin oral solution (Desmoda) and cannot swallow desmopressin tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience OR<br>– T**he patient can't administer nasal spray due to severe nasal obstruction or prior nasal surgery**<br><br>Non-FDA approved uses are not approved<br>PA does not expire |
| • doxecitine / doxribtimine 2 gram packet for oral solution (Kygevvi)<br><br>**Miscellaneous Metabolic Agent: Replacement Enzymes** | Manual PA criteria apply to all new users of doxecitine and doxribtimine powder for oral solution (Kygevvi)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Prescribed by or in consultation with a neurologist, geneticist, or physician who specializes in metabolic and/or neuromuscular disorders<br>• Patient has had a genetic test confirming the diagnosis of Thymidine Kinase 2 Deficiency (TK2d) with biallelic pathogenic or likely pathogenic variants in the TK2 gene<br>• Patient had symptom onset consistent with Thymidine Kinase 2 Deficiency (TK2d) at 12 years of age or less<br><br>Non-FDA approved uses are not approved<br>PA does not expire |
| • etripamil nasal spray (Cardamyst)<br><br>**Calcium Channel Blocker** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of Cardamyst<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• **Prescribed by or in consultation with a cardiologist or electrophysiologist.**<br>• Patient has ECG documentation of previous episodes of paroxysmal supraventricular tachycardia (PSVT)<br>• Previous PSVT episodes have lasted 20 minutes or longer<br>• **Patient has experienced at least one episode of PSVT that required hospitalization or ER visit in the past 12 months**<br>• **Patient is currently receiving oral pharmacological therapy for prevention of PSVTs**<br>• **Patient has ~~refused~~ declined ablation or is not a candidate for ablation based on disease or other medical considerations OR**<br>▪ Patient has post-ablation PSVT |

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| | ▪ **The patient is aware of the safety and effectiveness of ablation as the preferred therapy**<br>• **The patient has been educated on the use of vagal maneuvers in PSVT, and self-administration of etripamil (Cardamyst)**<br><br>Non-FDA approved uses are not approved.<br>PA expires after 1 year. Initial TRICARE coverage required for approval. PA will be approved indefinitely if the following applies:<br>• The patient has responded to therapy and is complying with the administration instructions. |
| • icotrokinra (Icotyde)<br><br>**TIBs: IL-23 Inhibitors** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all new and current users of icotrokinra (Icotyde)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Provider acknowledges that adalimumab (Humira) is TRICARE's preferred biologic product<br>▪ Patient had an inadequate response to adalimumab (Humira) or the patient experienced an adverse reaction to adalimumab (Humira) that is not expected to occur with icotrokinra (Icotyde) or the patient has a contraindication to adalimumab (Humira)<br>• Provider acknowledges that ustekinumab-**aauz (Otulfi**) is TRICARE's preferred IL-23 product<br>▪ Patient had an inadequate response to ustekinumab-aauz (Otulfi) or the patient experienced an adverse reaction to ustekinumab-aauz (Otulfi) that is not expected to occur with icotrokinra (Icotyde) or the patient has a contraindication to ustekinumab-aauz (Otulfi)<br>• **Provider acknowledges that a trial of ixekizumab (Taltz) is required**<br>▪ **Patient had an inadequate response to ixekizumab (Taltz) or the patient experienced an adverse reaction to ixekizumab (Taltz) that is not expected to occur with icotrokinra (Icotyde) or the patient has a contraindication to ixekizumab**<br>• Patient is 12 years of age or older<br>• Patient has moderate to severe plaque psoriasis and is a candidate for phototherapy or systemic therapy<br>• 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<br>Non-FDA approved uses are not approved<br>PA expires in 1 year<br>Renewal criteria: Note initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:<br>• The patient has responded to therapy and<br>• Patient will not be receiving any other targeted immunomodulatory biologics concurrently |

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

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| • lerodalcibep-liga injection (Lerochol)<br><br>**Antilipidemic-1 Agent; Protein convertase subtilisin/kexin type 9 (PCSK9) inhibitor** | Manual PA criteria apply to all new users of lerodalcibep (Lerochol)<br>Manual PA Criteria: Lerochol is approved if all criteria are met<br>• Patient tried and failed therapy or experienced a significant adverse reaction with evolocumab (Repatha)<br>• Patient is 18 years of age or older<br>*For HeFH*<br>• The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses<br>• Patient experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms while on statin therapy OR<br>• Patient has undergone at least 2 trials of statin rechallenges with reappearance of muscle symptoms OR<br>• Patient has had a creatine kinase level greater than 10 times the upper limit of normal OR rhabdomyolysis with CK greater than 10,000 international units per liter (IU/L) that is unrelated to statin use OR<br>• Patient has contraindication to a statin<br>• Prescribed dosage is documented as 300 mg once monthly<br>*For ASCVD*<br>• Patient will be on concurrent statin therapy at maximal tolerated dose while on the requested medication OR<br>• Patient experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms while on statin therapy OR<br>• Patient has undergone at least 2 trials of statin rechallenges with reappearance of muscle symptoms OR<br>• Patient has had a creatine kinase level greater than 10 times the upper limit of normal OR rhabdomyolysis with CK greater than 10,000 international units per liter (IU/L) that is unrelated to statin use OR<br>• Patient has contraindication to a statin<br>• Patient is at very high risk for future ASCVD events AND patient has LDL level greater than 55 mg/dL despite statin at maximal tolerated doses OR<br>• Patient is not very high risk for future ASCVD events AND has an LDL greater than 70 mg/dL despite statin at maximal tolerated doses<br>• Patient tried EITHER atorvastatin (Lipitor) at a dose of 40 mg to 80 mg OR rosuvastatin (Crestor) at a dose of 20 mg to 40 mg for at least 4 to 6 weeks each OR<br>• Patient tried any statin at a maximally tolerated dose in combination with ezetimibe (Zetia) for at least 4 to 6 weeks OR<br>• Patient tried ezetimibe (Zetia) as monotherapy (alone) for at least 4 to 6 weeks<br>• Prescribed dosage is documented as 300 mg once monthly<br>*For patients at high risk for ASCVD*<br>• Patient has LDL level greater than 190 mg/dL OR<br>• Patient has diabetes and LDL level less than 190 mg/dL OR<br>• Patient has LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD greater than 7.5% OR<br>• Patient has LDL level less than 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 |

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

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| | 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<br>• Patient tried EITHER atorvastatin (Lipitor) at a dose of 40 mg to 80 mg OR rosuvastatin (Crestor) at a dose of 20 mg to 40 mg for at least 4 to 6 weeks each OR<br>• Patient tried any statin at a maximally tolerated dose in combination with ezetimibe (Zetia) for at least 4 to 6 weeks OR<br>• If patient statin intolerant has tried ezetimibe (Zetia) as monotherapy (alone) for at least 4 to 6 weeks<br>• Prescribed dosage is documented as 300 mg once monthly<br>*For all indications*<br>• Patient is not pregnant or breastfeeding— applies to all indications<br>Non-FDA approved uses are not approved<br>PA does not expire |
| • lisdexamfetamine dimesylate 10 mg/mL oral solution (Arynta)<br><br>**ADHD Agents: Stimulant** | Manual PA criteria apply to all new users of lisdexamfetamine dimesylate oral solution (Arynta)<br><u>Manual PA criteria</u>: Coverage is approved if all criteria are met:<br>• Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)<br>• Patient is 6 years of age or older<br>• Patient tried and failed mixed amphetamine salts ER (Adderall XR, generics) or another long-acting amphetamine or amphetamine derivative type drug<br>• Patient tried and failed methylphenidate OROS (Concerta, generics) or another long-acting methylphenidate or methylphenidate derivative type drug<br>• Provider must document why the patient cannot take lisdexamfetamine dimesylate capsules or chewable tablets<br>▪ Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in lisdexamfetamine dimesylate capsules; OR the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience<br>OR<br>• Patient has a diagnosis of moderate to severe Binge Eating Disorder (BED)<br>• Patient is 18 years of age or older<br>• Patient tried and failed OR had a contraindication to an SSRI (for example, citalopram, fluoxetine, sertraline)<br>• Patient tried and failed OR had a contraindication to topiramate or zonisamide<br>• Provider must document why the patient cannot take lisdexamfetamine dimesylate capsules or chewable tablets.<br>▪ Acceptable responses include: the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to an excipient in lisdexamfetamine dimesylate capsules; OR the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience<br>Non-FDA approved uses are not approved<br>PA does not expire |

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

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| • methocarbamol 750 mg/5 mL oral suspension (Atmeksi)<br><br>**Skeletal Muscle Relaxants and Combinations** | Manual PA criteria apply to all new users of methocarbamol oral suspension (Atmeksi)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 16 years of age or older<br>• Provider must document why the patient cannot take methocarbamol tablets<br>▪ 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.<br><br>Non-FDA approved uses are not approved<br>PA does not expire |
| • navepegritide powder for injection (Yuviwel)<br><br>**Growth Stimulating Agent** | Manual PA criteria apply to all new users of navepegritide (Yuviwel)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 2 years of age or older<br>• Prescribed by or in consultation with a pediatric endocrinologist<br>• Patient has a documented diagnosis of achondroplasia with open epiphyses<br>• Provider acknowledges that Yuviwel was FDA approved in accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials AND provider acknowledges that a clinical benefit with Yuviwel has not been proven<br>• Patient/caregiver has been instructed on how to properly use, store, and administer Yuviwel<br>• Provider agrees to monitor growth and adjust dose according to body weight<br>• Provider agrees to permanently discontinue Yuviwel upon closure of epiphyses<br><br>Non-FDA approved uses are not approved.<br>PA expires in 1 year. When the PA expires, the next fill/refill will require submission of a new PA |
| • orforglipron (Foundayo)<br><br>**Metabolic Dysfunction Agents: Weight Loss** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all new users of Foundayo<br>Manual PA Criteria: Coverage for Foundayo is approved if:<br>• The provider will acknowledge that “Under penalties for false claims against the United States government, I declare that I have examined the patient, and the statements made are true, correct, and complete to the best of my professional knowledge”<br>• Is the prescriber an MTF or TRICARE Network provider who has billed TRICARE for the professional services provided to assess the patient and develop a treatment plan?<br>▪ If yes, subject to verification, proceed to the next question<br>▪ If no, coverage is not approved<br>• What TRICARE Plan is the patient enrolled in? |

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| | ▪ TRICARE Select – proceed to the next question<br>▪ TRICARE Prime – proceed to the next questions<br>▪ TRICARE For Life– Coverage is not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.<br>• If the diagnosis is Diabetes Mellitus and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.<br>• The provider has verified and documented in the medical record that the patient engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification for at least 6 months, has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. Medical record documentation will be made available to TRICARE for audit, if requested.<br>• The provider will document the major condition and comorbidities treated selecting all that apply:<br>▪ Obesity<br>▪ Diabetes or impaired glucose tolerance<br>▪ Obstructive sleep apnea<br>▪ Osteoarthritis<br>▪ Metabolic syndrome<br>▪ Dyslipidemia<br>▪ Hypertension<br>▪ Metabolic dysfunction-associated steatohepatitis (MASH)<br>▪ Established cardiovascular disease with a history of stroke<br>▪ Established cardiovascular disease with a history of myocardial infarction<br>▪ Established cardiovascular disease with a history of peripheral artery disease<br>• Patient is 18 years of age or older<br>• 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<br>▪ The provider will document the BMI<br>– For BMI less than 27, coverage is not approved<br>– For BMI ranging between 27 and 29 with a comorbidity<br>– For BMI ranging between 30 to 34<br>– For BMI ranging between 35 to 39<br>– For BMI greater than or equal to 40<br>• Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response<br>▪ Phentermine: Date_____ Duration of therapy _____<br>OR<br>• **Patient has achieved greater than equal to 5 percent weight loss from baseline while on phentermine, benzphetamine, diethylpropion IR/SR or phendimetrazine IR/SR but BMI and central adiposity remain high, and further reduction is needed to attain optimal outcomes**<br>• The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke**, or a patient not meeting blood pressure goal on 2 or more antihypertensives)** OR |

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| | • The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Foundayo<br>For all patients<br>• Concomitant use of this medication with another GLP1-RA is not allowed (e.g., exenatide, Trulicity, Victoza, liraglutide, Soliqua, Xultophy) *(November 2025 meeting updates)*<br>• The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2<br>• Patient is not pregnant<br>Non-FDA approved uses are not approved including diabetes mellitus<br>PA expires in 12 months for initial therapy; annual renewal required<br>Renewal PA Criteria: Note that initial TRICARE PA approval is required for renewal. Foundayo will be approved for an additional 12 months if the following are met:<br>• The provider will document the BMI for renewal:<br>▪ BMI less than 27,<br>▪ BMI ranging between 27 and 29<br>▪ BMI ranging between 30 to 34<br>▪ BMI ranging between 35 to 39<br>▪ BMI greater than or equal to 40<br>For Obesity:<br>• The provider continues to verify and will maintain documentation in the medical record that the patient is currently engaged in a comprehensive lifestyle intervention that includes diet, exercise, and behavioral health modification. Medical record documentation will be made available to TRICARE for audit, if requested.<br>• The patient has lost greater than or equal to 5% of baseline body weight since starting medication<br>• The patient is not pregnant<br>• The patient does not have a history of or a family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 |
| • pegzilarginase-nbln injection (Loargys)<br><br>**Metabolic Agents Miscellaneous** | Manual PA criteria apply to all new users of pegzilarginase-nbln (Loargys)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 2 years of age or older<br>• Prescribed by or in consultation with a neurologist or metabolic disease specialist<br>• Patient has a confirmed diagnosis of Arginase 1 Deficiency (ARG1-D)<br>• Patient has a plasma arginine level greater than or equal to 250 µmol/L<br>• Patient will continue a protein-restricted diet in conjunction with Loargys<br>• Provider has educated the patient or caregiver to recognize and treat anaphylaxis appropriately<br>• Patient will receive Loargys administration at home under the supervision of a healthcare provider<br>Non-FDA approved uses are not approved<br>PA does not expire |

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

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| • pivmecillinam (Pivya)<br><br>**Antibiotics: Beta Lactams** | Manual PA criteria apply to all new users of pivmecillinam.<br>Automated PA criteria: when prescribed by a urologist, urogynecologist, or infectious disease physician, prior authorization is not required.<br>Manual PA criteria: coverage is approved if all criteria are met<br>• Patient is a female 18 years of age or order<br>• Patient has an uncomplicated urinary tract infection (uUTI) due to *Escherichia coli, Proteus mirabilis, Klebsiella spp, Enterobacter spp, Citrobacter spp* or *Staphylococcus saprophyticus*<br>• Patient has a contraindication to or has a culture-proven resistance to all routine oral antibiotic treatment options (i.e., nitrofurantoin, sulfamethoxazole/trimethoprim, amoxicillin/clavulanate, cephalexin, fosfomycin, or fluoroquinolone)<br>• Patient has no known history of carnitine deficiency or porphyria<br>Non-FDA approved uses are not approved<br>PA renewal is not allowed and no refills are allowed; each course of therapy requires a new PA |
| • tizanidine 2 mg/5 mL oral solution (Ontralfy)<br><br>**Skeletal Muscle Relaxants and Combinations** | Manual PA criteria apply to all new users of tizanidine oral solution (Ontralfy)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Provider acknowledges that tizanidine tablets and other formulary muscle relaxants are available without the need of a prior authorization<br>• Provider must explain why the patient requires tizanidine oral solution and cannot take tizanidine tablets or one of the other cost-effective formulary alternatives.<br>▪ Acceptable responses include: The patient requires tizanidine oral solution (Ontralfy) and cannot swallow tizanidine tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience<br>Non-FDA approved uses are not approved<br>PA does not expire |

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

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| • tocilizumab-anoh injection (Avtozma)<br><br>**TIBs: IL-6 Inhibitor Actemra biosimilar** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all **new and current** users of tocilizumab (Actemra) **and tocilizumab-anoh (Avtozma)**<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Provider acknowledges the ~~Department of Defense~~ **TRICARE benefit** requires a trial of Humira. Has the patient tried Humira? **(Note: Applies to RA and pJIA)**<br>▪ Patient had inadequate response OR experienced an adverse reaction OR has a contraindication to Humira<br>• Provider acknowledges ~~the Department of Defense~~ **TRICARE's** preferred IL-1, IL-6, CTLA4-Ig is Tyenne. Has the patient tried Tyenne? **(Note: Applies to all indications)**<br>▪ Patient had an inadequate response OR experienced an adverse reaction OR has a contraindication to Tyenne<br>• Patient has: ~~tried Humira:~~<br>▪ Moderate to severely active RA and has had an inadequate response to at least 1 or more DMARDs<br>▪ Active polyarticular Juvenile Idiopathic Arthritis (pJIA)<br>~~• Patient has not tried Humira and has an indication for which adalimumab is not approved:~~<br>▪ Giant cell arteritis<br>▪ Systemic sclerosis-associated lung disease<br>▪ Systemic Juvenile Idiopathic Arthritis (sJIA)<br>• Patient will not be receiving any other targeted immunomodulatory biologics with the requested agent, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, rituximab<br><br>Non-FDA approved uses are not approved~~, except as noted above~~<br>PA does not expire |
| **Utilization Management PAs** | |
| • desloratadine solution<br><br>**Antihistamine-1: Second Generation and Combinations** | Manual PA criteria apply to all new and current users of desloratadine solution<br>Manual PA criteria: desloratadine solution is approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of antihistamines are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires desloratadine solution and cannot take cost-effective alternatives (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (e.g., hives/anaphylaxis) to one or more inactive ingredients in currently available desloratadine tablet, loratadine solution, and levocetirizine solution.<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |

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

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| • hydrocortisone rectal suppository (Anusol HC, Proctocort)<br><br>**Corticosteroids-Immune Modulators: Low Potency** | Manual PA criteria apply to all new and current users of hydrocortisone rectal suppository (Anusol HC, Proctocort)<br>Manual PA criteria: hydrocortisone rectal suppository (Anusol HC, Proctocort) is approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of hydrocortisone rectal suppository are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires hydrocortisone rectal suppository (Anusol HC, Proctocort) and cannot take cost-effective alternatives (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (e.g., hives/anaphylaxis) to one or more inactive ingredients in currently available hydrocortisone rectal suppositories.<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |
| • metformin 625 mg IR tablet<br><br>**Diabetes Non-Insulin: Biguanides** | Manual PA criteria apply to all new and current users of metformin IR 625 mg tablets.<br>Manual PA criteria: metformin IR 625 mg tablets are approved if all criteria are met:<br>• Provider acknowledges other metformin formulations, including the 500 mg and 850 mg immediate release tablets, and 750 mg and 1000 mg extended release tablets are available without requiring prior authorization.<br>• The provider must explain why the patient can't take a different metformin formulation. (blank write-in)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available metformin tablets<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |
| • ranitidine<br><br>**Histamine (H2) Blockers and Other Antiulcer Agents** | Manual PA criteria apply to all new and current users of ranitidine<br>Manual PA criteria: ranitidine is approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of H2 blockers are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires ranitidine and cannot take cost-effective alternatives (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (e.g., hives/anaphylaxis) to one or more inactive ingredients in currently available cimetidine, famotidine, and nizatidine<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |

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| • ibuprofen 300 mg tablet<br><br>**Pain: NSAIDs** | Manual PA criteria apply to all new and current users of ibuprofen 300 mg tablets.<br>Manual PA criteria: ibuprofen 300 mg tablet is approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of ibuprofen and other NSAIDs are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires ibuprofen 300 mg and cannot take cost-effective generic ibuprofen formulations (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available ibuprofen tablets<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |
| • ketoprofen (Orudis) 75 mg capsule<br><br>**Pain: NSAIDs** | Manual PA criteria apply to all new and current users of ketoprofen (Orudis) 75 mg capsules<br>Manual PA criteria: ketoprofen (Orudis) 75 mg capsules are approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of ketoprofen and other NSAIDs are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires ketoprofen (Orudis) 75 mg capsules and cannot take cost-effective alternatives (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available ketoprofen capsules<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |
| • tizanidine 8 mg capsule<br><br>**Skeletal Muscle Relaxants and Combinations** | Manual PA criteria apply to all new and current users of tizanidine 8 mg capsules<br>Manual PA criteria: tizanidine 8 mg capsule are approved if all criteria are met:<br>• Provider acknowledges that tizanidine tablets and other formulary muscle relaxants are available to TRICARE beneficiaries without the need for prior authorization. Please consider changing the prescription to the tizanidine tablets or another formulary muscle relaxant.<br>• Please explain why the patient requires tizanidine capsules and cannot take tizanidine tablets or one of the other cost effective formulary alternatives.<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (i.e., hives/anaphylaxis) to one or more inactive ingredients in currently available tizanidine tablets<br>Non-FDA-approved uses are not approved.<br>Prior authorization does not expire. |

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| • metaxalone 640 mg tablet<br><br>**Skeletal Muscle Relaxants and Combinations** | Manual PA criteria apply to all new and current users of metaxalone 640 mg tablets<br><br>Manual PA criteria: metaxalone 640 mg tablet is approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of metaxalone and other muscle relaxants are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires metaxalone 640 mg tablets and cannot take cost-effective alternatives (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (e.g., hives/anaphylaxis) to one or more inactive ingredients in currently available metaxalone generics.<br><br>Non-FDA-approved uses are not approved.<br><br>Prior authorization does not expire. |
| • metoprolol tartrate 12.5 mg IR tablet<br><br>**Beta Blockers and HCTZ Combinations** | Manual PA criteria apply to all new and current users of metoprolol tartrate 12.5 mg IR tablet<br><br>Manual PA criteria: metoprolol tartrate 12.5 mg IR tablet is approved if all criteria are met:<br>• Provider is aware and acknowledges that other formulations of metoprolol tartrate are available to TRICARE beneficiaries without the need for prior authorization. Providers are encouraged to consider changing the prescription to one of these products.<br>• Provider must explain why the patient requires metoprolol tartrate 12.5 mg IR tablet and cannot take cost-effective alternatives (fill-in the blank)<br>▪ Acceptable responses include the patient has experienced a serious allergic reaction (e.g., hives/anaphylaxis) to one or more inactive ingredients in currently available metoprolol tartrate generics.<br><br>Non-FDA-approved uses are not approved.<br><br>Prior authorization does not expire. |
| • sodium phenylbutyrate (Olpruva, Pheburane)<br><br>**Gastrointestinal-2 Agents** | Manual PA criteria apply to all new users of sodium phenylbutyrate packets for oral suspension (Olpruva) and sodium phenylbutyrate oral pellets (Pheburane).<br><br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Provider acknowledges that generic sodium phenylbutyrate powder is available at the lowest copay and doesn't require a PA and can be mixed with liquids and/or specialized formula and common soft foods to improve taste<br>• Patient has a diagnosis of urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) confirmed through genetic, biochemical or enzymatic test<br>• Patient has inadequate response to dietary interventions AND will continue to manage the urea cycle disorder with dietary measures, including protein restriction and/or amino acid supplementation<br>• Provider acknowledges Olpruva and Pheburane can't be administered through a feeding tube<br>• Prescription is written by a specialist in diagnosing and treating urea cycle disorders<br>• The patient has tried and failed or has a contraindication to sodium phenylbutyrate powder OR<br>• Patient is unable to tolerate sodium phenylbutyrate powder due to excessive nausea/vomiting or allergy to its inactive ingredients OR |

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| | • Patient is under 18 and cannot tolerate it due to palatability despite mixing with other foods to mask its taste<br>Non-FDA approved uses are not approved<br>PA does not expire |
| • budesonide/albuterol (Airsupra)<br><br>**Pulmonary-1 Agents: Short-acting Beta Agonists** | Manual PA criteria apply to new users of budesonide/albuterol (Airsupra)<br>Manual PA criteria: budesonide/albuterol (Airsupra) is approved if all criteria are met:<br>• Provider acknowledges that generic budesonide/formoterol is available at the lowest copay and does not require a PA<br>• Patient is 18 years of age or older<br>• Patient has a diagnosis of asthma<br>• Patient has tried and failed rescue use of ICS/formoterol or albuterol plus a separate ICS OR<br>• Patient has been receiving a medium to high-dose inhaled ICS/LABA or ICS with LAMA for at least 3 months using spacer and appropriate technique and has demonstrated inadequate symptom control with frequent exacerbations and/or night-time awakenings OR<br>• Patient has a documented allergic reaction (e.g., anaphylaxis) to formoterol<br>Non-FDA approved uses are not approved<br>PA does not expire |
| • gepotidacin (Blujepa)<br><br>**Antibiotics** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to all new users of gepotidacin (Blujepa)<br>Automated PA Criteria: When prescribed by a urologist, urogynecologist, or infectious disease provider prior authorization is not required and 12 years of age or older. OR<br>Manual PA criteria: If automated criteria are not met, coverage is approved if all criteria are met:<br>• Patient is 12 years of age or older<br>• Patient weighs 40 kilograms or more<br>• Patient has an uncomplicated urinary tract infection (uUTI) (i.e., afebrile, infection that is limited to the bladder, and non-catheter associated infection)<br>• Patient has a urine culture indicating the organism is *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* or *Enterococcus faecalis*<br>• Patient has a contraindication to or has culture proven resistance to ALL alternative oral antibiotic treatment options (i.e. nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin, fluoroquinolones, penicillins, and cephalosporins)<br>• **Or Patient has *Neisseria gonorrhoeae* infection with culture proven resistance and/or contraindications to ceftriaxone, gentamicin/azithromycin, and cefixime**<br>• **Or Patient is a sexual partner of an individual who has been diagnosed with a *Neisseria gonorrhoeae* strain that is resistant to ceftriaxone, gentamicin, azithromycin, and cefixime**<br>Non-FDA approved uses are not approved<br>Each course of therapy requires a new PA. No refills allowed |

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| • dupilumab (Dupixent)<br><br>**Atopy: IL-13, IL-31** | Manual PA is required for all new users<br>Note that there were no changes to the PA criteria for Dupixent's other indications; see the August 2022 P&T Committee meeting minutes for the full criteria.<br>Manual PA Criteria: Coverage is approved if all criteria are met:<br>For allergic fungal rhinosinusitis:<br>• The patient is 6 years of age or older<br>• The drug is prescribed by an allergist, immunologist, pulmonologist, or otolaryngologist<br>• The patient has a diagnosis of allergic fungal rhinosinusitis<br>• Patient has past surgical history or endoscopic surgical intervention or has a contraindication to surgery<br>• Symptoms are inadequately controlled despite topical treatments (e.g. corticosteroids, saline irrigation)<br>• Coverage is not provided for concomitant use with other targeted immunobiologics including but not limited to: TNF inhibitors, interleukins, JAK inhibitors<br>Non-FDA-approved uses are not approved<br>Prior authorization expires after 12 months<br>Renewal Criteria: Note initial Tricare PA approval is required for renewal. Renewal PA criteria will be approved indefinitely if all the following apply:<br>The patient's disease severity has improved and stabilized to warrant continued therapy |
| • rucaparib (Rubraca)<br><br>**Breast Cancer Agents: PARP Inhibitors** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of Rubraca<br>Manual PA Criteria: Coverage will be approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Rucaparib is prescribed by or in consultation with a hematologist/oncologist or urologist<br>• Patient has a deleterious BRCA mutation as detected by an FDA-approved test<br>• **Patient has a diagnosis of either of the following:**<br>▪ **Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer with a complete or partial response to platinum-based chemotherapy**<br>▪ **Metastatic castration-resistant prostate cancer treated with androgen receptor-directed therapy and**<br>– **Patient is receiving concurrently with a gonadotropin – releasing hormone (GnRH) analog (e.g., leuprolide, Eligard, Triptorelin, Goserelin) or has had a bilateral orchiectomy**<br>~~• Rubraca will be prescribed for one of the following:~~<br>~~▪ Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene (for example, ATM)-mutated metastatic castration-resistant prostate cancer (mCRPC) and has progressed following prior androgen receptor-directed therapy and taxane-based chemotherapy~~<br>~~▪ Treatment of recurrent, high-grade, epithelial ovarian cancer (platinum-sensitive or platinum-resistant), fallopian tube or primary peritoneal cancer AND~~<br>~~– Rubraca will be used as a single agent~~ |

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| | ~~• Maintenance of relapsed platinum-sensitive ovarian cancer, fallopian tube or primary peritoneal cancer AND~~<br>~~– Patient has received 2 or more lines of platinum-based chemotherapy AND~~<br>~~– Patient was in objective response (either complete or partial) to most recent treatment regimen AND~~<br>~~– Rubraca will not be combined with bevacizumab (Avastin)~~<br>~~• Newly diagnosed, advanced, high-grade, ovarian cancer, fallopian tube or primary peritoneal cancer AND~~<br>~~– Patient has had a complete or partial response to primary therapy with a platinum-based therapy AND~~<br>~~– Rubraca will not be combined with bevacizumab (Avastin)~~<br>• The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **to facilitate approval, please list the diagnosis, guideline version, and page number ~~If so, please list the diagnosis~~**: _____.<br>~~• Female patients are not pregnant or planning to become pregnant and will take highly effective contraception while taking Rubraca and for 6 months after the last dose.~~<br>~~• Male patients will the patient use effective contraception while taking the requested medication and for at least 3 months after cessation of therapy~~<br>Other non-FDA-approved uses are not approved<br>Prior authorization does not expire |
| • ferric maltol (Accrufer)<br><br>**Electrolyte-Mineral-Trace Element Replacement** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of Accrufer<br>Manual PA criteria: Accrufer is approved if all criteria are met:<br>• Patient has a documented diagnosis of iron deficiency<br>• Patient is **10 ~~18~~** years of age or older<br>• Patient has tried and failed two oral iron products (must be different salts e.g., ferrous sulfate, ferrous gluconate, ferrous fumarate) for at least six weeks in duration for each product, unless contraindicated or clinically significant adverse effects are experienced.<br>▪ The provider must provide the date of when the patient previously tried each medication, or the contraindication or clinically significant adverse effect that the patient experienced:<br>▪ Oral iron product:_____ Date:_____ Contraindication or clinically significant adverse effect:_____<br>▪ Oral iron product:_____ Date:_____ Contraindication or clinically significant adverse effect:_____<br>• Provider acknowledges there is insufficient data on drug interactions at this time.<br>Non-FDA-approved uses are not approved.<br>Prior authorization expires in 6 months.<br>Renewal criteria: Note that initial TRICARE PA approval is required for renewal.<br>Coverage will be approved for an additional 6 months for continuation of therapy if:<br>• Patient is still iron deficient<br>• Documentation of clinically significant improvement in patient's iron deficiency required |

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

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| • flibanserin (Addyi)<br><br>**Gynecological Agents Miscellaneous** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria applies to all new users of Addyi.<br>Manual PA Criteria: Addyi is approved if all criteria are met:<br>• Patient is 18 **to 64** years of age ~~**or older**~~<br>• The drug is prescribed for **a** ~~**premenopausal female**~~ **woman** with hypoactive sexual desire disorder (HSDD) not due to a co-existing medical or psychiatric condition, problems within the relationship, or effects of a medication or other drug substance<br>• Patient has been counseled to wait 2 hours after consuming 1 or 2 standard alcoholic drinks before taking Addyi at bedtime or to skip their Addyi dose if they have consumed 3 or more standard alcoholic drinks that evening. After taking Addyi, the patient should not use alcohol until the following day.<br>• Patient does not have hepatic impairment (Child-Pugh score > 6)<br>• Patient not on a concomitant moderate or strong CYP3A4 inhibitor (e.g. ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)<br>• The patient has been informed that other treatment options such as cognitive-behavior therapy, sexual therapy, or couples therapy, may provide benefit without risk of side effects<br>Non-FDA-approved uses are NOT approved.<br>PA expires after 3 months. Renewal PA criteria will be approved indefinitely.<br>Renewal Criteria: (initial TRICARE PA approval is required for renewal) AND<br>Patient has documented improvement in symptoms without serious side effects |
| • zongertinib (Hernexeos)<br><br>**Lung Cancer: HER2+** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of zongertinib (Hernexeos)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Prescribed by or in consultation with a hematologist or oncologist<br>• Patient has a diagnosis of unresectable or metastatic NSCLC with confirmed HER2 (ERBB2) tyrosine kinase domain activating mutations<br>• ~~**Patient has received prior systemic therapy**~~<br>• The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number<br>Other non-FDA approved uses are not approved except as noted above<br>PA does not expire |
| • pegvaliase-pqpz (Palynziq)<br><br>**Metabolic Agents Miscellaneous** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of Palynziq.<br>Manual PA criteria: Palynziq is approved for initial therapy if all criteria are met:<br>• Patient is **12** ~~**18**~~ years of age or older<br>• Patient has uncontrolled blood phenylalanine concentrations > 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, or prior treatment with Kuvan [sapropterin dihydrochloride tablets and powder for oral solution])<br>• Palynziq is prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses on the treatment of metabolic diseases)<br>• Provider acknowledges and has educated the patient on the risk of anaphylaxis |

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

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| | • Patient has a prescription for self-administered SQ epinephrine<br>• Patient is not using Palynziq concomitantly with Kuvan **or Sephience**<br>Non-FDA-approved uses are NOT approved.<br>PA expires in 6 months.<br>Renewal criteria (maintenance/continuation therapy): Coverage will be approved for 1 year if:<br>• ~~**The patient's blood phenylalanine concentration is ≤ 600 micromol/L OR**~~<br>• ~~**The patient has achieved a ≥ 20% reduction in blood phenylalanine concentration from pre-treatment baseline (i.e., blood phenylalanine concentration before starting Palynziq therapy) AND**~~<br>• ~~**Patient is not using Palynziq concomitantly with Kuvan**~~<br>**The patient's disease severity has improved and stabilized to warrant continued therapy** |
| • niraparib/abiraterone acetate (Akeega)<br><br>**Oncological Agents** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of niraparib and abiraterone acetate (Akeega)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• Akeega is prescribed by or in consultation with hematologist, oncologist or urologist<br>• Akeega will be used in combination with prednisone<br>• **Patient has a diagnosis of one of the following:**<br>▪ **Deleterious or suspected deleterious BRCA-mutated metastatic castration-sensitive prostate cancer**<br>▪ Deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer **and**<br>– Patient is using Akeega concurrently with a gonadotropin – releasing hormone (GnRH) analog (e.g., leuprolide, Eligard, Triptorelin, Goserelin) or has had a bilateral orchiectomy<br>• The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: **to facilitate approval, please list the diagnosis, guideline version, and page number ~~If so, the provider must list the diagnosis~~:_____.**<br>AND<br>• ~~**Males with female partners will use effective contraception during treatment and for 4 months after the last dose**~~<br>• ~~**Provider is aware of the warnings, screening and monitoring precautions for Akeega.**~~<br>Other non-FDA-approved uses are not approved except as noted above<br>PA does not expire |
| • deucravacitinib (Sotyktu)<br><br>**Targeted Immunomodulatory Biologics** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Step therapy and manual PA criteria apply to all new users of deucravacitinib (Sotyktu). Note that Humira is the ~~**Department of Defense**~~ **TRICARE's** preferred targeted biologic agent.<br>Manual PA Criteria: Coverage is approved for Sotyktu if:<br>• **Humira is TRICARE's preferred targeted biologic agent**<br>• **Patient had an inadequate response to Humira OR had an adverse reaction to Humira that is not expected to occur with the requested agent OR has a contraindication to Humira AND** |

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| | • **Patient had an inadequate response to Taltz OR had an adverse reaction to Taltz that is not expected to occur with the requested agent OR has a contraindication to Taltz AND**<br>• **Patient had an inadequate response to ustekinumab OR had an adverse reaction to ustekinumab that is not expected to occur with the requested agent OR has a contraindication to ustekinumab AND**<br>• ~~**The patient has a contraindication or has had an inadequate response to Humira and Cosentyx OR**~~<br>• ~~**The patient has had an adverse reaction to Humira and Cosentyx that is not expected with the requested non-step-preferred TIB AND**~~<br>• Patient is 18 years of age **or older with:**<br>▪ ~~**Patient is diagnosed with**~~ **M**oderate to severe plaque psoriasis and is a candidate for systemic therapy or phototherapy **(PsO)**<br>▪ **Active psoriatic arthritis (PsA)**<br>• ~~**Has the p**~~ **P**atient had an inadequate response**, intolerance, or contraindication** to non-biologic systemic therapy (i.e. methotrexate, corticosteroids)<br>• **Coverage is not provided for concurrent use with other targeted immunobiologics including but not limited to, TNF inhibitors, interleukins, JAK inhibitors**<br>• ~~**The patient will not be receiving other potent immunosuppressants concomitantly.**~~<br>• ~~**Provider is aware of the FDA safety alerts and boxed warnings and precautions.**~~<br>• ~~**Patient has negative TB test result in past 12 months (or TB is adequately managed).**~~<br>Non-FDA-approved uses are not approved<br>PA does not expire |
| • octreotide (Mycapssa)<br><br>**Endocrine Agents Miscellaneous** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA is required for all new users of Mycapssa<br>Manual PA Criteria: Mycapssa is approved if all criteria are met:<br>• Patient has a diagnosis of acromegaly<br>• The drug is prescribed by or in consultation with an endocrinologist<br>• Patient **has had an adequate clinical response to** an injectable formulation of octreotide (e.g., Sandostatin generics, Sandostatin LAR Depot, Bynfezia) **or lanreotide (Somatuline Depot)** ~~**and failed therapy due to lack of response**~~<br>• **Please provide clinical rationale as to why the patient cannot continue taking injectable octreotide or lanreotide _____(Blank Write-in)**<br>▪ **Acceptable responses:**<br>– **Patient has documented hypersensitivity to excipients in an injectable formulation OR**<br>– **Patient has severe injection site reactions (e.g. lipoatrophy, abscesses)**<br>– **Patient is unable to inject at home due to dexterity, cognitive, or caregiver limitations AND is unable to receive injections in clinic (e.g. distance from clinic, transportation issues)**<br>Non-FDA-approved uses are not approved including vasoactive intestinal peptide tumors (VIPomas) and carcinoid tumors<br>Prior authorization does not expire |

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

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| • avacopan (Tavneos)<br><br>**Hematological Agents** | **Updates from the May 2026 meeting are in bold**<br>Manual PA criteria apply to new users of Tavneos<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• Patient is 18 years of age or older<br>• The medication is prescribed by or in consultation with a rheumatologist or nephrologist<br>• **Provider acknowledges the FDA released new safety information related to risk related to drug induced liver injury (DILI) and vanishing bile duct syndrome (VBDS)**<br>• Patient has a documented diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's) and microscopic polyangiitis (MPA)<br>• Patient meets one of the following criteria (either a or b):<br>▪ Positive ELISA test for anti-proteinase-3 (PR-3)<br>▪ Positive ELISA test for anti-myeloperoxidase (MPO)<br>• Patient has experienced or has a high probability to experience significant adverse effect from prednisone<br>• Tavneos is prescribed in combination with cyclophosphamide or rituximab, unless clinically significant adverse effects are experienced or both cyclophosphamide or rituximab are contraindicated<br>Non-FDA-approved uses are not approved including Immunoglobulin A nephropathy, Hidradenitis suppurativa, acne inversa, and C3 Glomerulopathy (C3G)<br>Prior Authorization expires after 6 months<br>Renewal criteria: (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply:<br>• Patient has responded positively to therapy as evidenced by a reduction in symptoms or remission AND<br>• If request is for a dose increase, new dose does not exceed 60 mg (2 tabs) per day |
| • mavacamten (Camzyos)<br><br>**Miscellaneous Cardiovascular Agents Miscellaneous** | **Updates from May 2026 are in bold and strikethrough**<br>Manual PA criteria apply to all new users of Camzyos<br>Manual PA criteria: Camzyos is approved if all criteria are met:<br>• The patient is 18 years of age and older<br>• Drug is prescribed by a cardiologist<br>• The patient has documented evidence of obstructive hypertrophic cardiomyopathy (HCM)<br>• Left ventricular outflow tract (LVOT) pressure gradient is greater than or equal to 50 mmHg<br>• The patient has NYHA Class II to III obstructive HCM that is symptomatic (e.g., dyspnea, chest pain, lightheadedness, syncope, fatigue, reduced exercise capacity)<br>• The patient's left ventricular ejection fraction (LVEF) is greater than or equal to 55%<br>• Patient has failed therapy with at least one agent from both of the following classes:<br>▪ Beta blocker (non-vasodilating) – propranolol, metoprolol AND<br>▪ Calcium channel blockers (non-dihydropyridine) – verapamil, diltiazem<br>• Patient must not be on dual calcium channel blocker and beta blocker therapy concurrently<br>• Patient must not be receiving ranolazine or disopyramide concurrently |

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| | ~~• Patient and provider must be aware of the risks of systolic dysfunction as outlined by REMS~~<br>~~• Provider and patient must agree to comply to all requirements of the REMS program, including echocardiogram at 0, 4, 8, 12 weeks follow by every 12 weeks and drug interaction monitoring requirements~~<br>~~• If the patient is of child-bearing age, the patient must not be pregnant and will receive counseling for effective contraception during therapy and for 4 months after the last dose~~<br>• Camzyos will not be used concomitantly with Myqorzo<br><br>Non-FDA-approved uses are not approved<br>PA expires in 1 year<br>Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be renewed indefinitely if the following applies<br>The patient has responded to therapy, as evidenced by improvement in obstructive hypertrophic cardiomyopathy symptoms |
| • nerandomilast (Jascayd)<br><br>**Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of nerandomilast (Jascayd)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>Idiopathic Pulmonary Fibrosis (IPF)<br>• Provider acknowledges pirfenidone (Esbriet generic) is the ~~**Department of Defense**~~ **TRICARE's** preferred drug for Idiopathic Pulmonary Fibrosis (IPF)<br>• Patient is 18 years of age or older<br>• Prescribed by a pulmonologist<br>• Patient is non-smoking<br>• Patient has documented diagnosis of idiopathic pulmonary fibrosis (IPF) AND<br>▪ Patient requires add-on therapy with nerandomilast (Jascayd) and:<br>– Patient tried and failed pirfenidone (Esbriet generic) due to progression of disease as defined as greater than 10% decline of forced vital capacity (FVC) OR<br>– Patient tried and failed nintedanib (Ofev) due to progression of disease as defined as greater than 10% decline of forced vital capacity (FVC)<br>OR<br>▪ Patient requires monotherapy with nerandomilast (Jascayd) and:<br>– Patient tried and failed pirfenidone (Esbriet generic) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with pirfenidone (Esbriet generic) OR<br>– Patient tried and failed nintedanib (Ofev) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with nintedanib (Ofev)<br>**Progressive Pulmonary Fibrosis (PPF)**<br>• **Patient has documented diagnosis of progressive pulmonary fibrosis (PPF) AND**<br>▪ **Patient tried and failed nintedanib (Ofev) due to experiencing intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) or is taking a drug that will interact with nintedanib (Ofev)** |

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| | ▪ **Patient tried and failed nintedanib (Ofev) due to progression of disease as defined as forced vital capacity decline ≥ 10% or forced vital capacity decline ≥ 5% to < 10% with worsening symptoms and/or worsening imaging**<br>• Patient is not receiving triple therapy with nerandomilast (Jascayd), pirfenidone (Esbriet, generics), and nintedanib (Ofev)<br>Non-FDA approved uses are not approved**~~; usage for progressive pulmonary fibrosis is not approved at this time~~**<br>PA expires in 12 months<br>Renewal criteria: Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if all criteria are met:<br>• Prescribed by a pulmonologist<br>• Patient has shown clinical benefit with therapy |
| • nintedanib (Ofev)<br><br>**Pulmonary-1 Agents: Idiopathic Pulmonary Fibrosis** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new and current users of nintedanib (Ofev)<br>Manual PA criteria: Coverage is approved if all criteria are met:<br>• **~~Esbriet is the Department of Defense's~~ Provider acknowledges Esbriet is TRICARE's** preferred Idiopathic Pulmonary Fibrosis Agent. The patient must have tried Esbriet<br>• Patient is non-smoking<br>• **~~The patient is being actively managed by a pulmonologist~~ Prescribed by a pulmonologist**<br>• **~~The patient is not currently receiving pirfenidone (Esbriet) and nintedanib (Ofev) concomitantly (no dual therapy)~~**<br>• Patient has a documented diagnosis of:<br>▪ Idiopathic pulmonary fibrosis (IPF) AND<br>▪ Patient has had a trial of Esbriet and either:<br>– Failed therapy with Esbriet due to progression of IPF rate of decline of forced vital capacity (FVC) of > minus 10% OR<br>– Experienced intolerable adverse effects (e.g., rash, photosensitivity; GI adverse events) OR<br>▪ The provider will note the Patient clinical factors where Esbriet is not appropriate<br>**OR**<br>• Patient has a documented diagnosis of: Systemic sclerosis-associated interstitial lung disease (SSc-ILD)<br>• Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype<br>Non-FDA-approved uses are not approved<br>Prior authorization expires in one year<br>**~~Renewal criteria: (initial TRICARE PA approval is required for renewal)~~**<br>• **~~Patient continues to refrain from smoking~~**<br>• **~~Request submitted by a pulmonologist~~**<br>• **~~Patient experienced significant reduction in the annual rate of decline of forced vital capacity (FVC)~~**<br>**Renewal criteria: Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies:**<br>• **Prescribed by a pulmonologist**<br>• **Patient has shown clinical benefit with therapy** |

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

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| • etanercept (Enbrel)<br><br>**Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Step therapy and manual PA criteria apply to all new users. Note that Humira is ~~**the Department of Defense's**~~ **TRICARE's** preferred targeted biologic agent.<br>~~**Automated PA criteria: The patient has filled a prescription for adalimumab (Humira) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND**~~<br>Manual PA criteria: ~~**If automated criteria are not met,**~~ Coverage is approved **if all criteria are met:** ~~**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**~~<br>Note that a trial of non-biologic systemic therapy, adalimumab ~~**(Humira),**~~ **ustekinumab, and ixekizumab** is required for both Adult and Pediatric Indications AND<br>• **The patient had an inadequate response to adalimumab** (Humira) **OR experienced an adverse reaction to adalimumab** (Humira) **that is not expected to occur with etanercept (Enbrel) OR the patient has a contraindication to adalimumab** (Humira) **(Note: applies to all adult and pediatric indications)**<br>• **The patient had an inadequate response to ustekinumab-aauz (Otulfi) OR experienced an adverse reaction to ustekinumab-aauz (Otulfi) that is not expected to occur with etanercept (Enbrel) OR the patient has a contraindication to ustekinumab-aauz (Oltulf) (Note: applies to all adult and pediatric PsO and PsA)**<br>• **The patient had an inadequate response to ixekizumab (Taltz) OR experienced an adverse reaction to ixekizumab (Taltz) that is not expected to occur with etanercept (Enbrel) OR the patient has a contraindication to ixekizumab (Note: applies to ax-SpA, adult psoriatic arthritis, and adult and pediatric plaque psoriasis if aged 6 or older)**<br>• Coverage approved for patients 18 years of age or older with:<br>▪ Moderate to severe active rheumatoid arthritis<br>▪ Moderate to severe active psoriatic arthritis<br>▪ Active ankylosing spondylitis<br>▪ Moderate to severe chronic plaque psoriasis who are candidates for systemic or phototherapy<br>• Coverage approved for pediatric patients 2–17 years of age with:<br>▪ Moderate to severe active polyarticular Juvenile Idiopathic Arthritis<br>▪ Juvenile Psoriatic Arthritis.<br>• Coverage approved for pediatric patients 4-17 years of age with:<br>▪ **Moderate to severe** 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.**~~<br>• Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) (Note: ax-SpA indications do not apply)<br>• Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to ax-SpA ONLY)<br>• **Coverage is not provided for concomitant use with other targeted immunobiologics including but not limited to, TNF inhibitors, interleukins, JAK inhibitors** |

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| | • ~~**Coverage is NOT provided for concomitant use with other TIBs including but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, PDE4, S1p, JAK inhibitors**~~<br>Non-FDA-approved uses are not approved Prior Authorization does not expire |
| • anakinra (Kineret)<br><br>**Targeted Immuno-modulatory Biologics: IL-1, IL-6, CTLA-4** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>Manual PA criteria apply to all new users of anakinra (Kineret)<br>Manual PA Criteria: Kineret is approved if all criteria are met:<br>• Prescriber is aware that Tyenne is ~~**the Department of Defense's**~~ **TRICARE's** preferred IL-1, IL-6, and CTLA4-Ig. The patient must have tried Tyenne and Humira and had an inadequate response to Tyenne and Humira OR the patient experienced an adverse reaction to Tyenne and Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Tyenne and Humira (Note: Tyenne and Humira trial required for rheumatoid arthritis)<br>• Patients 18 years of age or older with:<br>▪ Moderate to severe active rheumatoid arthritis<br>▪ **Gout or calcium pyrophosphate deposition disease (pseudogout) flares**<br>– **Prescribed by or in consultation with a rheumatologist AND**<br>– **Patient has had an inadequate response, intolerance, or contraindication to colchicine, NSAIDS, and glucocorticoids AND**<br>– **Patient will have urate lowering therapy optimized as appropriate AND**<br>– **Treatment will be for shortest duration possible and not for chronic prophylaxis**<br>• Patients 12 years of age or older with:<br>▪ Recurrent pericarditis<br>– Prescription has been written by or in consultation with a cardiologist OR rheumatologist AND<br>– Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR<br>– Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids<br>• Patients (all ages) with:<br>▪ Neonatal-Onset Multisystem Inflammatory Disease (NOMID)<br>▪ Chronic Infantile Neurological Cutaneous and Articular (CINCA) disease<br>▪ Cryopyrin Associated Period Syndrome (CAPS)<br>▪ Systemic Juvenile Idiopathic Arthritis (sJIA)<br>▪ Still's Disease with active systemic features of moderate to high disease activity<br>▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA)<br>• **Coverage is not provided for concurrent use with other targeted immunobiologics including but not limited to, TNF inhibitors, interleukins, JAK inhibitors**<br>• ~~**Coverage is NOT provided for concomitant use with other TIBs including, but not limited to: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors**~~<br>Non-FDA-approved uses are not approved except as noted above |

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

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| | Prior authorization does not expire**, except for gout and pseudogout flares, which expires annually and will require submission of a new PA** |

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

| Drug / Drug Class | Quantity Limits |
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| • concizumab-mtci (Alhemo)<br>• marstacimab-hncq (Hympavzi)<br><br>**Antihemophilic Agents: Non-Factor Agents** | **Updates from the May 2026 meeting are in bold and strikethrough**<br>▪ Retail: 30-day supply<br>▪ MTF/TMOP: ~~**30**~~ **60**-day supply |
| • emicizumab-kxwh (Hemlibra)<br><br>**Antihemophilic Agents: Non-Factor Agents** | ▪ Retail: 30-day supply<br>▪ MTF/TMOP: 60-day supply |
| • fitusiran (Qfitlia)<br><br>**Antihemophilic Agents: Non-Factor Agents** | ▪ MTF/TMOP/Retail: 60-day supply |
| • etripamil (Cardamyst)<br><br>**Calcium Channel Blockers** | ▪ MTF/TMOP/Retail: 2 cartons per 30 days |
| • icotrokinra (Icotyde)<br><br>**Targeted Immunomodulatory Biologics: IL-23 Inhibitors** | ▪ MTF/TMOP/Retail: 60-day supply |
| • lerodalcibep-liga (Lerochol)<br><br>**Antilipidemics-1: PCSK9** | ▪ Retail: 1 pen<br>▪ MTF/TMOP: 3 pens for once monthly dosing |
| • methocarbamol (Atmeksi)<br><br>**Skeletal Muscle Relaxants and Combinations** | ▪ MTF/TMOP/Retail: 6 bottles per 30-day supply |
| • navepegritide SC (Yuviwel)<br><br>**Growth Stimulating Agent** | ▪ MTF/TMOP/Retail: 30 day-supply |
| • orforglipron (Foundayo)<br><br>**Metabolic Dysfunction Agents: Weight Loss Agents** | ~~▪ Retail: 30 day-supply~~<br>~~▪ MTF/TMOP: 60 day-supply~~<br>▪ Retail: 30 tabs per 30 days with a 30-day supply limit<br>▪ MTF/TMOP: 60 tabs per 60 days with a 60-day supply limit |
| • pivmecillinam (Pivya)<br><br>**Antibiotics: Beta-lactam antibiotics** | ▪ Retail/MTF: 27 tablets per fill, no refills allowed |
| • tizanidine (Ontralfy)<br><br>**Skeletal Muscle Relaxants and Combinations** | ▪ MTF/TMOP/Retail: 6 bottles per 30-day supply |

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

| Drug / Drug Class | Quantity Limits |
|---|---|
| • tocilizumab-anoh (Avtozma)<br><br>Targeted Immunomodulatory Biologics: IL-1,IL-6, CTLA-4 | ▪ MTF/TMOP/Retail: 60 day-supply |

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

| Generic (Trade)<br>UF Class | Comparators | Strength/ Form/ Dosing | Indications | Adverse Events | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| • aficamten (Myqorzo)<br><br>**Miscellaneous Cardiovascular Agents**<br>**Miscellaneous** | • mavacamten (Camzyos)<br>• disopyramide | • 5 mg, 10 mg, 15 mg, 20 tabs<br>• Starting dose of 5 mg PO QD; max dose of 20 mg PO QD | • Treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms in adults | • drug interactions leading to increased risk of heart failure or loss of effectiveness<br>• hypertension | • Second cardiac myosin inhibitor approved for obstructive hypertrophic cardiomyopathy (oHCM), after mavacamten (Camzyos)<br>• Oral reversible cardiac myosin inhibitor which reduces hypercontractility and left ventricular outflow tract (LVOT) obstruction—hallmark features of oHCM<br>• The SEQUOIA HCM Phase 3 study showed an increase in the primary endpoint measuring exercise capacity (measured by peak oxygen uptake) with Myqorzo vs. no change in patients given placebo and also significantly improved QOL (clinically relevant increase in KCCQ score)<br>• Myqorzo and Camzyos both carry a Boxed Warning for the risk of heart failure and are only available through a REMS program<br>• Camzyos requires ongoing cardiac ECHO monitoring to assess cardiac structure and function – burdensome to the patient & has fetal toxicity warnings<br>• Camzyos has substantial drug-drug interactions and prolonged t 1/2 that increase the risk of systolic dysfunction and HF.<br>• Both agents are dosed once daily and require assessment of LVEF and LVOT-Gradient prior to initiation; neither drug is recommended for patients with LVEF < 55%<br>• Conventional beta-blockers, diltiazem, verapamil and disopyramide do not have proven disease-modifying effects and are often poorly tolerated<br>• Cardiac myosin inhibitors may reduce the need for invasive septal reduction surgeries | • UF<br>• PA |

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

| Generic (Trade)<br>UF Class | Comparators | Strength/ Form/ Dosing | Indications | Adverse Events | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| | | | | | • Long term safety and mortality benefits remain to be determined<br>• Provides an alternative to Camzyos for oHCM | |
| • amlodipine powder for oral solution (Sdamlo)<br><br>**Calcium Channel Blocker** | • amlodipine tablets<br>• amlodipine oral solution (Norliqva)<br>• amlodipine oral suspension (Katerzia) | • 2.5 mg, 5 mg, 10 mg powder in single-dose bottles for reconstitution into oral solution | • Treatment of hypertension, to lower blood pressure in adults and pediatric patients 6 years of age and older as monotherapy or as a combo<br><br>• Coronary artery disease in adults | • peripheral edema | • Oral solution formulation of amlodipine that must be reconstituted<br>• Must be consumed within 1 hour of reconstitution<br>• Third DHP CCB available in a liquid formulation after Katerzia oral suspension and Norliqva oral solution<br>• First agent with unit-dose packaging<br>• No new clinical efficacy studies; approved via 505(b)(2)<br>• Provides no compelling clinical advantages over existing agents | • Complete Exclusion<br>• Temporary PA until implementation |
| • copper histidinate injection (Zycubo)<br><br>**Electrolyte Mineral Trace Elements: Replacement Enzymes** | • not applicable | • Single dose vial: 2.9 mg of copper histidinate as a lyophilized powder | • Treatment of Menkes disease in pediatric patients | • pneumonia<br>• respiratory failure<br>• seizure<br>• bacterial infection<br>• hemorrhage<br>• hypotension<br>• vomiting<br>• tachycardia<br>• pyrexia<br>• diarrhea<br>• fungal infection<br>• anemia<br>• site reaction | • Efficacy data demonstrated improved overall survival in Zycubo treated patients compared to natural cohort arms<br>• Requires monitoring for copper accumulation and potential risk for toxicity<br>• Adverse event profile is consistent with natural history of disease state<br>• Provides a pharmacologic treatment option for this rare disorder | • UF<br>• PA<br>• Specialty<br>• Safety Net |
| • desmopressin acetate 0.05 mg/mL oral solution (Desmoda)<br><br>**Miscellaneous Endocrine Agents Miscellaneous** | • desmopressin tablets<br>• desmopressin intranasal<br>• desmopressin injection | • oral solution: 0.05mg/mL | • Management of central diabetes insipidus as antidiuretic replacement therapy for adults and pediatric patients | • headache<br>• dizziness<br>• nausea<br>• abdominal pain<br>• hypertension<br>• diarrhea | • Oral solution formulation of desmopressin for management of central diabetes insipidus in pediatrics and adults<br>• No new clinical efficacy studies; approved via 505(b)(2)<br>• This formulation must be taken on empty stomach (1 hour before or 2 hours after meals) and has a slightly longer half-life and Tmax than the tablets<br>• Must refrigerate and discard 120 days after opening | • NF<br>• PA<br>• MN<br>• 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 | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| | | | | | • Provides little to no compelling clinical advantage over existing agents | |
| • doxecitine / doxribtimine 2 gram packet for oral solution (Kygevvi)<br><br>**Miscellaneous Metabolic Agent: Replacement Enzymes** | • None | • 2 g packet for ora solution | • Treatment of thymidine kinase 2 deficiency (TK2d) in adults and pediatric patients with an age of symptom onset on or before 12 years | • diarrhea<br>• abdominal pain<br>• vomiting<br>• increased LFTs | • Combination of two pyrimidine nucleoside products (doxecitine and doxribtimine) used for treatment of thymidine kinase 2 deficiency<br>• Pooled data from prospective, retrospective and expanded access programs demonstrated an 86% reduction in the risk of death in those with symptom onset of ≤ 12 years of age<br>• Non-cGMP pyrimidine nucleoside products were used in varying doses in some of these studies with low sample size, limiting study integrity and applicability of conclusions, but providing evidence for potential efficacy<br>• Provides an option in the management of selected patients with thymidine kinase 2 deficiency | • UF<br>• PA |
| • etripamil nasal spray (Cardamyst)<br><br>**Calcium Channel Blocker** | • Adenosine IV (inpatient use only)<br>• Diltiazem IV(inpatient use only) | • 70 mg per nasal canister, contains 2 sprays | • Conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults | • nasal discomfort<br>• nasal irritation<br>• rhinorrhea<br>• throat irritation<br>• epistaxis | • One pivotal phase 3 study demonstrated higher conversion rates compared with placebo. Open label studies show successful conversion in vast majority of patients if vagal maneuvers were not effective, but lack of controls limit result applicability along with marginal decrease in ER visits.<br>• Median time to conversion to sinus rhythm was approximately 17 minutes; but extensive patient education is required for proper self-administration.<br>• Cardamyst was well-tolerated with most adverse events related to its intranasal route of administration<br>• Provides a self-administered option for acute treatment of PSVT | • NF<br>• PA<br>• 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 | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| • icotrokinra (Icotyde)<br><br>**TIBs: IL-23 Inhibitors** | • Humira<br>• ustekinumab<br>• Taltz<br>• Otezla<br>• Sotyktu | • 200 mg tabs<br>• 200 mg PO QD | • Treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy | • headache<br>• nausea<br>• cough<br>• fungal infection<br>• fatigue | • Oral IL-23 receptor blocker for the treatment of moderate to severe plaque psoriasis<br>• Icotyde binds directly to the IL-23 receptor on T-cells, where biologic IL-23 inhibitors bind to the p19 subunit of IL-23 cytokine<br>• Approved via NDA rather than BLA due to oral peptide formulation rather than monoclonal antibody<br>• Four pivotal trials demonstrated efficacy versus placebo<br>• Two direct comparisons with Sotyktu demonstrated that patients who received Icotyde had better IGA 0/1 and PASI 90 results at Week 16 and 24<br>• Indirect comparisons suggest incrementally higher PASI response with IL-17 blockers and injectable IL-23 blockers than with Icotyde<br>• Adds to the available treatment options for the management of plaque psoriasis and is an alternative to biologics and other targeted oral synthetic small molecule drugs | • NF, non-step-preferred<br>• PA<br>• MN<br>• QL<br>• Specialty<br>• TRICARE Maintenance Drug List |
| • lerodalcibep-liga injection (Lerochol)<br><br>**Antilipidemic-1 Agents: PCSK9 inhibitors** | • Repatha<br>• Praluent<br>• Leqvio (Medical Benefit) | • 300 mg/1.2 mL pre-filled syringe<br>• 300 mg monthly | • Adjunct to diet and exercise: to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterol-emia, including heterozygous familial hypercholesterol-emia (HeFH) | • injection site reactions<br>• nasopharyngitis<br>• diarrhea<br>• nausea<br>• peripheral edema | • Once monthly SC PCSK9 inhibitor with flat dosing and stability at room temperature for 90 days<br>• LDL-lowering efficacy of 50%-55% is similar to Repatha, Praluent and Inclisiran<br>• LIBERATE HR: High risk of CVD: LDL lowering of 56%<br>• LIBERATE CVD: ASCVD: LDL lowering of 62%<br>• LIBERATE HeFH: LDL Lowering of 59%<br>• No data available on cardiovascular outcomes related to LDL-C reduction<br>• Similar side effect and efficacy profiles as the other PCSK-9 inhibitors<br>• Not approved in the pediatric population unlike Repatha or Praluent | • NF, non-step-preferred<br>• QL<br>• MN<br>• 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 | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| | | | | | • Structure is designed for convenience with a small injection volume, long-term stability at room temperature (up to 3 months), and high efficacy for treating hypercholesterolemia and cardiovascular risk<br>• Despite the convenience, does not offer compelling clinical advantages over the other PCSK-9 inhibitors, and has not shown benefits on CV outcomes | |
| • lisdex-amfetamine dimesylate 10 mg/mL oral solution (Arynta)<br><br>**ADHD Agents: Stimulant** | • Vyvanse cap<br>• Vyvanse chew | • Solution: 10mg/mL in 100 mL bottle | • ADHD in patients 6 years and older<br>• Moderate to severe BED in adults | • anorexia<br>• anxiety<br>• decreased weight<br>• diarrhea<br>• dizziness<br>• dry mouth<br>• insomnia<br>• nausea<br>• abdominal pain<br>• vomiting | • No new clinical efficacy studies; approved via 505(b)(2) using data from Vyvanse<br>• lisdexamfetamine dimesylate is also available as generic capsules or chewable tablets; the capsule may be opened and sprinkled<br>• Arynta must be discarded after 30 days<br>• Provides no compelling clinical advantage over existing agents | • NF<br>• PA<br>• MN |
| • methocarbamol 750 mg/5 mL oral suspension (Atmeksi)<br><br>**Skeletal Muscle Relaxants and Combinations** | • methocarbamol tablets<br>• Ontralfy<br>• baclofen soln<br>• baclofen susp | • Oral suspension: 750mg/5mL | • Adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions in patients 16 and older | • anaphylactic reaction<br>• angioneurotic edema<br>• fever<br>• bradycardia<br>• hypotension<br>• thrombophlebitis<br>• jaundice<br>• leukopenia<br>• amnesia<br>• diplopia<br>• insomnia<br>• mild muscular incoordination<br>• vertigo<br>• nystagmus<br>• sedation<br>• seizures<br>• conjunctivitis<br>• metallic taste | • Oral suspension formulation of methocarbamol indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions in patients ≥16 years of age<br>• No new clinical efficacy studies; approved via 505(b)(2)<br>• Methocarbamol tablets do not have an age cutoff as does Atmeksi<br>• FDA labeling does not prohibit crushing of methocarbamol tablets<br>• Methocarbamol tablets are large and have a bitter, metallic taste<br>• Provides little to no compelling clinical advantage over existing agents | • NF<br>• PA<br>• MN<br>• QL<br>• TRICARE Maintenance Drug List |

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

| Generic (Trade)<br>UF Class | Comparators | Strength/ Form/ Dosing | Indications | Adverse Events | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| • navepegritide powder for injection (Yuviwel)<br><br>**Growth Stimulating Agent** | • Vosoritide (Voxzogo) | • 1.3 mg, 2.8 mg, 5.5 mg powder in SDV for reconstitution<br>• Weight-based dosing administered SQ weekly | • Increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses. | • injection site reactions<br>• nausea<br>• vomiting<br>• extremity pain | • Second C-type natriuretic peptide (CNP) analog (after Voxzogo) approved to increase linear growth in pediatric patients with achondroplasia<br>• Phase 2b study demonstrated increases in annualized growth velocity with an least squared (LS) mean annualized growth velocity of 5.89 cm/year vs. 4.41 cm/year with placebo (treatment difference of 1.49 cm/year)<br>• Voxzogo demonstrated an increased annualized growth velocity by a LS mean of approximately 1.6 cm/year vs. placebo, but requires daily use compared to Yuviwel<br>• Yuviwel is only approved in patients ≥ 2 years of age and has not been studied in patient 12 years and older; while Voxzogo has been studied through 18 years of age and has over 10,000 patient-years of data demonstrating skeletal growth improvements<br>• Yuviwel was FDA approved in an accelerated fashion and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials; a clinical benefit with Yuviwel has not been proven | • UF<br>• PA<br>• QL |
| • orforglipron (Foundayo)<br><br>**Metabolic Dysfunction Agents: Weight Loss** | • Wegovy tablets<br>• Wegovy injection<br>• Zepbound | • Tablets: 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, 17.2 mg<br>• 1 tab daily | • In combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight- | • nausea<br>• constipation<br>• diarrhea<br>• vomiting<br>• dyspepsia<br>• abdominal pain<br>• headache<br>• abdominal distension<br>• fatigue<br>• eructation<br>• gastroesophageal reflux disease | • Second oral GLP-1 agonist for weight loss and weight maintenance in adults with obesity or overweight and a weight-related comorbidity when used in combination with lifestyle modification<br>• Two phase 3 studies demonstrated greater weight loss compared with placebo and a substantial proportion of patients achieved clinically meaningful weight reduction thresholds<br>• Unlike Wegovy tablet, there are no administration constraints with Foundayo | • UF<br>• PA<br>• QL |

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

| Generic (Trade)<br>UF Class | Comparators | Strength/ Form/ Dosing | Indications | Adverse Events | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| | | | related comorbid condition | • flatulence<br>• hair loss | • Indirect comparisons demonstrate that weight loss with Foundayo appears slightly less than Wegovy 2.4 mg injection/Wegovy 25 mg tablet<br>• Alternative to Wegovy injection, Wegovy tablet, or Zepbound in adults with obesity or with overweight and one or more weight-related comorbid condition | |
| • pegzilarginase-nbln injection (Loargys)<br><br>**Metabolic Agents Miscellaneous** | • N/A | • Single dose vial: 2mg/0.4mL or 5 mg/mL | • Treatment of hyperargininemia in patients 2 years of age and older with Arginase-1 Deficiency, in conjunction with dietary protein restriction | • vomiting<br>• pyrexia<br>• infusion reactions<br>• constipation | • Regulatory approval was granted under the accelerated approval pathway based on reduction of plasma arginine<br>• Phase 3 study demonstrated a statistically significant decrease in arginine levels vs. placebo at week 24<br>• Carries a black box warning for anaphylaxis and requires healthcare provider supervision for home administration<br>• Provides a pharmacologic option that addresses the underlying deficiency in patients with this ultra rare disorder | • UF<br>• PA<br>• Specialty Drug List |
| • pivmecillinam (Pivya)<br><br>**Antibiotics: Beta Lactams** | • Bactrim DS, Nitrofurantoin, Fosfomycin, gepotidacin (Blujepa), sulopenem edzadroxil and probenecid (Orlynvah) | • 185 mg tablets<br>• 1 tablet po tid x 7 days | • Treatment of female patients 18 years of age and older with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of Escherichia coli, Proteus mirabilis and Staphylococcus saprophyticus | • diarrhea<br>• nausea | • Pivya is included in multiple clinical guidelines and is recommended as a first-line therapy in female adults with uncomplicated UTIs alongside other options such as nitrofurantoin, TMP-SMX, and fosfomycin<br>• Pivmecillinam has been used extensively in Europe for over 30 years, however it is not effective when pyelonephritis is suspected, due to poor tissue penetration.<br>• Therapeutic alternative to other established options when the choices are contraindicated, in cases of ESBL isolates, or if the patient failed previous treatments with any of these agents | • UF<br>• QL<br>• PA |

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

| Generic (Trade)<br>UF Class | Comparators | Strength/ Form/ Dosing | Indications | Adverse Events | Clinical Summary | Recommendation |
|---|---|---|---|---|---|---|
| • tizanidine 2 mg/5 mL oral solution (Ontralfy)<br><br>**Skeletal Muscle Relaxants and Combinations** | • tizanidine capsules<br>• tizanidine tablets<br>• baclofen soln<br>• baclofen susp | • Oral solution:2mg/ 5mL | • Treatment of spasticity in adults | • dry mouth<br>• somnolence<br>• asthenia<br>• dizziness | • Oral solution formulation of tizanidine<br>• Indicated for the treatment of spasticity in adults<br>• No new clinical efficacy studies; approved via 505(b)(2)<br>• Capsules can be sprinkled on apple sauce; FDA labeling does not prohibit crushing of tablets<br>• Provides little to no compelling clinical advantage over existing agents | • NF<br>• PA<br>• MN<br>• QL |
| • tocilizumab-anoh injection (Avtozma)<br><br>**TIBs: IL-6 Inhibitor Actemra biosimilar** | • Actemra<br>• Tyenne | • Prefilled syr: 162 mg/0.9 mL<br>• Autoinjector: 162 mg/0.9 mL<br>• SDV: 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL | • Actemra biosimilar | • upper respiratory tract infections<br>• nasopharyngitis<br>• headache<br>• hypertension<br>• increased ALT<br>• injection site reactions | • 3rd Actemra biosimilar to receive approval<br>• No new clinical efficacy studies; approved via 351(k)<br>• First interchangeable tocilizumab product with Actemra; where the autoinjector is the only dosage form that is not interchangeable with Actemra<br>• The first biosimilar Tyenne is currently preferred<br>• Provides little to no compelling clinical advantage over existing agents | • NF, non-step-preferred<br>• PA<br>• MN<br>• QL<br>• Specialty<br>• 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*

| P&T Meeting | ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement) | Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement) |
|---|---|---|
| May 2026 | **Drug Class Reviews**<br><br>**Antihemophilic Agents: Non-Factor Agents**<br>***Designated UF***<br>*Retain current status (currently on the TMDL)*<br>• emicizumab-kxwh (Hemlibra)<br><br>**Leukemia and Lymphoma Agents: BCR ABL Tyrosine Kinase Inhibitors**<br>***Designated UF***<br>*Retain current status (currently on the TMDL)*<br>• imatinib (Gleevec; brand only)<br>• dasatinib (Sprycel; brand only)<br>• nilotinib HCl (Tasigna; brand only)<br>• bosutinib tab and cap (Bosullif) | **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)**<br>***Designated UF***<br>*Do not add (acute use)*<br>• pivmecillinam (Pivya)<br>• tizanidine solution (Ontralfy)<br>*Do not add (not cost effective)*<br>• orforglipron (Foundayo)<br>*Do not add (feasibility unclear)*<br>• pegzilarginase-nbln (Loargys)<br><br>***Designated NF***<br>*Do not add (acute use)*<br>• etripamil (Cardamyst)<br>*Do not add-controlled substance*<br>• lisdexamfetamine dimesylate solution (Arynta)<br><br>**TMDL Updates**<br>***Designated UF***<br>*Remove from/do not add to TMDL – not cost effective*<br>• octreotide (Bynfezia Pen) |

***Legal/Regulatory Authorities**

- 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 (TMDL).
- 32 CFR 199.21(r) implements 10 USC 1074g(a)(9) and sets out operation of the TMDL in detail.
- 32 CFR 199.21(h)(2)(ii) requires that non-formulary pharmaceutical agents be "generally not available in military treatment facilities or in the retail point of service." As a result, NF/Tier 3 agents (including generics) must be on the TMDL unless a reason exists to exempt the agent from the NF TMOP requirement (e.g., acute use, clinical considerations, not available at TMOP, cost effectiveness).
- 32 CFR 199.21(g)(5) covers formulary status and review of newly approved drugs (other than generics), which are added to the UF unless the P&T Committee recommends NF/Tier 3 status within 120 days of approval. In the meantime, newly approved drugs are considered to be in a classification pending status and available under the same terms as NF/Tier 3 medications.

## 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

| P&T Meeting | ADD to the TRICARE Maintenance Drug List (if Formulary, Add; if NF, NOT Exempted from NF TMOP Requirement) | Do NOT Add to the TRICARE Maintenance Drug List (if Formulary, Do Not Add; if NF, Exempted from NF TMOP Requirement) |
|---|---|---|
| May 2026 | **Drug Class Reviews**<br><br>**Antihemophilic Agents: Non-Factor Agents**<br>***Designated UF***<br>*Retain current status (currently on the TMDL contingent list)*<br>• concizumab-mtci (Alhemo)<br>• marstacimab-hncq (Hympavzi)<br><br>***Designated NF***<br>*Retain current status (currently on the TMDL contingent list)*<br>• fitusiran (Qfitlia)<br><br>**Leukemia and Lymphoma Agents: BCR ABL Tyrosine Kinase Inhibitors**<br>***Designated UF***<br>*Retain current status ((currently on the TMDL contingent list)*<br>• ascimiinib (Scemblix)<br>• dasatinib (Phyrago)<br>• imatinib solution (Imkeldi)<br>• ponatinib (Iclusig)<br><br>***Designated NF***<br>*Retain current status (currently on the TMDL contingent list)*<br>• nilotinib tartrate (Danziten)<br><br>**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)**<br><br>**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)~~)~~**<br>***Designated UF***<br>• aficamten (Myqorzo)<br>• copper histidine (Zycubo)<br>• doxecitine; doxribtimine (Kygevvi)<br>• navepegritide (Yuviwel)<br><br>***Designated NF***<br>*Add - no reason to exempt from TMOP NF requirement*<br>• desmopressin (Desmoda)<br>• lerodalcibep-liga (Lerochol)<br>• methocarbamol suspension (Atmeksi)<br>• icotrokinra (Icotyde)<br>• tocilizumab-anoh (Avtozma) | |

## Implementation Dates for UF Recommendations/Decisions*

*Due to the volume of recommendations requiring implementation due to the UF Beneficiary Advisory Panel pause, one week was added to implementation, which is reflected in the dates below.*

**Upon signing:** July 20, 2026

**Two weeks after signing:** August 12, 2026

**30 days after Signing**: August 26, 2026

**60 days after signing:** September 29, 2026

**90 days after signing:** October 28, 2026

**120 days after signing:** December 2, 2026, due to the Thanksgiving Day holiday

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

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## Appendix H—Complete Exclusion Drugs and Therapeutic Alternatives*

| P&T Committee Meeting Date | Drug Class | Completely Excluded Products | Formulary Alternatives | Implementation |
|---|---|---|---|---|
| May 2026 | Calcium Channel Blocking Agents | • amlodipine powder for oral solution (Sdamlo) | • amlodipine tablets<br>• amlodipine 1 mg/mL oral suspension (Katerzia)<br>• amlodipine 1 mg/mL oral solution (Norliqva) | • 120 days |
| May 2026 | Leukemia Lymphoma Agents: BCR ABL TKIs | • Nilotinib d-tartrate 50 mg, 150 mg, 200 mg caps (Nilceya) | • nilotinib monohydrate monochloride (Tasigna, generic)<br>• bosutinib<br>• dasatinib<br>• imatinib<br>• nilotinib tartrate (Danziten) NF | • 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.