DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
May 2025

I. CONVENING

The DoD Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 7th and 8th, 2025.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February 2025 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 2025 P&T Committee meeting minutes will also be delayed.

B. Clarification of previous meeting minutes

- **Feb 2025**
  - **Wakefulness Promoting Agents—solriamfetol (Sunosi) Prior Authorization (PA) criteria–**it is not operationally feasible to solely have specialist criteria, therefore clinical PA criteria were added back to the PA.
  - **Ophthalmic: Dry Eye Agents—cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose) –** it is not operationally feasible to solely have specialist criteria, therefore clinical PA criteria were added back to the PA.
  - **Pain Agents: Topical—lidocaine 5% patch Tridacaine XL** – this product is supplied by a re-packing company and is not part of TRICARE pharmacy benefit.
  - **Narcotic Analgesics and Combinations Tramadol 75 mg PA criteria**– implementation occurred on May 30, 2025, using the P&T Committee Administrative Authorities.
- **November 2024**
  - **Hematological Agents—iptacopan (Fabhalta) PA criteria**–The criteria regarding previous medication history were updated to read the patient has not received immunosuppressants including corticosteroids or Filspari in the past 90 days (instead of 2 weeks), consistent with the clinical trial used to gain FDA approval for immunoglobulin A nephropathy.
  - **Targeted Immunomodulatory Biologics (TIBs): Interleukin IL-23 Inhibitors—ustekinumab (Stelara) 45 mg/0.5 mL single dose vials**: **Clarification of TRICARE Pharmacy Benefit Inclusion**–The Stelara 45 mg/0.5 mL vials are covered under the pharmacy benefit, as this formulation is intended for self-

administration. The 130 mg/26 mL single dose vials are labeled for IV infusion and are covered under the TRICARE medical benefit.

- **May 2024**
  - **Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound) PA criteria** – Minor changes were made to the PA form to collect information on body mass index ranges and comorbidities. No changes were made to the actual PA coverage criteria and the PA forms reflect the intent of the Committee as outlined at the May 2024 class review. The updates were implemented on April 11, 2025.

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to Section 199.21(g)(5) of Title 32 Code of Federal Regulations (CFR) 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 Section 1074g(a)(10) of Title United States Code (USC). 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. Targeted Immunomodulatory Biologics (TIBs): Interleukin (IL)-1, IL-6 and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig) Subclasses

Background—The Targeted Immunomodulatory Biologics (TIBs) class is comprised of several subclasses, including the tumor-necrosis factor (TNF) inhibitors (e.g., adalimumab [Humira]) non-TNF inhibitors, and miscellaneous interleukin subclasses. The entire TIBs class was last reviewed at the August 2014 P&T Committee meeting and branded adalimumab (Humira) is currently step-preferred for most indications. Since the original review, 18 new drugs with multiple new mechanisms of action have entered the market. These newer agents have strong clinical evidence in specific

disease states. Two subclasses were reviewed at the November 2024 meeting, the interleukin (IL)-17s, and the IL-23s.

Biosimilar entrants have now entered the market for the originator tocilizumab (Actemra) formulation and are on the horizon for abatacept (Orencia). The advent of biosimilars is expected to reshape treatment options and create opportunities to participate in a Joint National Contract (JNC) with other Federal partners to align formularies for continuity of care and produce cost avoidance. Therefore, to address the growing complexity of the TIBs class, additional subclasses were created, the Interleukin-1 inhibitors (IL-1), Interleukin-6 inhibitors (IL-6), and Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin (CTLA4-Ig).

The drugs in the subclasses include the following:

- IL-1: anakinra (Kineret), rilonacept (Arcalyst)
- IL-6: tocilizumab (Actemra), tocilizumab-aazg (Tyenne, a biosimilar for Actemra), sarilumab (Kevzara), satralizumab (Enspryng)
- CTLA4-Ig: abatacept (Orencia)

Relative Clinical Effectiveness Conclusion—The clinical review focused on clinical practice guidelines, meta-analyses and systematic reviews, differences in FDA-labeling, use in pediatrics, and safety profiles. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1 Agents

- **anakinra (Kineret)** is indicated for rheumatoid arthritis (RA), cryopyrin-associated periodic syndromes (CAPS), neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA). There is substantial supporting evidence for off-label utilization for systemic juvenile idiopathic arthritis (sJIA), Adult-Onset Still's Disease (AOSD), familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells Syndrome (MWS), and recurrent pericarditis (RP). Despite carrying the FDA approval anakinra is not recommended by contemporary guidelines for use in RA. Limitations include frequent dosing intervals, requiring daily injections.
- **rilonacept (Arcalyst)** is indicated for CAPS, DIRA, FCAS, MWS, and RP. Most indications are approved for patients aged 12 and older, with the exception of DIRA which is indicated for use in infants weighing 10 kilograms (kg) or more. Limitations include lack of approval for more common disease states, including RA or JIA.

Interleukin-6 Agents

- **tocilizumab (Actemra, and the biosimilar Tyenne)** is FDA indicated for RA, pJIA, sJIA, giant cell arteritis (GCA), and systemic sclerosis-associated interstitial lung disease (SSc-ILD) which are available as part of the TRICARE pharmacy benefit. Indications available as IV infusions under the medical benefit include treatment of cytokine release syndrome

(CRS) and hospitalized patients with COVID-19 (C19). There is substantial off-label evidence for AOSD, neuromyelitis optica spectrum disorder (NMOSD), and polymyalgia rheumatica (PMR). Advantages include evidence to support use in young children, while limitations include multiple uses without formal FDA-approved labeling. Biosimilars are considered identical to the reference product for efficacy and safety, based on the conclusions from the August 2024 DoD P&T Committee meeting minutes' "Process for Evaluating Biosimilars and Biologics" section.

- *Biosimilars:* There are currently three FDA-approved biosimilars to the reference tocilizumab (Actemra). These include Tofidence, Tyenne, and Avtozma. Tofidence infusion is available under the TRICARE medical benefit. Tyenne has both a subcutaneous (SC) injection (available under the TRICARE pharmacy benefit) and a vial for infusion (available under the TRICARE medical benefit.) Avtozma is FDA-approved but had not launched at the time of the meeting and was not reviewed for formulary status. *(Refer to the November 2022 and August 2024 DoD P&T Committee meeting minutes for the "Process for Evaluating Biosimilars and Biologics" for additional information on biosimilars in TRICARE).*

- **sarilumab (Kevzara)** is indicated for RA, pJIA in patients two years of age or older and weighing at least 63 kg and is the only FDA-approved therapy for PMR.
- **satralizumab (Enspryng)** is indicated for treatment of neuromyelitis optica spectrum disorder in adult patients who are aquaporin-4 immunoglobulin G (AQP4-IgG) positive. Advantages include that it is the only FDA-approved outpatient medication for this indication. Disadvantages include approval for adults only and lack of approval or data in AQP4-IgG negative disease.

Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin Agents

- **abatacept (Orencia)** is indicated for RA, pJIA, and psoriatic arthritis (PsA) under the pharmacy benefit and under the medical benefit as an IV infusion for graft versus host disease (GVHD). Advantages include approval for use in pediatrics as young as two years old as well as the risk of causing less immunosuppression than the other TIBs. Disadvantages include a relatively lower level of efficacy per rheumatoid arthritis and psoriatic arthritis guidelines. Orencia additionally carries risk for unique side effects including cytomegalovirus (CMV) and Epstein-Barr virus (EBV), which was primarily seen in the studies for GVHD.
    - *Biosimilars:* Based on patent expiration, abatacept (Orencia) will likely have the next biosimilar within this subclass.

Rheumatoid Arthritis (IL-1s, IL-6s, and CTLA4-Ig)

- After failure of a TNF inhibitor, use of the IL-6s tocilizumab and sarilumab (Kevzara) are equally recommended in professional treatment guidelines. The CTLA4-Ig (abatacept) is also recommended after failure of other agents or in patients at very high risk of infections, specifically non-tuberculosis mycobacterium infections.
- Although anakinra (Kineret) is FDA-approved for rheumatoid arthritis, it is not mentioned or recommended in the RA guidelines by the American College of Rheumatology (ACR), European Alliance of Associations for Rheumatology (EULAR), or French rheumatoid arthritis guidelines

Polyarticular Juvenile Idiopathic Arthritis (IL-6, CTLA4-Ig)

- ACR guidelines recommend non-biologics including non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and methotrexate as first-line therapy. A biologic can be considered after failure of a non-biologic disease modifying antirheumatic drug (DMARD). These guidelines indicate a TNF inhibitor is the most commonly used biologic in children, and that all agents approved at the time of publication were equally recommended, including both the IL-6 tocilizumab and IL-1 abatacept.

Systemic Juvenile Idiopathic Arthritis, Adult-Onset Still's Disease (IL-1, IL-6)

- Literature within the space of systemic juvenile idiopathic arthritis (sJIA) and Adult-Onset Still's Disease (AOSD) is rapidly evolving. Newly published joint EULAR/PReS (Paediatric Rheumatology European Society) guidelines have combined these two, previously considered distinct, disease states into one disease called Still's Disease. These new guidelines recommend for patients without macrophage activation syndrome (MAS), early treatment with either anakinra, an IL-1, or tocilizumab, an IL-6 is clinically appropriate. For patients with MAS, the European guidelines indicate treatment with an IL-1 is preferred due to the amount of clinical experience by the guideline committee, specifically in those patients aged 16 years or older.
- ACR guidelines from 2021 for sJIA, prior to the European combination of the disease recommend early treatment of sJIA with anakinra, an IL-1, or tocilizumab, an IL-6 as clinically appropriate for patients with or without MAS.
- Tocilizumab is FDA-approved for treating sJIA, while anakinra (Kineret) is approved by the European Medicines Agency (EMA) for treating Adult-Onset Still's Disease. This EMA approval and guideline statement recommending IL-1 therapy over IL-6 therapy is likely reflective of the approval status of anakinra in Europe. Based on the published literature and guidelines, it is unclear whether therapy with anakinra or tocilizumab is more safe or efficacious than the other at this time.

Psoriatic Arthritis (CTLA4-Ig)

- Various guidelines for psoriatic arthritis recommend TNF-inhibitors, IL-23 inhibitors and IL-17 inhibitors as first-line. Contemporary guidelines from both the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis

(GRAPPA) and EULAR list abatacept (Orencia) as an option only after failure of one or more other targeted therapies due to limited efficacy.

Neuromyelitis optica spectrum disorder (IL-6)

- Satralizumab (Enspryng) is the only FDA-approved pharmacy benefit drug approved for treating adult patients with AQP4-IgG positive NMOSD. There are several additional medical benefit products, including eculizumab (Soliris), ravalizumab (Ultomiris) and rituximab (Rituxan and biosimilars) which are labeled for NMOSD. Additionally, tocilizumab has substantial evidence for efficacy and safety in treating AQP4-IgG positive and negative NMOSD, despite lack of formal FDA-approval.
- A systematic review evaluating safety and efficacy of IL-6 therapy with either satralizumab or tocilizumab was published in 2021, but included studies published prior to the FDA-approval of satralizumab for NMOSD. It concluded that both tocilizumab and satralizumab were effective at decreasing the annualized relapse rate in NMOSD. Additionally, tocilizumab, but not satralizumab, significantly improved both pain and fatigue compared to placebo. Adverse events were similar between the two agents.

Polymyalgia Rheumatica (IL-6)

- Guidelines for polymyalgia rheumatica (PMR) are outdated and were last published in 2015. The British Society of Rheumatology is currently working on an update with an anticipated 2025 release. The scoping document states both tocilizumab and sarilumab have data in new-onset and refractory PMR. Sarilumab (Kevzara) is the only FDA-approved biologic pharmacy benefit drug for treating patients with PMR but does not carry this labeling in Europe or the UK.
- There are ongoing studies for additional treatment mechanisms for PMR and a closely related condition, giant cell arteritis (GCA). Tocilizumab is FDA-approved for GCA, and Rinvoq, a JAK inhibitor not included in this review, recently gained FDA approval for this indication.

Recurrent Pericarditis (IL-1)

- Rilonacept (Arcalyst) is the only FDA-approved biologic pharmacy benefit item for treating patients aged 12 years and older with recurrent pericarditis. Arcalyst was not yet under broad investigation during the most recent recurrent pericarditis guideline update from 2015. Guidelines at that time from the European Society of Cardiology (ESC) recommended the standard of care including NSAIDs, colchicine, and corticosteroids. The ESC guidelines also recommended anakinra (Kineret) as a category IIB level of evidence. It is unknown when the guidelines will be updated to include Arcalyst.
- Since the publication of the 2015 ESC guidelines, both anakinra (Kineret) and rilonacept (Arcalyst) have completed additional clinical trials demonstrating their effectiveness in decreasing instances of recurrence and increasing time to recurrence. One published study continues to recommend either anakinra

(Kineret) or rilonacept (Arcalyst) for the treatment of colchicine-refractory recurrent pericarditis (2021 Journal of the American Heart Association).

Safety

- Published clinical practice guidelines do not make a distinction among individual IL-1, IL-6, or CTLA4-Ig agents in terms of safety, with the distinction of abatacept (Orencia) as potentially preferred if the patient has a history of non-tuberculosis mycobacterium infection.
- Noted adverse events for all the products include hypersensitivity risk, increased risk of infections including tuberculosis, injection site reactions, and warnings against concurrent use of live vaccines. IL-6 agents all carry the additional risk for hepatotoxicity and gastrointestinal perforation. Unique safety concerns were discussed with the individual product summaries.
- A review of the package inserts, guidelines, and other published literature of the adverse events with IL-1, IL-6, and CTLA4-Ig found the following:
    - The most common adverse drug reactions across all therapies included injection site reactions, infections, nasopharyngitis or upper respiratory tract infection, and headaches.
    - Overall, agents within this subclass appear well-tolerated with acceptable safety profiles.

Other Factors

- Special populations:
    - The agents are generally considered safe during the pregnancy planning phase but are discontinued once pregnancy is confirmed. There is no compelling evidence that one IL-1, IL-6, or CTLA4-Ig should be preferred over another during pregnancy. TNF inhibitors are also considered safe and effective in pregnancy.
    - All agents are approved for use in the pediatric patient population with the exception of satralizumab (Enspryng), based on FDA-labeling.
- Provider opinion:
    - Military Health System (MHS) rheumatologists voiced that a TNF inhibitor should remain first-line for RA and pJIA, while subsequent therapy with an IL-6, CTLA4-Ig, or a JAK inhibitor is appropriate based on patient characteristics. Pediatric providers are more likely to utilize tocilizumab for pJIA rather than sarilumab (Kevzara), due to the minimum weight requirement with Kevzara. Providers did note that SC administration of abatacept (Orencia) is less effective than other choices.

- For treatment of psoriatic arthritis, providers were in agreement that abatacept was less effective than drugs with other mechanisms of action. Providers were supportive of the requirement to utilize an IL-17 prior to use of a CTLA4-Ig for treatment of psoriatic arthritis.
- For treatment of Still's Disease, encompassing both systemic JIA and AOSD, rheumatologists were highly supportive of increasing access to both the IL-1 anakinra (Kineret) and the IL-6 tocilizumab as first-line agents. The providers agreed that a step requirement was not appropriate due to the multitude of patient factors, including those currently stabilized on therapy.
- Ophthalmologists and neuroimmunologists relayed opinions on using tocilizumab and satralizumab (Enspryng) for NMOSD and MOGAD. While feedback was mixed on the use of tocilizumab in adults, for the pediatric population there was full support for utilizing tocilizumab as the preferred outpatient therapy for NMOSD as it is useful in both AQP4-Ig positive and negative disease, as well as MOGAD. Since Enspryng is the only FDA-approved agent for this condition, a step requirement was not recommended.
- MHS rheumatologists were supportive of increasing options for evidence-based treatment of polymyalgia rheumatica. At this time, only sarilumab (Kevzara) carries the FDA-approved labeling for this condition, however other agents, including tocilizumab are used off-label, therefore a step requirement was not recommended.
- For treatment of recurrent pericarditis, providers were in agreement with increasing access to multiple treatment options. Rilonacept (Arcalyst) is the only FDA-approved biologic treatment, however older guidelines and current treatment algorithms recommend therapy with either anakinra (Kineret) or rilonacept (Arcalyst). Due to off label utilization of anakinra, a step requirement was not recommended.

Overall Conclusion

- Based on FDA indication and published guidelines it is reasonable to continue to require a trial of Humira first for many rheumatologic diseases including rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, consistent with the previous class review in 2014.
- Biosimilars are interchangeable to the reference product. Market launch of tocilizumab biosimilars in 2024 provides an opportunity for contracting initiatives with other Federal agencies via a Joint National Contract. Abatacept (Orencia) is the next biosimilar expected to enter the market.

- Within the subclass, when the agents are compared to one another, there are no compelling differences in efficacy and safety. Individual patients may show variability in response to different agents.
- Provider feedback overwhelmingly supported increasing accessibility to several agents, including optimizing PA pathways to allow off-label indications for which these medications are considered standard of care.
- For clinical coverage, at least one IL-1, IL-6, and CTLA4-Ig agent is needed on the formulary to cover each indication of RA, pJIA, and Still's Disease (sJIA, AOSD) to meet the needs of MHS beneficiaries. Additional options should be considered to provide more choices for providers based on individual patient characteristics.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 0 absent) the following:

Interleukin-1s, Interleukin-6s, Cytotoxic T-Lymphocyte Associated Antigen-4 Immunoglobulin

- CMA results showed that the formulary placement of tocilizumab (Tyenne) as UF and step-preferred was cost-effective.
- BIA and sensitivity results showed cost avoidance by designating Tyenne as step-preferred and all the other IL-1s, IL-6s, and CTLA4-Ig as non-step-preferred.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended for the IL-1, IL-6s, and CTLA4-Igs (18 for, 0 opposed, 0 abstained, 0 absent) the following:
    - UF and step-preferred
        - IL-6: tocilizumab-aazg (Tyenne) *moves from UF non-step-preferred to UF step-preferred*
    - UF and non-step-preferred
        - IL-1: anakinra (Kineret) *moves from NF non-step-preferred to UF non-step-preferred*
        - IL-6: sarilumab (Kevzara) *moves from NF non-step-preferred to UF non-step-preferred*
    - NF and non-step-preferred
        - IL-6: tocilizumab (Actemra)
        - CTLA-4Ig: abatacept (Orencia)
        - IL-1: rilonacept (Arcalyst) *moves from UF to NF non-step-preferred*

        - IL-6: satralizumab (Enspryng) *moves from UF to NF (no step required)*
    - Complete Exclusion: None
    - Note, as part of this recommendation a trial of adalimumab (Humira) and tocilizumab aazg (Tyenne) are required prior to use of the non-step-preferred IL-1, IL-6, and CTLA4-Ig products in all new patients, depending on the clinical indications.
    - Enspryng is not subject to the step therapy requirements for its indication of NMOSD.

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updated manual and step therapy PA criteria for the IL-1, IL-6, and CTLA4-Ig products as outlined below. See Appendix C for the full criteria.
    - *General Changes*:
        - Updating the step therapy requirements as outlined in the formulary recommendation and adding new indications as necessary.
        - Streamlining the list of medications that should not be used concurrently by drug classes rather than individual agents (new medications, biosimilars).
    - *IL-1s:* Current PA criteria for the IL-1s require a trial of Humira first for all overlapping indications. The recommended PA changes for the IL-1s include the following:
        - For Kineret, which is now the UF non-step-preferred IL-1, clarifying that a trial of Tyenne and Humira are both required for rheumatoid arthritis only, unless the patient has had an inadequate response, contraindication or adverse reaction to Humira and Tyenne. Neither Humira nor Tyenne will be required prior to Kineret for non-RA indications. The indications for recurrent pericarditis and chronic infantile neurological cutaneous and articular (CINCA) disease will be added.
        - For Arcalyst, a trial of Kineret is now required first for treatment of deficiency of interleukin receptor 1 antagonist (DIRA). Rheumatologists will also be able to prescribe Arcalyst for recurrent pericarditis, in addition to cardiologists. Kineret is not required prior to use of Arcalyst for recurrent pericarditis.
    - *IL-6s*: For the IL-6 agents, currently Humira is required first for all overlapping indications. The recommended PA changes include the following:

- For Tyenne, which is now UF step-preferred, an automated drug lookback for utilization of either Humira or Actemra will be added. New indications for Still's Disease, polymyalgia rheumatica (PMR), neuromyelitis optica spectrum disorder (NMOSD), and myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) were added to the PA form.
- For Actemra, which is the NF non-step-preferred tocilizumab product, all new and current users will be required to move to Tyenne. The current automated Humira lookback will be removed. A trial of Tyenne will be required for all indications, and a trial of Humira will be required for appropriate indications. All new and current users of Actemra and the other tocilizumab biosimilars (when they are marketed) will require a trial of Tyenne first.
- For Kevzara, which moves to UF non-step-preferred status, a trial of Tyenne will be added for the conditions of RA and pJIA; the Humira step requirement will remain.
- Enspryng will not be subject to step-therapy requirements as there are currently no overlapping FDA-approved indications with either Humira or Tyenne. Any future indications that may overlap with Humira or Tyenne will require step-therapy. Documentation will now be required to demonstrate aquaporin-4 immunoglobulin G (AQP4-IgG) positivity.

- *CTLA4-Igs*: For the CTLA4-Ig agents, currently Humira is required first for all indications. The recommended PA changes include the following:
  - Orencia will maintain the requirement for a trial of Humira first. A Tyenne step will be added for rheumatoid arthritis and pJIA. A trial of the IL-17 ixekizumab (Taltz) will be added for adult psoriatic arthritis. The automated drug lookback for Humira will be removed. The PA changes will apply to new users.
  - Biosimilars for the CTLA4-Ig Orencia are expected to launch in 2026. This will allow formulary addition of a cost effective abatacept product in a future review.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) new MN criteria for Enspryng and Arcalyst, and updated MN criteria for Actemra and Orencia. See Appendix B.
4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs of a 60-day supply at all points of service for all the drugs in the subclass. See Appendix D.

5. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining all the drugs in the subclass on the Specialty Drug List and TRICARE Maintenance Drug List, if feasible. See Appendix F for the TRICARE Maintenance Drug List details.
6. ***RAPID RESPONSE***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) adding satralizumab (Enspryng) and rilonacept (Arcalyst) to the Rapid Response (Safety Net program) maintained by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.
7. ***COMMITTEE ACTION: UF, PA, MN, QLs, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, , RAPID RESPONSE and IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following 1) an effective date of the first Wednesday 90 days after signing of the minutes, and 2) that DHA will send letters to beneficiaries receiving Enspryng and Arcalyst who will be affected by the formulary status change and to beneficiaries receiving Actemra due to the PA changes affecting both new and current users. See Appendix G.

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

Background—The P&T Committee evaluated the relative clinical effectiveness of the CDK inhibitor subclass used for advanced or metastatic hormone receptor-positive (HR(+)), human epidermal growth factor receptor 2-negative (HER2(-)) breast cancer. The drugs in the class include abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali). The drugs were last reviewed for formulary status in February 2021. Since the last review, the formulation of ribociclib co-packaged with the aromatase inhibitor letrozole (Kisqali Femara Co-Pack) has been removed from the market. Updates to clinical practice guidelines and FDA-approved indications were reviewed.

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

Efficacy

- A comprehensive review of the evidence shows that each CDK inhibitor offers a statistically and clinically significant advantage in median progression free survival and objective response rate (ORR) relative to the respective controls used in the individual clinical trials.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) both provide a statistically and clinically significant advantage in invasive disease-free survival (iDFS), relative to the respective controls used in the individual clinical trials for

early breast cancer treatment. This is a new indication for both agents that was not present in the prior class review.

- There are no high-quality head-to-head trials available directly comparing one CDK inhibitor with another.

Professional Treatment Guidelines

- The National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines recommend abemaciclib (Verzenio), palbociclib (Ibrance), and ribociclib (Kisqali) in the treatment of advanced or metastatic HR(+)/HER2(-) breast cancer as preferred first-line, second-line, or subsequent therapy. In the NCCN Guidelines, all agents carry a Category 1 recommendation in specific settings.
- Abemaciclib (Verzenio) and ribociclib (Kisqali) are now also recommended in the setting of early breast cancer. Both agents carry the same level of recommendations in this setting by the NCCN and ESMO Guidelines.
- Other guidelines (e.g., American Society of Clinical Oncology, European Society for Medical Oncology) are in agreement with one another and make no distinction in the choice of a particular agent. Each CDK inhibitor has the same preference and strength of recommendation.

Safety

- There is no one clearly superior CDK inhibitor in terms of safety or tolerability.
- The safety profiles of the CDK inhibitors overlap, however, there are unique adverse events associated with each agent. Hematologic adverse events (e.g., neutropenia, anemia, and thrombocytopenia) are considered class effects.
    - Palbociclib (Ibrance) has the highest rate of thrombocytopenia.
    - Abemaciclib (Verzenio) has a higher relative risk for diarrhea and unique warnings for venous thromboembolism (VTE).
    - Ribociclib (Kisqali) has a higher relative risk for QT interval prolongation.

Overall Clinical Conclusion

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

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

- CMA results showed that ribociclib, abemaciclib and palbociclib were all cost-effective.
- BIA was performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating all CDK inhibitors as UF demonstrated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the following.
   - UF
     - abemaciclib (Verzenio)
     - palbociclib (Ibrance)
     - ribociclib (Kisqali)
   - NF – none
   - Complete Exclusion – none
2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***— Manual PA currently apply to all three CDK inhibitors. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) streamlining the criteria by removing questions on detailed indication criteria, removing the safety and monitoring questions, and standardizing the verbiage for updates to NCCN criteria, consistent with the actions taken for other oncology drug PA criteria. See Appendix C for the full criteria.
3. ***COMMITTEE ACTION: QLs***—QLs currently apply to the class. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining a 28 day supply QL at all points of service for Ibrance, Verzenio, and Kisqali. See Appendix D.
4. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS*** —The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining Ibrance, Verzenio and Kisqali on the both lists. See Appendix F for the TRICARE Maintenance Drug List details.
5. ***COMMITTEE ACTION: UF, PA QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS and IMPLEMENTATION PERIOD—*** The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G.

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

The products were divided into two groups when presented at the DoD P&T Committee meeting. The generic names are included below. Group 1 included Zunveyl, Alhemo, Inzirqo, Xromi, Prevymis, Gomekli, Raldesy, and six ustekinumab biosimilars (Steqeyma, Otulfi, Pyzchiva, Yesintek, Selarsdi, and an ustekinumab-ttwe unbranded private label). Group 2 included Journavx, Vykat extended release (XR) and Romvimza.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 16 for, 0 opposed, 1 abstained, and 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 2025 DoD 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 (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following:
    - UF
        - concizumab-mtci (Alhemo) – Antihemophilic Agents
        - diazoxide choline (Vykat XR) – Miscellaneous Metabolic Agent for hyperphagia in Prader-Willi Syndrome
        - hydroxyurea 100 mg/mL oral solution (Xromi) – Oncological Agent for Sickle Cell Anemia
        - letermovir extended release (ER) pellets (Prevymis) – Antiviral for cytomegalovirus (CMV) infection
        - mirdametinib (Gomekli) – Oncological Agent for neurofibromatosis
        - suzetrigine (Journavx) – Pain Agents
        - ustekinumab-aauz (Otulfi) – Targeted Immunomodulatory Biologics (TIBs): Interleukin-23 (IL-23) inhibitors; biosimilar for Stelara
        - ustekinumab-stab (Steqeyma) – TIBs IL-23s; biosimilar for Stelara
        - vimseltinib (Romvimza) – Oncological Agent for tenosynovial giant cell tumor
    - NF
        - hydrochlorothiazide 10 mg/mL powder for oral suspension (Inzirqo) – Diuretic Agents
        - trazodone 10 mg/mL oral solution (Raldesy) – Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor

        - ustekinumab-ttwe (Pyzchiva) – TIBs IL-23s; biosimilar for Stelara
        - ustekinumab-kfce (Yesintek) – TIBs IL-23s; biosimilar for Stelara
        - ustekinumab-aekn (Selardsi) – TIBs IL-23s; biosimilar for Stelara
    - Complete Exclusion
        - ustekinumab-ttwe (unbranded private label) – TIBs IL-23s; biosimilar for Stelara by Quallent
            - The ustekinumab-ttwe private label brand was recommended for complete exclusion status as it has little to no clinical benefit relative to other ustekinumab biosimilars, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), ustekinumab-stab (Steqeyma), and ustekinumab (Stelara).
        - benzgalantamine (Zunveyl) – Alzheimer's Agents
            - Zunveyl was recommended for complete exclusion status as it has little to no clinical benefit relative to the other Alzheimer's Agents, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include galantamine, galantamine ER and donepezil.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Inzirqo, Raldesy, Pyzchiva, Yesintek, and Selarsdi. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria. See Appendix C for the full criteria.
    - Applying manual PA criteria to new users of the UF ustekinumab products Otulfi and Steqeyma, similar to what is required for all non-step-preferred Interleukin-23 inhibitors, where a trial of adalimumab (Humira) will be required first. These products are non-step-preferred.
        - For the NF ustekinumab products Pyzchiva, Yesintek, and Selardsi, the PA will also apply to new users and require a trial of Humira, plus a trial of all the UF ustekinumab products. These products are non-step-preferred.

        - Additionally, PA criteria will apply to unbranded ustekinumab-ttwe, until implementation of the complete exclusion status. Providers will need to document why the unbranded product is required, rather than using the UF and NF ustekinumab products.
    - Applying manual PA criteria to new users of Alhemo, similar to the PA requirements for other hemophilia agents.
    - Applying temporary manual PA criteria to new users of Zunveyl, until implementation of complete exclusion status.
    - Applying manual PA criteria to new users of Vykat XR, Xromi, Gomekli, Inzirqo, Raldesy, and Romvimza.

4. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 for, 0 opposed, 0 abstained, 1 absent QLs for Alhemo, Vykat XR, Prevymis, Gomekli, Journavx, and the six ustekinumab biosimilars. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent – all Group 1 agents) adding Zunveyl, Gomekli, Otufli, Steqeyma, Pyzchiva, Selardsi, Yesintek, and ustekinumab-ttwe (unbranded) to the Rapid Response program managed by the TRICARE pharmacy contractor. The program identifies beneficiaries who have not received a prescription fill after the initial reject.

6. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS***—The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 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 to be added to the Specialty Drug List are listed in Appendix E.

7. ***COMMITTEE ACTION: UF, MN, PA, QL, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, and IMPLEMENTATION PERIOD***— The P&T Committee recommended (Group 1: 18 for, 0 opposed, 0 abstained, 0 absent and Group 2: 17 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

a) **Anti-infectives: Antihelmintics—mebendazole (Emverm)—**Emverm is indicated to treat a variety of parasitic worm infections. The price of Emverm has increased exponentially in recent years and some commercial health plans require a PA for Emverm. MTF providers support the addition of a PA restricting use to parasitic indications and requiring a step of over-the-counter (OTC) pyrantel pamoate, ivermectin, or albendazole. Off-label uses for indications other than parasitic infections will not be allowed.

b) **Keratolytics—urea 41% cream—**Topical urea is used as a moisturizer and keratolytic and is available in a variety of strengths including 10%, 20%, and 40%. The 41% strength is notably not cost-effective. The committee recommended PA criteria requiring providers to explain why the 41% strength is needed.

c) **Endocrine Agents Miscellaneous: Antihyperglycemic-Glucocorticoid Receptor Blocker—mifepristone (Korlym)—**Korlym is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym is more costly than other alternatives used to treat Cushing's syndrome. A manual PA was recommended for Korlym to restrict use to its FDA-approved indication in new and current users, to require prescribing by an endocrinologist, and a trial of at least one other agent for Cushing's syndrome in new users. MTF providers supported establishment of PA criteria.

d) **Leukotriene Modifying Agents—zileuton (Zyflo), zileuton ER generic—**Zileuton is indicated to treat asthma and is less cost-effective than other agents in the class. Hepatic monitoring is required for zileuton due to liver function test elevations. A manual PA affecting new and current users was recommended requiring a trial of montelukast (generic Singulair) and zafirlukast (generic Accolate) first, due to safety concerns. Zyflo will be added to the Rapid Response/Safety Net program, which will provide additional outreach to beneficiaries who have not received a prescription after an initial PA reject.

COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended

(17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Emverm in new users and for urea 41% cream, Korlym, and zileuton in new and current users. 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 currently receiving urea 41%, Korlym, zileuton IR and zileuton ER. See Appendix C for the full criteria.

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

   Manual PA criteria were recommended for two 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 the newly approved drug reviews and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

   a) **Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet—** Numerous other more cost-effective generic metformin IR and ER tablets are available.

   b) **Narcotic Analgesics and Combinations—tramadol 100 mg immediate release (IR) tablet—**There are other tramadol formulations available, including tramadol 50 mg tablets, that are more cost-effective than this 100 mg strength.

   COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for metformin 750 mg IR tablets and tramadol 100 mg tablets 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.

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

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

   a) **Miscellaneous Metabolic Agents—setmelanotide (Imcivree)—** The manual PA criteria were expanded to include children 2 years of age and older with certain syndromic or monogenic forms of obesity.

   b) **Immunological Agents Miscellaneous: Oral Agents—house dust mite allergen extract (Odactra)—**The manual PA criteria were expanded to include children ages 5 to 11 years old.

c) **TIBs: IL-23— guselkumab (Tremfya)—**Tremfya is now indicated for the treatment of Crohn's Disease in adults. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the Ulcerative Colitis criteria for this drug.

d) **Leukemia and Lymphoma Agents: BTK Inhibitors—acalabrutinib (Calquence)**—The manual PA criteria were updated to allow for treatment of a subset of previously untreated mantel cell lymphoma patients.

e) **Oncological Agents: Lung Cancer—sotorasib (Lumakras)**—Lumakras received a new indication for KRAS G12C-mutated metastatic colorectal cancer. The manual PA was updated to include this indication and require coadministration with panitumumab in patients who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy based on the FDA label. Additionally, edits were made to match the recent changes in other oncology PAs as part of the ongoing oncology standardization process.

f) **Diabetes Non-Insulin: GLP-1RAs—semaglutide (Ozempic)—** Semaglutide under the trade name Ozempic is now indicated to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, and cardiovascular death in adults with chronic kidney disease and type 2 diabetes. Current treatment guidelines recommend a renin angiotensin system inhibitor (ACE inhibitor or angiotensin receptor blocker) and sodium-glucose co-transporter 2 (SGLT-2) inhibitor. The Ozempic PA and MN criteria were updated to require use of the cost effective guideline-recommended therapies first.

g) **Diabetes Non-Insulins: GLP-1RAs – semaglutide (Ozempic) and tirzepatide (Mounjaro) MN criteria—**The MN criteria for the NF diabetic GLP1-RAs was updated to include that the patient has tried and failed dulaglutide (Trulicity), based on provider feedback.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Imcivree, Odactra, Tremfya, Calquence, Lumakras, and Ozempic in new users, and recommended (17 for, 0 opposed, 0 abstained, 1 absent) the MN updates for the diabetic GLP-1RAs Ozempic and Mounjaro in new users. Implementation for the MN criteria updates for the diabetic GLP-1RAs will be effective on signing, and implementation for the new PA criteria for the agents listed above will be effective the first Wednesday 60 days after the signing of the minutes. See Appendices B and C for the full criteria.

4. Updated PA and MN 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.

a) **Corticosteroids-Immune Modulators: Atopic Dermatitis—crisaborole (Eucrisa)—**An age edit was added allowing patients two years of age and younger to bypass the PA as other non-steroid treatments are only approved for children older than age two.

b) **Antigout Agents: Chronic—febuxostat (Uloric)**—An automated drug lookback for allopurinol 300 mg was added to the Uloric PA. Patients with a prescription claim for allopurinol in the past 180 days will bypass the Uloric PA. In addition, the safety questions were removed.

c) **Oncological Agents—fedratinib (Inrebic), selumetinib (Koselugo), pomalidomide (Pomalyst), ripretinib (Qinlock), midostaurin (Rydapt), capmatinib (Tabrecta), tepotinib (Tepmetko), pexidartinib (Turalio), quizartinib (Vanflyta), larotrectinib (Vitrakvi), dacomitinib (Vizimpro), and gilteritinib (Xospata)**— Updates were made as part of the continuing process for oncology PA standardization, to include removing monitoring and safety criteria, and standardizing wording for National Cancer Care Network (NCCN) guideline updates. For more details on oncology PA standardization, please refer to the November 2024 meeting minutes. Additionally, the PA for Pomalyst was updated to add the Kaposi Sarcoma indication.

d) **Metabolic Agents Miscellaneous—odevixibat (Bylvay) and maralixibat (Livmarli)**—Bylvay and Livmarli are FDA-approved to treat pruritus due to progressive familial intrahepatic cholestasis or Alagille syndrome. The drugs treat the pruritic symptoms, but do not change the underlying disease course. Both drugs were reviewed as innovators and were designated as NF with a PA requiring a trial of five other generic, well-established agents first. Bylvay and Livmarli are not yet included in professional treatment guidelines. Based on a review of MHS prescription claims, the PA will expand the options to the six drugs included in the current treatment guidelines, but only require a trial of three products first, prior to Bylvay or Livmarli. Other updates included standardizing the new nomenclature for non-alcoholic fatty liver disease (NAFLD), now known as metabolic dysfunction-associated steatotic liver disease (MASLD).

e.) **Antipsychotic Agents: Parkinson's Psychosis—pimavanserin (Nuplazid)—** Nuplazid will now require a trial of clozapine first, unless the patient has a contraindication, intolerability to, or has failed treatment with clozapine. The reasons for the clozapine step are due to removal of the previous clozapine Risk Evaluation and Mitigation System (REMS) program, network meta-analysis data supporting its use before Nuplazid, and provider feedback supporting using Nuplazid as a later-line agent. Additionally, clozapine is more cost-effective than Nuplazid.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Eucrisa, Uloric, Inrebic, Koselugo, Pomalyst, Qinlock, Rydapt, Tabrecta, Tepmetko, Turalio, Vanflyta, Vitrakvi, Vizimpro, Xospata, Bylvay, Livmarli, and Nuplazid in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

5. **Removal of PAs**

   a) **Multiple Sclerosis Agents: Methyl Fumarate—dimethyl fumarate (Tecfidera)—**Tecfidera is designated as UF. Generic formulations of Tecfidera are now available and dimethyl fumarate is the most cost-effective methyl fumarate agent. The Tecfidera PA will be removed for these reasons.

   b) **Alzheimer's Agents—memantine ER (Namenda XR)—**Currently, memantine IR (Namenda) is designated as UF while memantine ER (Namenda XR) is designated as NF with a PA. Namenda XR is administered once daily and is available as a generic. Due to clinical and cost considerations, the PA will be removed for Namenda XR, but Namenda XR will remain as NF.

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

B. Quantity Limits

1. **Anti-infectives: Antihelmintics—mebendazole (Emverm)—**QLs of 12 tablets per 30 days, with no refills allowed, were recommended for Emverm. The QLs will allow for two treatment courses at the FDA-labeled dosing regimen. Infectious Disease specialists will be able to bypass the QL if the prescription is used to treat parasitic infections.

COMMITTEE ACTION: EMVERM QLs and IMPLEMENTATION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) adding QLs for Emverm. Implementation will occur the first Wednesday two weeks after signing of the minutes. See Appendix D.

C. Line Extensions

The P&T Committee clarified the formulary status for two 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. **Neurological Agents Miscellaneous—**designating **risdiplam (Evrysdi) tablet** with the same formulary status (UF), PA, and Specialty drug list as the parent Evrysdi solution. However, the current QL for the solution is 36 days' supply at all points of service (POS); for the tablet it will be 30 tablets for 30 days at all POS. See Appendix D.
2. **Continuous Glucose Monitoring (CGM) Systems: Therapeutic CGM Systems—**designating **Dexcom G7 15 Day Sensor** with the same formulary status (UF), PA, and QL as the Dexcom G7 Sensor. The QLs will be adjusted as the Dexcom G7 Sensor lasts 10 days and the new sensor lasts 15 days. The QL will be 2 sensors/30 days at retail and 6 sensors/90 days at MTF and TMOP The PA will be adjusted to reflect the FDA approved age of the new sensor (18 years of age or older). The committee also voted to add the Dexcom G7 15 Day Sensor to the TRICARE pharmacy benefit. See Appendices C and D.

   COMMITTEE ACTION: LINE EXTENSION, ADDITION OF DEXCOM G7/15 DAY SENSOR TO THE BENEFIT AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, MN, and Specialty and TRICARE Maintenance Drug Lists status for Evrysdi tablet and Dexcom G7 15 Day Sensor. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR ADDITION FOR SACUBITRIL/VALSARTAN (ENTRESTO)

Renin-Angiotensin Antihypertensives: Combinations—Sacubitril/valsartan (Entresto) tablets are designated as UF without a PA. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, the branded Entresto tablets will continue to be dispensed at all three points of service, and the generics will only be available with prior authorization. The Tier 1 copay for brand Entresto is recommended.

COMMITTEE ACTION: ENTRESTO BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) requiring brand Entresto tablets over the generics in new users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Entresto tablets. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

VIII. WEIGHT LOSS DRUGS REGULATORY AND STATUTORY REQUIREMENTS, AND PA UPDATE

The P&T Committee reviewed utilization and cost trends for the weight loss drugs, which are covered under the TRICARE Pharmacy benefit based on an Interim Final Rule published on September 29, 2017, (DOD-2017-HA-RIN 0720). The Final Rule authorizes coverage for

TRICARE Prime and TRICARE Select beneficiaries for medically necessary treatment of obesity, even if it is the sole or major condition treated when prescribed by a network provider. Obesity drugs were added to the TRICARE pharmacy benefit at the November 2017 P&T Committee meeting.

A. Regulatory and Statutory Requirements

The PA criteria for the weight loss drugs were updated to explicitly define which TRICARE beneficiaries are eligible to receive a weight loss drug and to clarify that weight loss drugs must be prescribed by network providers. The revised PA criteria will apply to the older amphetamine derivatives (phentermine, benzphetamine, diethylpropion, and phendimetrazine IR and SR), phentermine/topiramate (Qsymia), bupropion/naltrexone (Contrave), phentermine 8 mg (Lomaira), orlistat (Xenical) and the injectable glucagon-like peptide-1 receptor agonists (GLP1-RAs) liraglutide (Saxenda), semaglutide (Wegovy), and tirzepatide (Zepbound).

The following statements will be added to the PA criteria for all the weight loss drugs, to ensure alignment with statutory and regulatory requirements. The changes will apply to all new and current users and will be implemented immediately following patient notification.

1. 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."

2. 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? If the answer is "no" then coverage will be denied. Affirmative answers are subject to verification.

3. What TRICARE plan is the patient enrolled in? For more information see https://tricare.mil/Plans/HealthPlans. TRICARE Select and TRICARE Prime will be approved. Other TRICARE health plan enrollment that is not TRICARE Select or TRICARE Prime will not be approved. If the patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, the provider should consider these alternatives.

See Appendix C for the updates noted above. PA criteria are not currently in place for the amphetamine derivatives, therefore new PA criteria with the above three questions will apply for phentermine, benzphetamine, diethylpropion and phendimetrazine IR and SR.

A plan edit will apply for all weight loss drugs; coverage is not approved for Non-TRICARE Prime or Non-TRICARE Select patients.

B. PA Updates for the Weight Loss Drugs – Comprehensive Lifestyle Intervention

The current PA criteria for the weight loss drugs was reviewed. The Committee recommended adding to the PA criteria that the patient has had verifiable participation in a comprehensive lifestyle intervention that targets all three aspects of

weight management: diet, physical activity, and behavioral changes on both treatment initiation and annual renewal. This will apply to all drugs in the class.

COMMITTEE ACTION: PA CRITERIA TO REQUIRE COMPREHENSIVE LIFESTYLE INTERVENTION—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) to require documentation of verifiable participation in a comprehensive lifestyle intervention (including dietary, exercise and behavioral health programs) for all new users and for all current users on the annual PA renewal period for all the weight loss drugs. Implementation will occur the first Wednesday 60 days after signing of the minutes in all three points of service. See Appendix C.

IX. SECTION 703, NATIONAL DEFENSE AUTHORIZATION ACT (NDAA) FOR FISCAL YEAR (FY) 2008

The P&T Committee reviewed one drug from pharmaceutical manufacturers that were not included on a DoD Retail Refund Pricing Agreement; this drug was not in compliance with FY08 NDAA, Section 703, permanently codified at 10 USC 1074g(f). If a drug is not compliant, it will be designated NF on the UF and will be restricted to the TRICARE Mail Order Pharmacy, requiring pre-authorization prior to use in the retail point of service (POS) and medical necessity at MTFs.

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) that the Section 703 non-compliant national drug code numbers (NDCs) of the following product remain designated as NF on the UF:

- Wokhardt: bupropion extended release 450 mg (*New Drug Application-NDC 64679-0830-01)* authorized generic for Forfivo XL

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs:

1. Use of the formulary alternatives are contraindicated. The formulary alternatives include bupropion immediate release, sustained release and extended-release generic and Forfivo XL 450 mg.
2. Obtaining the product by home delivery would be detrimental to the patient.

These pre-authorization criteria do not apply to any other point of service other than retail network pharmacies.

C. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the MN criteria currently in place for Forfivo XL. See Appendix B for the full criteria.

COMMITTEE ACTION: IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes for the non-compliant NDCs and

that DHA send letters to the affected beneficiaries. After the pricing agreement is signed, this drug will be automatically returned to the previous formulary status.

X. DoD P&T COMMITTEE ADMINISTRATIVE AUTHORITY

Background—The Administrative Authorities document outlines which P&T Committee functions can be performed administratively prior to the quarterly meeting, and subsequently presented to the P&T Committee for formal recommendation; those functions which require both Uniform Formulary Beneficiary Advisory Panel (UF BAP) and Director, DHA review; and those which solely require Director, DHA review and do not fall under the purview of the UF BAP panel. The administrative authorities document was most recently updated at the February 2025 P&T Committee meeting.

Recommendation—Terminology included in the new Specialty program and TPharm 5 contract language has prompted an update to the Administrative Authorities document. Changes include removing outdated language and updating to current terms: the specialty agent reporting list to the TRICARE Specialty Drug List; Tier 4 to "complete exclusion"; changing from the Expanded MTF Mail Pharmacy Initiative ("EMMPI") or the maintenance medication list to "TRICARE Maintenance Drug List"; and changing to Retail Pharmacies from "Retail Network Pharmacies"

Justification—The changes will align with updated terminology.

COMMITTEE ACTION: P&T COMMITTEE ADMINISTRATIVE AUTHORITY UPDATE—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) to update the Administrative Authorities document to as outlined above, including modifications based on the Specialty program and TPharm5 terminology changes. See Appendix H, page 81.

XI. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

A. Annual Utilization Management Review: The Committee reviewed a summary of 164 UM actions from the four P&T Committee meetings held in FY2024 (November 2023 to August 2024). A focused review of actions showed that there were more PA removals than additions. Additionally, specialist provider bypass was highlighted as a new tool to decrease provider administrative requirements for PAs. The Committee reviewed analysis of the effects of PAs on MHS utilization and spend.

B. Therapeutic Interchange: The P&T Committee discussed how the direct care network could optimize current utilization management through formal therapeutic interchange recommendations for MTF providers to MTF pharmacies.

C. Medications used in the treatment of Gender Dysphoria: The P&T Committee was notified of the changes to coverage of Gender Dysphoria for minors and for initiation of therapy for active duty as directed by law, executive order, regulation, and direction from DoD leadership.

D. Oncological Agents – Second Generation Anti-Androgens darolutamide (Nubeqa)—The P&T Committee briefly evaluated the prostate cancer medications and no updates to the Nubeqa PA were recommended at this time.

XII. ADJOURNMENT

The meeting adjourned at 1430 hours on May 8th. The next meeting will be in August 2025.

Appendix A—Attendance: May 2025 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary during the May 2025 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Drugs with Complete Exclusion Status and Formulary Alternatives
Appendix I—DoD P&T Committee Administrative Authority

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

Signed/Signature on file

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

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.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
LTC Megan Donahue, MC	Army, Physician at Large
LTC Ryan Burkhart, MC	Army, Internal Medicine Physician
COL James Masterson, MSC	Army, Pharmacy Consultant
CDR Todd Hansen, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics
MAJ Loraine Baraki, MC	Army, OBGYN
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Maj Courtney Clutter, MC	Air Force, Internal Medicine Physician
Lt Col Sara DeSpain, MC	Air Force, Physician at Large
Col Soo Sohn, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
LCDR Shira Paul, MC	Navy, Oncology Physician
Lara Au, PharmD, BCOP	DHA, Oncology Pharmacist
CDR Chris McKnight, USCG	Coast Guard, Pharmacy
CDR Jackie Finocchio, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA (Day #2)	TRICARE Health Plan Chief Medical Officer
COL Yang Xia, MC (Day #1)	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Peter Glassman, MD	Department of Veteran's Affairs
Marsha Peterson	DHA Contracting Officer
Eugene Moore, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integration Branch
Lt Col Francisco Boral	Defense Logistics Agency
Guests	
CAPT Tiffany Cline, MSC	DHA POD Beneficiary Advisory Panel DFO
CPT Ji Yoon Kim, MSC	Army Pharmacist
CAPT Marisol Martinez, USPHS	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
Hazel Richardson, PharmD	CDC WTCHP
CDR Kendra Jenkins, PharmD	BoP Pharmacy
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
CDR Giao Phung, MSC	DHA POD Formulary Management Branch
Heather Johnson, PharmD, BCCP, BCCP	DHA POD Formulary Management Branch
Lt Col Pansy Uberoi, MC	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
Kirk Stocker, BS Pharm, MBA, MHSA	DHA POD Formulary Management Branch
Michael Lee, RPh, MBM, MPharm-Econ	DHA POD Formulary Management Branch

Appendix A—Attendance

David Folmar, RPh, MS, MBA	DHA POD Formulary Management Branch
Eric Parsons, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integratic Branch
Tracy Banks	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Stephanie Erpelding	DHA Contracting
Jules Canaley	DHA Contracting
Dwight Bonham	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity (MN) Criteria
Drug Class Reviews MN Criteria	
• abatacept (Orencia) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	**Updates from May 2025 are in bold and strikethrough** • Use **of all formulary agents** ~~adalimumab (Humira)~~ is contraindicated • The patient has experienced ~~or is likely to experience~~ significant adverse effects **from all formulary agents** ~~adalimumab (Humira)~~ • **Formulary agents** ~~adalimumab (Humira)~~ have resulted ~~or is likely to result~~ in therapeutic failure. • The patient previously responded to the nonformulary agent and changing to **a formulary agent** ~~adalimumab (Humira)~~ would incur unacceptable risk **for patients currently stabilized on IV abatacept** ~~• No alternative formulary agent applies only to:~~ ~~▪ abatacept (Orencia): The patient is transitioning from IV abatacept or has symptomatic congestive heart failure CHF.~~ **Formulary alternatives**: adalimumab (Humira), **tocilizumab-aazg (Tyenne), ixekizumab (Taltz)**
• rilonacept (Arcalyst) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents has resulted in therapeutic failure • The patient previously responded to the non-formulary agent and changing to a formulary agent would incur unacceptable risk • No alternative formulary agent Formulary alternatives: anakinra (Kineret)
• satralizumab (Enspryng) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents has resulted in therapeutic failure • The patient previously responded to the non-formulary agent and changing to a formulary agent would incur unacceptable risk • No alternative formulary agent Formulary alternatives: tocilizumab-aazg (Tyenne)
• tocilizumab (Actemra) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	**Updates from May 2025 are in bold and strikethrough** ~~• Use of formulary agents is contraindicated~~ • Patient has experienced significant adverse effects from formulary agents **Formulary alternatives**: adalimumab (Humira), **tocilizumab-aazg (Tyenne)**
New Drugs MN Criteria	
• hydrochlorothiazide 10 mg/mL oral suspension (Inzirqo) **Diuretic Agents**	• No alternative formulary agent: patient has documented swallowing difficulties and cannot take a loop diuretic and thiazide in tablet form **Formulary alternatives**: HCTZ tablets and capsules; chlorthalidone tabs; furosemide tabs

• trazadone 10 mg/mL oral solution (Raldesy) **Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Agonist and Reuptake Inhibitor**	• Use of formulary agents is contraindicated • Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** trazadone tablets, SSRIs: citalopram, escitalopram, fluoxetine, sertraline, fluvoxamine, paroxetine hydrochloride IR); SNRIs: venlafaxine IR, venlafaxine ER, desvenlafaxine succinate ER,
• ustekinumab-ttwe (Pyzchiva) • ustekinumab-kfce (Yesintek) • ustekinumab-aekn (Selarsdi) • ustekinumab-ttwe (unbranded, until moves to complete exclusion status) **TIBs: IL-23**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents **Formulary alternatives**: adalimumab (Humira), ixekizumab (Taltz), ustekinumab-stab (Steqeyma), ustekinumab-aauz (Otulfi), ustekinumab-auub (Wezlana), ustekinumab (Stelara)
• semaglutide (Ozempic) **Non-Insulin Diabetes Drugs: GLP-1RAs**	**Updates from the May 2025 meeting are in bold** For Type 2 Diabetes Mellitus: • Patient has experienced or is likely to experience significant adverse effects from dulaglutide (Trulicity) which is not expected to occur with Ozempic • **All formulary agents have resulted in therapeutic failure.** Formulary alternatives for T2DM: dulaglutide (Trulicity) **For Chronic Type 2 Diabetes Mellitus (T2DM) with Chronic Kidney Disease (CKD):** • **All formulary agents have resulted in therapeutic failure.** **Formulary alternatives for T2DM with CKD: ACE inhibitors, Angiotensin Receptor Blockers, SGLT2 inhibitors (empagliflozin, dapagliflozin, canagliflozin)** **PA does not expire**
• tirzepatide (Mounjaro) **Non-Insulin Diabetes Drugs: GLP-1RAs**	**Updates from the May 2025 meeting are in bold** For Type 2 Diabetes Mellitus: • Patient has experienced or is likely to experience significant adverse effects from dulaglutide (Trulicity) which is not expected to occur with Mounjaro • **All formulary agents have resulted in therapeutic failure.** Formulary alternatives for T2DM: dulaglutide (Trulicity)
Section 703 Drugs MN Criteria	
• bupropion 450 mg ER authorized generic for Forfivo XL **Antidepressants**	• Use of formulary agents is contraindicated and treatment with other formulary antidepressants is not clinically appropriate **Formulary alternatives**: bupropion SR, bupropion IR, bupropion ER

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• abatacept (Orencia) **TIBs: IL-1s, IL-6-s, CTLA4-lgs**	**Updates from the May 2025 meeting are in bold.** Manual PA criteria apply to all new users of abatacept (Orencia). ~~Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND~~ Manual PA Criteria: ~~If automated criteria are not met,~~ Orencia is approved if all criteria are met. • **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-lg is Tyenne. The patient must have tried Tyenne AND** ▪ **The patient has had an inadequate response to Tyenne OR** ▪ **The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR** ▪ **The patient has a contraindication to Tyenne** ▪ **A trial of Tyenne is not required for adult or pediatric psoriatic arthritis** • **Humira is the Department of Defense's preferred targeted biologic agent.** The patient must have tried Humira AND: ▪ The patient had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Humira • **The patient must have tried Taltz AND:** ▪ **The patient had an inadequate response to Taltz OR** ▪ **The patient experienced an adverse reaction to Taltz that is not expected to occur with the requested agent OR** ▪ **The patient has a contraindication to Taltz** ▪ **A trial of Taltz is not required for adult or pediatric psoriatic arthritis** • Coverage approved for patients 18 years of age or older with one of the following diagnoses/indications: ▪ Moderate to severely active rheumatoid arthritis ▪ Active psoriatic arthritis ~~• Patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], etc.)~~ • Coverage approved for patients 2 to 17 years of age with one of the following diagnoses/indications: ▪ Moderately to severely active polyarticular juvenile idiopathic arthritis ▪ Active psoriatic arthritis. Note that a trial of non-biologic systemic therapy and Humira is required ~~• Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ • ~~May not be used concomitantly with other TIBs agents~~ • **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, C5 inhibitors, or rituximab**

Appendix C—Table of Prior Authorization (PA) Criteria

	Non-FDA-approved uses are not approved. Prior Authorization does not expire
• anakinra (Kineret) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria applies to all new users of anakinra (Kineret). Manual PA Criteria**:** Kineret is approved if all criteria are met: • **Provider acknowledges the Department of Defense requires a trial of Humira. The patient must have tried Humira AND** ▪ **The patient has had an inadequate response to Humira OR** ▪ **The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR** ▪ **The patient has a contraindication to Humira AND** • **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-Ig is Tyenne. The patient must have tried Tyenne AND** ▪ **The patient has had an inadequate response to Tyenne OR** ▪ **The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR** ▪ **The patient has a contraindication to Tyenne AND** • Patient is 18 years of age or older with: ▪ ~~Adult-Onset Still's Disease (AOSD) with active systemic features of moderate to high disease activity (Trial of Humira not required) OR~~ ▪ Moderate to severe active rheumatoid arthritis ~~AND~~ - ~~Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications~~ - ~~The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent~~ - ~~The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine])~~ • **Patients 12 years of age or older with** ▪ **Recurrent pericarditis** - **Prescription has been written by or in consultation with a cardiologist or rheumatologist AND** - **Patient has a contraindication to colchicine and at least ONE of the following drug classes** o **aspirin** o **NSAIDs OR** - **Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes** o **aspirin** o **NSAIDs** o **corticosteroids** • ~~Pediatrics~~ **Patients** (all ages) with: ▪ Neonatal-Onset Multisystem Inflammatory Disease (NOMID) ~~a subset of cryopyrin-associated periodic syndrome~~ ~~(Trial of Humira not required)~~ ▪ **Chronic Infantile Neurological Cutaneous and Articular (CINCA) disease**

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ **Cryopyrin-Associated Periodic Syndrome (CAPS**). ~~(Trial of Humira not required)~~ ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) ~~(Trial of Humira not required).~~ ▪ ~~Adult-Onset~~ Still's Disease with active systemic features of moderate to high disease activity ▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA~~) (Trial of Humira not required).~~ • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: ~~adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER)~~ **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors** **Non-FDA-approved uses are not approved, except as noted above** **Prior authorization does not expire**
• rilonacept (Arcalyst) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of rilonacept (Arcalyst) Manual PA criteria: Arcalyst is approved if all criteria are met: • Patient **is 12 years of age or older with** one of the following diagnoses: ▪ Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) – ~~Patient is 12 years of age of older~~ ▪ Recurrent pericarditis – ~~Patient is 12 years of age of older~~ – Prescription is **written by or in consultation with a cardiologist or rheumatologist** – Patient has a contraindication to colchicine and at least ONE of the following drug classes: aspirin, NSAIDs OR – Patient has tried and failed a treatment course of at least 6 months with colchicine and at least ONE of the following drug classes: aspirin, NSAIDs, corticosteroids • **Patients of all ages with** ▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA) – The patient weighs at least 10 kg (22 pounds) – **Patient has had an inadequate response to anakinra OR** – **Patient has experienced an adverse reaction to anakinra that is not expected to occur with the requested agent OR** – **Patient has a contraindication to anakinra** • ~~The patient is not concurrently receiving a TNF inhibitor (e.g., Humira, Enbrel, Cimzia, and Simponi) due to the increased risk of serious infections.~~ • **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** Non-FDA-approved uses are not approved, including rheumatoid arthritis, neonatal-onset multisystemic inflammatory disease (NOMID), cardiovascular disease other

	than pericarditis (MI, acute coronary syndrome, atherosclerosis, heart failure, and Kawasaki disease), and gout. Prior authorization does not expire.
• sarilumab (Kevzara) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Kevzara Manual PA criteria: Kevzara is approved if all criteria are met: • Kevzara is prescribed by or in consultation with a rheumatologist • Provider acknowledges ~~Humira~~ **Tyenne** is the Department of Defense's preferred ~~targeted biologic agent~~ **IL-1, IL-6, CTLA4-Ig agent.** The patient must have tried Humira AND: ▪ The patient had an inadequate response to ~~Humira~~ **Tyenne** OR ▪ The patient experienced an adverse reaction to ~~Humira~~ **Tyenne** that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to ~~Humira~~ **Tyenne** ▪ **Note that a trial of Tyenne is not required for Polymyalgia Rheumatica** • The patient requires a trial of Humira. ▪ The patient has had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Humira ▪ **Note that a trial of Humira is not required for Polymyalgia Rheumatica** • Patient has a diagnosis of: ▪ Moderately to severely active rheumatoid arthritis OR ~~AND~~ – ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~ ▪ Active polyarticular juvenile idiopathic arthritis (pJIA) and weighs 63 kg or more OR ~~AND~~ – ~~Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)~~ ▪ Polymyalgia Rheumatica (PMR) (Trial of **Tyenne and** Humira is not required) AND – Patient has tried and/or failed ONE systemic corticosteroid; OR – The patient is not a candidate for corticosteroid therapy • ~~Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR~~ • **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** Non-FDA-approved uses are not approved ~~PA for non-PMR indications approved indefinitely.~~ **PA does not expire for indications other than Polymyalgia Rheumatica** **For Polymyalgia Rheumatica, PA expires after 12 months.** Renewal criterial: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if the following criteria are met:

Appendix C—Table of Prior Authorization (PA) Criteria

	The patient has had a positive response to therapy
• satralizumab (Enspryng) **TIBs: IL-1s, IL-6-s, CTLA4-lgs**	**Updates from the May 2025 meeting are in bold and ~~strikethrough~~** Manual PA is required for all new users of Enspryng Manual PA Criteria: Coverage is approved if all criteria are met: • The patient is 18 years of age or older • The drug is prescribed by or in consultation with a neurologist • The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) • **Provider acknowledges the Department of Defense's preferred IL-1, IL-6, CTLA4-lg product is tocilizumab-aazg (Tyenne). Tyenne is available for the treatment of aquaporin-4 (AQP4) seropositive or seronegative NMOSD** • Patient has aquaporin-4 (AQP4) antibody positive NMOSD **documentation must be submitted** • Patient has clinical evidence of at least 2 documented relapses (including first attack) in the last 2 years prior to screening, at least one of which has occurred in the 12 months prior to screening • ~~Patient has laboratory evidence of HBV negative and TB negative~~ • ~~Patient and provider are enrolled in the REMS program~~ • **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, C5 inhibitors, or rituximab** Non-FDA-approved uses are not approved PA does not expire
• tocilizumab-aazg (Tyenne) **TIBs: IL-1s, IL-6-s, CTLA4-lgs**	**Updates from the May 2025 meeting are in bold and strikethrough** **Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira) or tocilizumab (Actemra) at any MHS pharmacy point of service (MTFs, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND** Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne) Manual PA criteria: **if automated criteria are not met** coverage is approved if all criteria are met: • Provider acknowledges the Department of Defense~~ preferred targeted immune biologic is~~ **requires a trial of** Humira. The patient must have tried Humira AND ▪ The patient has had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Humira AND • Patient has moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs~~ OR • Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR • Patient has a diagnosis for which adalimumab is not approved including ▪ Giant cell arteritis **(GCA)** ▪ Systemic sclerosis-associated lung disease **(SSc-ILD)** ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) ▪ **Still's Disease with active systemic features of moderate- to high- disease activity**

	▪ **Polymyalgia Rheumatica (PMR) AND** – **Patient has tried and failed ONE systemic corticosteroid OR** – **Patient is not a candidate for corticosteroid therapy** ▪ **Neuromyelitis Optica Spectrum Disorder (NMOSD), aquaporin-4 (AQP4) seropositive or seronegative** ▪ **Myelin oligodendrocyte glycoprotein antibody associated disease (MOGAD**) ~~▪ If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~ • Patient is not receiving other targeted immunomodulatory biologics with Tyenne Non-FDA approved uses are not approved, **except as noted above** PA does not expire
• tocilizumab (Actemra) **TIBs: IL-1s, IL-6-s, CTLA4-Igs**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new **and current** users of tocilizumab (Actemra) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges the Department of Defense~~'s preferred targeted immune biologic is~~ **requires a trial of** Humira. The patient must have tried Humira AND ▪ The patient has had an inadequate response to Humira OR ▪ The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Humira AND • Provider acknowledges the Department of Defense's preferred ~~tocilizumab~~ **IL-1, IL-6, CTLA4-Ig product** is Tyenne. The patient must have tried Tyenne AND ▪ The patient has had an inadequate response to Tyenne OR ▪ The patient experienced an adverse reaction to Tyenne that is not expected to occur with the requested agent OR ▪ The patient has a contraindication to Tyenne AND • Patient has tried Humira **and has a diagnosis of** ▪ Moderate to severely active RA ~~then has patient has inadequate response to at least 1 or more DMARDs for example: methotrexate, aminosalicylates [for example, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [for example, azathioprine)~~ ▪ Active polyarticular Juvenile Idiopathic Arthritis (pJIA) • Patient has not tried Humira and has a diagnosis for which adalimumab is not approved: ~~AND is greater than 18 years of age:~~ ▪ Giant cell arteritis ▪ Systemic sclerosis-associated lung disease ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) ~~▪ If "other" diagnosis, please provide appropriate literature-based support documentation for the indication and utilization~~ • Patient is not receiving other targeted immunomodulatory biologics with ~~tocilizumab~~ the requested agent, included but not limited to the following; **TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors, rituximab** Non-FDA approved uses are not approved~~, **except as noted above**~~ PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• abemaciclib (Verzenio) **Breast Cancer Agents: CDK Inhibitors**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Verzenio. Manual PA Criteria: Verzenio is approved if all of the following criteria are met: • Drug is prescribed by or in consultation with an oncologist • ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~ • ~~For Verzenio only, the patient has hormone receptor HR(+)/HER2(-), node(+) early~~ breast cancer ~~at high risk of recurrence as determined by an FDA approved test.~~ • The patient has advanced or metastatic ~~hormone receptor~~ (HR(+))/HER2(-) breast cancer • ~~If the patient is female, the patient meets one of the following criteria:~~ ▪ ~~Verzenio will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~ ▪ ~~Verzenio will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR~~ ▪ ~~Verzenio will be used as monotherapy following metastatic progression on chemotherapy~~ • ~~If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~ • ~~Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~ • ~~Provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity~~ • ~~Female patients of childbearing age are not pregnant confirmed by ( ) HCG~~ • ~~Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~ • ~~Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~ • ~~Male patients have been informed of the risk of infertility~~ • The diagnosis is notlisted above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____.~~ **To facilitate approval please list the diagnosis, guidelines version and page number ._____** Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire
• palbociclib (Ibrance) **Breast Cancer Agents: CDK Inhibitors**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Ibrance Manual PA Criteria: Ibrance is approved if all of the following criteria are met: • Drug is prescribed by or in consultation with an oncologist • ~~The patient is not currently taking another cyclin-dependent kinase inhibitor~~ • The patient has ~~advanced or metastatic hormone receptor (~~HR(+)~~)~~/HER2(-) breast cancer • ~~If the patient is female, the patient meets one of the following criteria:~~ ▪ ~~Ibrance will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~ ▪ ~~Ibrance will be as first-line or later-line endocrine therapy in combination with fulvestrant~~

	~~• If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~ ~~• Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~ ~~• For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism~~ ~~• Female patients of childbearing age are not pregnant confirmed by (-) HCG~~ ~~• Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~ ~~• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~ ~~• Male patients have been informed of the risk of infertility~~ • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____.~~ **To facilitate approval please list the diagnosis, guidelines version and page number.** _____ Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire
• ribociclib (Kisqali) • ~~ribociclib co-packaged with letrozole (Kisqali Femara Co-Pack~~) **Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Kisqali~~, and Kisqali Femara Co-Pack.~~ Manual PA Criteria: Kisqali ~~or Kisqali Femara Co-Pack~~ is approved if all of the following criteria are met: • Drug is prescribed by or in consultation with an oncologist ~~• The patient is not currently taking another cyclin-dependent kinase inhibitor~~ • The patient has ~~advanced or metastatic hormone receptor (~~HR(+)~~)~~/HER2(-) breast cancer ~~• If the patient is female, the patient meets one of the following criteria:~~ ~~• Kisqali, or Kisqali Femara Co-Pack will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR~~ ~~• Kisqali or Kisqali Femara Co-Pack will be as first line or later line endocrine therapy in combination with fulvestrant; OR~~ ~~• If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.~~ ~~• Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease~~ ~~• For Kisqali and Kisqali Femara Co-Pack only: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity~~ ~~• Female patients of childbearing age are not pregnant confirmed by (-) HCG~~ ~~• Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment~~ ~~• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only~~ ~~• Male patients have been informed of the risk of infertility~~ ~~• For Kisqali Femara Co-Pack only, female patients have been informed of the risk of infertility from letrozole~~

Appendix C—Table of Prior Authorization (PA) Criteria

	• The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, the provider must list the diagnosis:_____.~~ **To facilitate approval please list the diagnosis, guidelines version and page number ._____** Non-FDA approved uses are not approved, except as noted above Prior authorization does not expire
Newly Approved Drug PAs	
• benzgalantamine (Zunveyl) **Alzheimer's Agents**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of Zunveyl Manual PA criteria**:** Coverage is approved if all criteria are met • **Provider acknowledges that Zunveyl will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the P&T Committee meeting minutes by the Director, DHA** • The patient is 18 years of age or older • The medication is being prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine • The patient is being treated for mild or moderate dementia of the Alzheimer's type • Provider must document why the patient cannot use galantamine immediate release and galantamine extended release and donepezil products. (blank write-in) ▪ Acceptable responses include the patient has had an adverse reaction to galantamine immediate release and galantamine extended-release products that are not likely to occur with benzgalantamine (Zunveyl) or ▪ The patient has had an inadequate response, experienced an adverse effect, or has a contraindication to donepezil Non-FDA approved uses are not approved ~~**PA expires in 120 days, when the complete exclusion status is implemented**~~ **PA does not expire until after implementation of Complete Exclusion status**
• concizumab-mtci (Alhemo) **Antihemophilic Factors: Non-Factor Agents**	Manual PA criteria apply to all new users of Alhemo Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 12 years of age or older • Prescribed by or in consultation with a hematologist • Patient has hemophilia A with factor VIII inhibitors or hemophilia B with factor IX inhibitors • Patient is not concurrently receiving factor VIII or factor IX therapy unless for the treatment of breakthrough bleeding Non-FDA approved uses are not approved PA does not expire
• diazoxide choline (Vykat XR) **Metabolic Agents Miscellaneous**	Manual PA criteria apply to all new users of diazoxide choline (Vykat XR) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 4 years of age or older • Prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome • Patient has a diagnosis of Prader-Willi Syndrome confirmed by genetic testing

	• Patient is being treated for hyperphagia • Patient weighs between 20 kg and 135 kg Non-FDA approved uses are not approved Initial PA expires in 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved annually for continuation of therapy if all the criteria are met: • The patient's hyperphagia has improved and stabilized to warrant continued therapy • Medication continues to be prescribed by a physician who specializes in the treatment of Prader-Willi Syndrome
• hydrochlorothiazide 10 mg/mL oral suspension (Inzirqo) **Diuretic Agents**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of hydrochlorothiazide suspension (Inzirqo) **who are over 12 years of age** **PA does not apply to patients 12 years of age and younger (age edit)** Manual PA criteria: Coverage is approved if all criteria are met • Patient has hypertension or edema from congestive heart failure, hepatic cirrhosis, or renal disease • Provider must write in why the patient requires Inzirqo and cannot take a loop diuretic AND a thiazide diuretic in a tablet formulation ▪ Acceptable responses: patient cannot swallow tablets due to some documented medical condition – dysphagia, etc., and not due to convenience Non-FDA-approved uses are not approved PA does not expire
• hydroxyurea 100 mg/mL oral solution (Xromi) **Oncological Agents**	Manual PA criteria apply to all new users of hydroxyurea oral solution (Xromi) who are 18 years of age and older PA does not apply to patients younger than 18 years of age (age edit) Manual PA criteria: Coverage is approved if all criteria are met: • Patient has sickle cell anemia with recurrent moderate to severe painful crises • Patient is not using Xromi for malignancy, including chronic myelocytic leukemia or other cancers • The provider must explain why the patient cannot use the preferred products generic hydroxyurea or Siklos dispersed in water ▪ Acceptable responses include the patient has swallowing difficulties, not just for convenience AND patient has sickle cell disease Non-FDA approved uses are not approved PA expires after 12 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient continues to have swallowing difficulties that preclude the use of hydroxyurea capsules AND Siklos tablets dispersed in water

Appendix C—Table of Prior Authorization (PA) Criteria

• mirdametinib (Gomekli) **Oncologic Agents**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of mirdametinib Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 2 years of age or older • Prescribed by or in consultation with a hematologist or oncologist • Patient has a diagnosis of neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas • **Patient has tried and had an inadequate response, adverse effect, or has a contraindication to selumetinib (Koselugo)** • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire
• trazodone 10 mg/mL oral solution (Raldesy) **Antidepressants and Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor**	Manual PA criteria apply to all new users of trazodone oral solution (Raldesy) Manual PA criteria: Coverage is approved if all criteria are met: • Patient has major depressive disorder (MDD) • Provider must explain why the patient requires Raldesy and cannot take trazadone tablets ▪ Acceptable responses include the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia) and not due to convenience Non-FDA approved uses are not approved PA does not expire
• ustekinumab-stab (Steqeyma) • ustekinumab-aauz (Otulfi) • ustekinumab-auub (Wezlana) • ustekinumab (Stelara) **TIBs: IL-23**	**Recommendations below are superseded by the recommendations from the February 2026 P&T Committee meeting** **Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of ustekinumab-stab (Steqeyma), ustekinumab-aauz (Otulfi), ustekinumab-auub (Wezlana), ustekinumab (Stelara) Manual PA Criteria: Coverage is approved if all criteria are met: • **Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira** • The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira • Patients may have used infliximab in lieu of Humira for UC and CD • Coverage is approved for patients 18 years of age or older with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy ▪ Moderately to severely active Crohn's Disease (CD) ▪ Moderately to severely active ulcerative colitis (UC) • Coverage is approved for patients ages 6 to 17 years of age with: ▪ Active psoriatic arthritis ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy

	• The criteria below apply to all patients unless noted:
	  ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
	  ▪ 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, S1p, JAK inhibitors
	Non-FDA approved uses are not approved
	PA does not expire

• ustekinumab-ttwe (Pyzchiva)
• ustekinumab-kfce (Yesintek)
• ustekinumab-aekn (Selarsdi)
 	
TIBs: IL-23
	Recommendations below are superseded by the recommendations from the February 2026 P&T Committee meeting
	Updates from the current PA criteria are in bold
	Manual PA criteria apply to all new users of ustekinumab-ttwe (Pyzchiva), ustekinumab-kfce (Yesintek), ustekinumab-aekn (Selarsdi)
	<u>Manual PA Criteria:</u> Coverage is approved if all criteria are met:
	• **Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira**
	• The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira
	• **The patient had an inadequate response to Steqeyma, Otulfi, Wezlana, and Stelara OR the patient experienced an adverse reaction to Steqeyma, Otulfi, Wezlana, and Stelara that is not expected to occur with the requested ustekinumab OR the patient has a contraindication to Steqeyma, Otulfi, Wezlana, and Stelara**
	• Patients may have used infliximab in lieu of Humira for UC and CD
	• Coverage is approved for patients 18 years of age or older with:
	  ▪ Active psoriatic arthritis
	  ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
	  ▪ Moderately to severely active Crohn's Disease (CD)
	  ▪ Moderately to severely active ulcerative colitis (UC)
	• Coverage is approved for patients ages 6 to 17 years of age with:
	  ▪ Active psoriatic arthritis
	  ▪ Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
	• The criteria below apply to all patients unless noted:
	  ▪ Patient has had an inadequate response, intolerance, or contraindication to nonbiologic systemic therapy (for example – methotrexate, aminosalicylates (e.g. sulfasalazine, mesalamine) corticosteroids, or immunosuppressants (e.g. azathioprine). (Note: Does not apply to CD, UC)
	  ▪ 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, S1p, JAK inhibitors
	Non-FDA approved uses are not approved
	PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• ustekinumab-ttwe (unbranded) **TIBs: IL-23**	**Recommendations below are superseded by the recommendations from the February 2026 P&T Committee meeting** Manual PA criteria apply to all new users of ustekinumab-ttwe (unbranded) Manual PA Criteria: Coverage is approved if all criteria are met: • Provider acknowledges that this unbranded ustekinumab ttwe will be completely excluded from the TRICARE Pharmacy benefit 120 days after signing of the P&T Committee meeting minutes by the Director, DHA. • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira • The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with ustekinumab OR the patient has a contraindication to Humira • The provider must write-in trial dates for Humira and the formulary ustekinumab products ▪ Humira Date_____ Duration of therapy _____ ▪ Otulfi Date_____ Duration of therapy _____ ▪ Steqeyma Date_____ Duration of therapy _____ ▪ Wezlana Date_____ Duration of therapy _____ ▪ Stelara Date_____ Duration of therapy _____ • The provider must explain why the patient requires unbranded ustekinumab-ttwe (unbranded) and cannot use on of the other ustekinumab biosimilar products. ▪ Acceptable response: Patient has an allergy to one or more inactive ingredients found in formulary ustekinumab products that is not found in unbranded ustekinumab-ttwe **Non-FDA approved uses are not approved** ~~**PA expires in 120 days, when the complete exclusion status is implemented**~~ **PA does not expire until after implementation of complete exclusion status**
• vimseltinib (Romvimza) **Oncological Agents**	**Updates from the current PA criteria are in bold and strikethrough** Manual PA criteria apply to all new users of vimseltinib (Romvimza) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist, or oncologist ~~**or orthopedic surgeon**~~ • Patient has symptomatic tenosynovial giant cell tumor • Tumor is not amenable to treatment with surgery • Patient has tried and had an inadequate response to pexidartinib (Turalio) OR • Patient has tried and had an adverse effect to pexidartinib (Turalio) OR • Patient has a contraindication to use of pexidartinib (Turalio) • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management PAs	
• mebendazole (Emverm) **Anti-infectives: Antihelmintics ~~Anthelmintics~~**	Manual PA criteria apply to all new users of Emverm Manual PA criteria: Emverm is approved if all criteria are met: • Patient has a diagnosis of pinworm (*Enterobius vermicularis)*, hookworm (*Ancylostoma duodenale* or *Necator americanus*), roundworm (*Ascaris lumbricoides*), or whipworm (Trichuris trichiura) OR • Medication is prescribed by an infectious disease specialist for another parasitic infection AND • For all indications, patient has a failure, contraindication, or intolerance to at least one of the following: OTC pyrantel pamoate, ivermectin, or albendazole Other non-FDA approved uses are not approved except as noted above including prostate cancer PA expires in one month. A new PA is required for each course of therapy
• mifepristone (Korlym) **Endocrine Agents Miscellaneous: Antihyperglycemic-Glucocorticoid Receptor Blocker**	The following manual PA criteria apply to all **new** users of Korlym Manual PA criteria: Korlym is approved if all criteria are met: • Patient is 18 years of age or older • Prescription is written by an endocrinologist • Patient has a diagnosis of endogenous Cushing's syndrome AND • Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND • Patient has failed surgery or is not a candidate for surgery • Patient has tried and failed one of the following for the treatment of endogenous Cushing's syndrome: ketoconazole tablets, mitotane (Lysodren), pasireotide (Signifor), osilodrostat (Isturisa) or cabergoline Non-FDA-approved uses are not approved including type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome PA expires in 1 year Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met: • Patient has had a positive clinical response while on Korlym The following manual PA criteria apply to all **current users** of Korlym Manual PA criteria: Korlym is approved if all criteria are met: • Patient has a diagnosis of endogenous Cushing's syndrome AND • Patient has a diagnosis of type 2 diabetes mellitus or glucose intolerance AND • Patient has failed surgery or is not a candidate for surgery Non-FDA-approved uses are not approved including type 2 diabetes mellitus to endogenous Cushing's syndrome. PA expires in 1 year Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met: • Patient has had a positive clinical response while on Korlym

Appendix C—Table of Prior Authorization (PA) Criteria

• zileuton (Zyflo), zileuton ER generic **Leukotriene Modifying Agents**	Manual PA criteria apply to all **new and current** users Manual PA criteria: zileuton is approved if all criteria are met: • Patient is being treated for asthma • Patient is 12 years of age or older • Patient has a contraindication to, intolerability to, or has failed treatment with both of the following: ▪ montelukast AND ▪ zafirlukast Non-FDA-approved uses are not approved PA expires in 1 year Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if the following apply: • The patient has had a positive response to therapy, as defined by one of the following: ▪ a decrease in asthma exacerbations ▪ improvements in forced expiratory volume in one second (FEV1) ▪ decrease in oral corticosteroid use
• metformin 750 mg IR tablet **Diabetes Non-Insulin: Biguanides**	Manual PA criteria apply to all new and current users of metformin 750 mg IR tablet. Manual PA criteria: metformin 750 mg IR Tablet is approved if all criteria are met: • Provider acknowledges other formulations of metformin are available without prior authorization. • Provider must explain why the patient requires metformin 750 mg IR Tablet and cannot take the cost-effective generic metformin formulations ▪ 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 formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• tramadol 100 mg tablet **Narcotic Analgesics and Combinations**	**Updates from the May 2025 meeting are in bold** Manual PA criteria apply to all new and current users of tramadol 25 mg, 75 mg an**d 100 mg** tablet Manual PA criteria: tramadol 25, 75 mg and **100 mg** tablet is approved if ALL criteria are met: • Provider is aware and acknowledges that tramadol 50 mg is available to TRICARE beneficiaries without the need of prior authorization and providers are encouraged to change the prescription to the preferred tramadol 50 mg product • This agent has been identified as having cost-effective alternatives. Please describe why this agent is required as opposed to available alternatives. (blank write in) ▪ Acceptable responses are that the patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to one or more inactive ingredients in currently available tramadol 50 mg IR tablets Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• setmelanotide (Imcivree) **Miscellaneous Metabolic Agents**	**Updates from May 2025 are in bold and strikethrough** Manual PA criteria apply to all new users of Imcivree. Manual PA criteria: Imcivree is approved if all criteria are met: • Patient is **two ~~six~~** years of age or older • Patient has a confirmed diagnosis (via genetic testing) of POMC-, PCSK1-, or LEPR-deficiency that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) OR • The patient has monogenic or syndromic obesity due to Bardet-Beidl syndrome (BBS) • Patient and provider agree to evaluate weight loss after 12-16 weeks of treatment. Imcivree should be discontinued if a patient has not lost at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential Non-FDA approved uses are NOT approved including Alström Syndrome, POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign, other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity Initial prior authorization expires in 4 months. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Imcivree is approved for 1 year for continuation of therapy for POMC-, PCSK1-, or LEPR deficiency or BBS if all criteria are met: • The patient has a documented improvement (a decrease from baseline) in at least 5% of baseline body weight, or 5% of baseline BMI for patients with continued growth potential.
• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	**Updates from May 2025 are in bold and strikethrough** Manual PA criteria apply to all new users of Odactra Manual PA criteria: Coverage will be approved if all criteria are met: • Odactra is prescribed by an allergist/immunologist • The patient is between the ages of **five ~~12~~** and 65 years • The patient has a diagnosis of house dust mite (HDM) allergic rhinitis confirmed with either a positive skin test or an in vitro test for pollen-specific for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites • The patient's symptoms of allergic rhinitis have not been controlled with a nasal corticosteroid (e.g., fluticasone) AND at least one of the following: oral antihistamine, nasal antihistamines, or a leukotriene receptor antagonist (montelukast) OR • The patient has a diagnosis of house dust mite-related allergic rhinitis and allergic asthma that has not responded to an adequate trial of inhaled steroids, and the patient's • Forced Expiratory Volume in 1 second (FEV1) is greater than 70% • The patient has received the first dose in the office setting and was observed for 30 minutes with no allergic reactions noted • The patient has a prescription for self-administered SC epinephrine • The patient does not have a history of severe local allergic reaction to sublingual immunotherapy • Patient is not receiving co-administered SC immunotherapy • Patient does not have severe, uncontrolled, unstable asthma Other off-label uses other than allergic asthma are not approved PA expires in 6 months

Appendix C—Table of Prior Authorization (PA) Criteria

	Renewal Criteria: **Note that initial TRICARE PA approval is required for renewal**. Coverage will be continued indefinitely if all the following apply: • The patient has responded positively to treatment • The patient is not receiving co-administered SC immunotherapy • The patient does not have severe, uncontrolled unstable asthma.
• guselkumab (Tremfya) **TIBs: IL-23s**	**Updates from the May 2025 meeting are in bold.** Step therapy and Manual PA Criteria apply to all new users of guselkumab (Tremfya). Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Taltz is available for treatment of plaque psoriasis without the requirement to try Humira • Patient had an inadequate response to Humira OR had adverse reaction to Humira that is not expected to occur with the requested agent OR has a contraindication to Humira • A trial of IV infliximab may be used in lieu of Humira for Ulcerative colitis **or Crohn's disease** AND • Patient is 18 years of age of older with the following indication/diagnosis: ▪ Active psoriatic arthritis (PsA) ▪ Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy ▪ Moderate to severely active ulcerative colitis (UC) ▪ **Moderately to severely active Crohn's Disease (CD)** • Patient had inadequate response, intolerance, or contraindication to non-biologic systemic therapy (For example: methotrexate, aminosalicylates, corticosteroids, immunosuppressants etc.) **(Note does not apply to UC or Crohn's disease)** • Patient will not be receiving any other targeted immunomodulatory biologics concurrently, including but not limited to the following: TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, S1p, JAK inhibitors Non-FDA approved uses are not approved PA does not expire
• acalabrutinib (Calquence) **Leukemia and Lymphoma Agents: BTK Inhibitors**	**Updates from the May 2025 meeting are in bold.** Automated PA Criteria: When prescribed by a hematologist or oncologist, prior authorization is not required. Once therapy is initiated by a hematologist or oncologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days. Manual PA apply to all new users of Calquence Manual PA Criteria: If automated criteria are not met for hematologist or oncologist specialist prescribing, coverage is approved if all criteria are met: • If the physician is a hematologist or oncologist, PA is approved OR • If the prescriber is not a hematologist or oncologist and the drug is prescribed in consultation with a hematologist/oncologist, then continue with the questions below: • Patient is 18 years of age or older • Patient has a diagnosis of either chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) or Mantle Cell Lymphoma (MCL) and received at least one prior therapy OR • **Patient has previously untreated Mantel Cell Lymphoma (MCL) and is ineligible for autologous hematopoietic stem cell transplantation (HSCT)**

	and acalabrutinib will be used in combination with bendamustine and rituximab (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 _____. Other non-FDA-approved uses are not approved, except as noted above PA does not expire
• sotorasib (Lumakras) **Oncological Agents: Lung Cancer**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Lumakras. Manual PA criteria: Lumakras is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)~~, as determined by an FDA approved test~~ **and has received at least one prior systemic therapy OR** • **Patient has laboratory evidence of KRAS G12C-mutated metastatic colorectal cancer (mCRC) AND will be used in combination with panitumumab in patients who have received prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy** • ~~**The patient will be monitored for interstitial lung disease and hepatotoxicity**~~ • ~~**Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment**~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis**~~: **To facilitate approval, please list the diagnosis, guideline version, and page number:** _____. Other non-FDA-approved uses are not approved Prior authorization does not expire

• semaglutide (Ozempic)
 	
Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)
	Updates from the May 2025 meeting are in bold
	Manual PA criteria—Coverage is approved if all criteria are met
	For Type 2 diabetes mellitus
	• The provider acknowledges that Trulicity is available to TRICARE beneficiaries at a lower copay than Ozempic. Trulicity also has an indication to reduce the risk of adverse cardiovascular events in adults with Type 2 diabetes mellitus (T2DM) who have established cardiovascular disease or multiple cardiovascular risk factors.
	• The patient has a confirmed diagnosis of Type 2 diabetes mellitus
	• The patient has tried metformin (alone or in combination) and failed to achieve blood glucose control OR
	• The patient has experienced any of the following issues on metformin:
	  • impaired renal function precluding treatment with metformin
	  • history of lactic acidosis OR
	• The patient has a contraindication to metformin
	For Type 2 diabetes mellitus with chronic kidney disease
	• **The patient has a diagnosis of type 2 diabetes and chronic kidney disease**
	• **The patient's estimated glomerular filtration rate (eGFR) is between 50 – 70 mL/min/m^2)**

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	• **The patient is currently receiving a renin angiotensin inhibitor (ACE inhibitor or ARB blocker) or has a contraindication, has had an adverse effect, or has failed therapy** • **The patient is currently receiving an SGLT-2 inhibitor or has a contraindication, has had an adverse effect or has failed therapy** Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• crisaborole (Eucrisa) **Corticosteroids-Immune Modulators: Atopic Dermatitis**	**Updates from the May 2025 meeting are in bold** **Age Edit: PA does not apply to children 2 years of age and younger** Manual PA Criteria: Coverage approved if all criteria are met: • Prescribed by a dermatologist, allergist, immunologist • Patient has mild to moderate atopic dermatitis • Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of at least one medium- to high-potency topical corticosteroid • Patient has a contraindication to, intolerability to, or failed treatment with a two-week trial of a second agent including ▪ An additional medium- to high-potency topical corticosteroid OR ▪ Topical calcineurin inhibitor (i.e., tacrolimus, Elidel) Off-label uses are not approved Prior Authorization does not expire
• febuxostat (Uloric) **Miscellaneous Antigout Agents: Chronic**	**Updates from the May 2025 meeting are in bold and strikethrough.** **Automated PA Criteria: The patient has received a prescription for at least 300 mg per day of allopurinol at any Military Health System pharmacy point of service (Military Treatment Facilities, retail pharmacies, or TRICARE mail order pharmacy) during the previous 180 days**. AND Manual PA Criteria: If automated criteria are not met, manual PA criteria apply to all new users of **febuxostat (Uloric)** is approved (e.g., a trial of allopurinol is not required) if: • The patient has experienced any of the following issues with at least one of the following with allopurinol, which is not expected to occur with febuxostat (Uloric): ▪ The patient has had an inadequate response to allopurinol (failure to achieve serum uric acid levels less than 6 mg/day) after an adequate trial (at least 300 mg per day of allopurinol) ▪ The patient has had intolerable adverse effects (e.g., hypersensitivity) to allopurinol ▪ The patient has a contraindication to allopurinol (e.g., renal impairment) ~~• **Patients with major cardiovascular (CV) disease should be informed of the potential CV risks when using this drug**~~ ~~• **The Healthcare provider should consider CV safety information from the CARES trial and the label when prescribing febuxostat**~~ Non-FDA-approved uses are NOT approved Prior authorization does not expire

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• fedratinib (Inrebic) **Oncological Agents: Myelofibrosis**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of **fedratinib (Inrebic)** Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is age 18 years of age or older • Fedratinib will be used for intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis • ~~**Provider acknowledges that serious and fatal encephalopathy including Wernicke's encephalopathy has occurred in patients treated with fedratinib. If thiamine deficiency is expected or confirmed, fedratinib should be discontinued immediately and the patient should receive emergent parenteral thiamine.**~~ • ~~**Patient does not have vitamin B1 deficiency.**~~ • ~~**Thiamine (Vitamin B1), CBC with platelets, Serum creatinine and BUN, hepatic panel and amylase and lipase will be assessed prior to starting fedratinib and periodically while patient is taking fedratinib**~~ • ~~**Nutritional status will be assessed prior to starting fedratinib and periodically while patient is taking edratinib**~~ • ~~**If the patient is female, she is not pregnant or planning to become pregnant.**~~ • ~~**Female patients will not breastfeed during treatment and for at least 1 month after discontinuation.**~~ • ~~**Females of reproductive potential will use effective contraception during treatment and for at least 1 month after discontinuation.**~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved, **except as noted above** PA does not expire
• selumetinib (Koselugo) **Oncological Agents**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of **selumetinib (Koselugo)** <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient diagnosed with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas. • ~~**Patient will be monitored for cardiomyopathy including a left ventricular functional assessment prior to initiation and at regular intervals during treatment**~~ • ~~**Monitor for ocular toxicity including retinal vein occlusion and retinal detachment via ophthalmic exams prior to initiation and at regular intervals during treatment.**~~ • ~~**Monitor for gastrointestinal toxicity and co-administer an anti-diarrheal if patient develops loose stools.**~~ • ~~**Monitor for severe skin rashes.**~~ • ~~**Monitor for rhabdomyolysis.**~~ • ~~**Provider is aware that Koselugo contains Vitamin E which can increase bleeding risk if co-administered with a Vitamin K antagonist.**~~ • ~~**Female patients of childbearing age are not pregnant confirmed by (-) HCG.**~~

	• ~~**Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment.**~~ • ~~**Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.**~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved**, except as noted above** PA does not expire
• pomalidomide (Pomalyst) **Oncological Agents: Multiple Myeloma**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of pomalidomide (Pomalyst) Manual PA Criteria: Coverage is approved if all criteria are met: ▪ The drug is prescribed by or in consultation with a hematologist/oncologist ▪ Patient is 18 years of age or older ▪ Patient is diagnosed with: ▪ Relapsed/refractory multiple myeloma that is refractory to lenalidomide AND all of the following: ▪ Patient has previously trialed bortezomib, carfilzomib, OR ixazomib ▪ Patient will be starting pomalidomide as third (or higher) line of therapy ▪ Must be used in combination with dexamethasone ▪ **AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy or in patients with Kaposi sarcoma who are HIV-negative** ▪ Myelofibrosis refractory to or with contraindications to alternative therapies (including lenalidomide) and erythropoietin levels ≥ 500 mU/ml ▪ Systemic light chain amyloidosis *with organ involvement* refractory to or with contraindications to alternative therapies including lenalidomide ▪ Patient is not using concurrent lenalidomide NOR thalidomide ▪ 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. i~~**f so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number:** _____. Non-FDA-approved uses are not approved, **except as noted above** PA does not expire

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• ripretinib (Qinlock) **Oncological Agents**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of ripretinib (Qinlock) Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is age 18 years of age or older • Patient has a pathologically confirmed advanced gastrointestinal stromal tumor (GIST) AND ▪ Patient has experienced disease progression on imatinib (Gleevec), sunitinib (Sutent) AND regorafenib (Stivarga) OR ▪ Patient has documented intolerance to any of these treatments ~~• **If the patient is female, she is not pregnant or planning to become pregnant.**~~ ~~• **Female patients have lack of pregnancy confirmed by (-) HCG testing**~~ ~~• **Both male and females of reproductive potential will use effective contraception during treatment and for at least 6 weeks after discontinuation.**~~ ~~• **Female patients will not breastfeed during treatment and for at least 2 weeks after discontinuation.**~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved, except as noted above PA does not expire
• midostaruin (Rydapt) **Oncological Agents**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Rydapt Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient uses Rydapt in combination with standard chemotherapy protocols AND • Patient has a diagnosis of acute myeloid leukemia (AML) AND tyrosine kinase 3 (FLT3)-positive ~~as detected by an FDA-approved test~~ • Patient has a diagnosis of advanced systemic mastocytosis (aggressive systemic agents mastocytosis; systemic mastocytosis associated with hematologic neoplasm) or mast cell leukemia • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved **PA does not expire** ~~PA expires in one year~~

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	~~Renewal criteria: Rydapt is approved indefinitely for continuation of therapy if patient documents clinical and/or symptom improvement.~~
• capmatinib (Tabrecta) **Oncological Agents: Lung Cancer**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of capmatinib (Tabrecta). Manual PA criteria: Coverage is approved if all criteria are met: • Must be prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years or older • Patient has metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping ~~**as detected by an FDA-approved test**~~ • ~~**Monitor for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity**~~ • ~~**Provider is aware and has counseled patient that capmatinib can cause photosensitivity and has counseled patients to avoid direct UV exposure**~~ • ~~**Female patients of childbearing age are not pregnant confirmed by (-) HCG.**~~ • ~~**Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment.**~~ • ~~**Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy.**~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA approved uses are not approved except as noted above PA does not expire
• tepotinib (Tepmetko) **Oncological Agents: Lung Cancer**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA applies to all new users of tepotinib (Tepmetko). Manual PA Criteria: Coverage is approved if all criteria are met: • Must be prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years or older • Patient has metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to laboratory-confirmed mesenchymal-epithelial transition (MET) exon 14 skipping. • ~~**Provider will monitor for Interstitial Lung Disease (ILD)/Pneumonitis and hepatotoxicity**~~ • ~~**Female patients of childbearing age are not pregnant confirmed by (-) HCG.**~~ • ~~**Female patients will not breastfeed during treatment**~~ • ~~**Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy**~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval,**

Appendix C—Table of Prior Authorization (PA) Criteria

	please list the diagnosis, guideline version, and page number: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• pexidartinib (Turalio) **Oncological Agents: Chronic Myelogenous Leukemia**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of pexidartinib (Turalio) Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and is not amenable to improvement with surgery and has not progressed on Turalio ~~• Patient will be monitored for hepatotoxicity~~ ~~• Prescriber is certified with REMS program~~ ~~• Patient is enrolled in REMS program~~ ~~• If the patient is female, she is not pregnant or planning to become pregnant.~~ ~~• Female patients will not breastfeed.~~ ~~• All patients (females AND males) of reproductive potential will use effective contraception during treatment and for 1 month after discontinuation in females and 1 week after discontinuation in males with female partners.~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **~~If so, please list the diagnosis:~~ To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved, **except as noted above** PA does not expire
• quizartinib (Vanflyta) **Oncological Agents: Acute Myelogenous Leukemia**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all **new** users of **Vanflyta** Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has newly diagnosed acute myeloid leukemia (AML) that is tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive **~~as detected by an FDA-approved test~~** **~~• The provider is aware of all warnings, monitoring and screening precautions for Vanflyta~~** **~~• Provider is certified to prescribe Vanflyta per REMS requirements~~** • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **~~If so, please list the diagnosis:~~ To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved PA does not expire

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• larotrectinib (Vitrakvi) **Oncological Agents**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all **new** users of **Larotrectinib (Vitrakvi) capsules or oral solution** Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is diagnosed with either: ▪ Advanced or metastatic NSCLC with NTRK gene fusion without a known acquired resistance mutation OR ▪ a solid tumor that meets all three of the following criteria: – has a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion without a known acquired resistance mutation – is metastatic **OR** where surgical resection is likely to result in severe morbidity – has no satisfactory alternative treatments OR that has progressed following such treatment(s) • ~~**Female patients will not breastfeed during treatment and for 1 week after cessation of treatment**~~ • ~~**All patients (females AND males) of reproductive potential will use highly effective contraception during treatment and for at least 1 week after cessation of treatment**~~ • For use of the oral solution, patient must have difficulty swallowing capsules • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved, **except as noted above** PA does not expire
• dacomitinib (Vizimpro) **Oncological Agents: EGFR+ Non-Small Cell Lung Cancer**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of dacomitinib (Vizimpro) Manual PA Criteria: Coverage is approved if all criteria are met: • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • Patient has histologically or cytopathologically confirmed stage IIIB/IV or recurrent non-small cell lung cancer with the presence of at least one documented epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutation ~~**as detected by an FDA-approved test**~~ • ~~**No evidence of: active infection, non-infectious pneumonitis, nor interstitial lung disease**~~ • Patient has no previous epidermal growth factor kinase inhibitor use (for example Tarceva, Iressa, Gilotrif, or Tagrisso) • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, please list the diagnosis:**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved, **except as noted above** PA does not expire

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• gilteritinib (Xospata) **Oncological Agents: Acute Myelogenous Leukemia**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of gilteritinib (Xospata). Manual PA criteria: Coverage is approved if all criteria are met: • Must be prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years or older • Patient has a diagnosis relapsed or refractory acute myeloid leukemia • Patient has laboratory confirmed evidence of Ferline McDonough Sarcoma (FMS)-like tyrosine kinase 3 (FLT3) mutation~~, as detected by an FDA-approved test~~ ~~• The patient will be monitored for posterior reversible encephalopathy syndrome (PRES), prolonged QTc, and pancreatitis~~ ~~• Patient is not pregnant or actively trying to become pregnant~~ • The diagnosis is not listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~If so, please list the diagnosis:~~ **To facilitate approval, please list the diagnosis, guideline version, and page number: _____.** Non-FDA-approved uses are not approved, **except as noted above** PA does not expire
• odevixibat (Bylvay) **Metabolic Agents Miscellaneous**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of odevixibat (Bylvay) Manual PA criteria: Coverage is approved if all criteria are met: • The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist • Patient is 3 months of age and older and weighs at least 5 kg and has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus OR • Patient is 12 months of age and older and has diagnosed Alagille Syndrome with severe refractory pruritus (ALGS) AND • Has been evaluated for possible orthotopic liver transplant (OLT) • Has previously tried and failed **three** ~~**all**~~ of the following: ▪ ursodiol ▪ cholestyramine ▪ rifampin ▪ naltrexone ▪ **sertraline** ▪ ~~**At least one**~~ **One** antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as ~~**non-alcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD),**~~ **metabolic dysfunction-associated steatohepatitis (MASH), metabolic dysfunction-associated liver disease (MASLD),** biliary atresia, and other cholestatic diseases are not approved PA expires every 6 months Renewal criteria: Initial TRICARE PA approval required. PA will be approved for an additional 6 months if: ▪ Patient must demonstrate significant improvement in pruritus symptoms

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• maralixibat (Livmarli) **Metabolic Agents Miscellaneous**	**Updates from the May 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of maralixibat (Livmarli) Manual PA criteria: Coverage is approved if all criteria are met: • The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist • Patient is 3 months of age or older and has diagnosed Alagille Syndrome with severe refractory pruritus OR • Patient is 12 months of age and older and has diagnosed progressive familial intrahepatic cholestasis (PFIC) with severe refractory pruritus AND • Has been evaluated for possible orthotopic liver transplant (OLT) • Has previously tried and failed **three ~~all~~** of the following: ▪ ursodiol ▪ cholestyramine ▪ rifampin ▪ naltrexone ▪ **sertraline** ▪ **~~At least one~~ One** antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as **~~non-alcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD),~~ metabolic dysfunction-associated steatohepatitis (MASH), metabolic dysfunction-associated liver disease (MASLD),** biliary atresia, and other cholestatic diseases are not approved PA expires every 6 months Renewal criteria: Initial TRICARE PA approval required. PA will be approved for an additional 6 months if: ▪ Patient must demonstrate significant improvement in pruritus symptoms
• pimavanserin (Nuplazid) **Antipsychotic Agents: Parkinson's Psychosis**	**Updates from the May 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of pimavanserin (Nuplazid) Manual PA Criteria: Nuplazid is approved if all of the following criteria are met: • Patient is age 18 years of age or older • Patient has a diagnosis of hallucinations and/or delusions associated with Parkinson's Disease psychosis • Nuplazid is being prescribed by or in consultation with a neurologist, psychiatrist, or gerontologist (i.e., geriatric medicine specialist) • **Patient has a contraindication to, intolerability to, or has failed treatment with clozapine** • Prescribing physician has attempted to adjust Parkinson's disease medications in order to reduce psychosis without worsening motor symptoms prior to requesting pimavanserin • Provider acknowledges black box warning for Nuplazid which states elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death • Provider acknowledges the FDA safety alerts, warnings, precautions, and drug interactions • Patient is not taking additional antipsychotics Non-FDA approved uses are not approved Prior authorization does not expire.

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• sacubitril/valsartan (Entresto) **Renin-Angiotensin Antihypertensives: Combinations**	Manual PA criteria applies to new users of sacubitril/valsartan tablets at all points of service. Manual PA criteria: sacubitril/valsartan generics are approved if all criteria are met: • Provider acknowledges that the brand Entresto tablet is the preferred product over generic sacubitril/valsartan tablets and is covered at the lowest copayment, which is the generic formulary copayment for non-Active-Duty patients, and at no cost share for Active-Duty patients. (Although Entresto is a branded product, it will be covered at the generic formulary copayment or cost share) • Please provide a patient-specific justification as to why the brand Entresto cannot be used in this patient. _____ (fill-in the blank). ▪ Acceptable reasons to include the patient has had an adverse reaction to an excipient in brand Entresto that would not be likely to occur with the generic sacubitril/valsartan PA does not expire
• FreeStyle Libre 2 and 3 • Dexcom G6 and G7 • **Dexcom G7 15 day sensor** **CGMs**	**Updates from the May 2025 meeting are in bold** Automated and manual PA criteria apply to all new users of Abbott FreeStyle Libre 2 and 3 and Dexcom G6 and G7. Automated PA criteria: The patient has filled a prescription for insulin (including basal or rapid acting insulin) at any MHS pharmacy point of service (MTFs, retail network pharmacies, or TRICARE mail order pharmacy) during the previous 180 days. AND Manual PA criteria: If automated criteria are not met, coverage is approved coverage is approved for FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6 and Dexcom G7 and **Dexcom G7 15 day sensor** if all criteria are met: • *Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria* • Patient has a diagnosis of diabetes • Patient is currently being treated with insulin. Please document the following: ▪ Insulin product: _____ ▪ Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days. • **For the Dexcom G7 15-day sensor – the patient is 18 years of age or older** Initial PA Expiration: annual Renewal expiration: annual for the manual PA Annual manual PA renewal criteria: • Patient has utilized CGM daily • Provider and patient will assess the usage of self monitoring of blood glucose (SMBG) at every visit with the goal of minimizing/discontinuing use • Patients with T2DM continue to require basal or prandial insulin injections daily • Patient continues to share data with managing healthcare professional for the purposes of clinical decision making • Patient continues to be treated with insulin. Please document the following: ▪ Insulin product: _____

	▪ Date last filled: _____ Note the patient must have filled an insulin prescription within the past 180 days.
• semaglutide (Wegovy) • tirzepatide (Zepbound) **Weight Loss Agents**	**Updates from May 2025 are in bold** Manual PA criteria apply to all new users of Wegovy and Zepbound Manual PA Criteria: Coverage for Wegovy or Zepbound is approved if: • **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"** • **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?** o **If yes subject to verification, proceed to the next question** o **If no, coverage is not approved** • **What TRICARE Plan is the patient enrolled in?** o **TRICARE Select – proceed to the next question** o **TRICARE Prime – proceed to the next questions** o **TRICARE For Life – Coverage not approved; if patient is diabetic and meets the prior authorization criteria for Trulicity, Victoza, Ozempic, or Mounjaro, please consider these alternatives.** • **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.** • **The provider will document the major condition and comorbidities treated selecting all that apply:** o **Obesity** o **Diabetes or impaired glucose tolerance** o **Obstructive sleep apnea** o **Osteoarthritis** o **Metabolic syndrome** o **Dyslipidemia** o **Hypertension** o **Metabolic dysfunction-associated steatohepatitis (MASH)** o **Established cardiovascular disease with a history of stroke** o **Established cardiovascular disease with a history of myocardial infarction** o **Established cardiovascular disease with a history of peripheral artery disease** For Wegovy and Zepbound for adults for obesity • Patient is 18 years of age or older • Patient has a BMI greater than or equal to 30, or a BMI greater than or equal to 27 in the presence of at least one weight-related comorbidity for those with risk factors in addition to obesity ~~(diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea)~~ o The provider will document the BMI

	▪ For BMI less than 27, coverage is not approved ▪ For BMI ranging between 27 and 29 with a comorbidity ▪ For BMI ranging between 30 to 34 ▪ For BMI ranging between 35 to 39 ▪ For BMI greater than or equal to 40 • Patient has tried 3 months of generic phentermine, benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR and had an inadequate response • Phentermine: Date_____ Duration of therapy _____ OR • The patient has a contraindication to generic phentermine (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension) OR • The patient has experienced an adverse reaction to phentermine benzphetamine, diethylpropion (IR/SR) or phendimetrazine IR/SR that is not expected to occur with Wegovy or Zepbound For Wegovy for adolescents (note that Zepbound is not currently FDA-approved for adolescents) for obesity • Patient is 12 years of age or older and younger than 18 years of age • Patient has a BMI greater than or equal to 95th percentile standardized for age For Zepbound for moderate to severe obstructive sleep apnea (OSA) in adults with obesity: • Patient is 18 years of age or older • Patient has moderate to severe OSA (documented apnea-hypopnea index greater than 15 events per hour) and a BMI greater than 30 For all patients • Concomitant use of this medication with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient is not pregnant Non-FDA approved uses are not approved including diabetes mellitus PA expires in 12 months for initial therapy; annual renewal required Renewal PA Criteria: Initial TRICARE PA approval required for renewal. Wegovy and Zepbound will be approved for an additional 12 months if the following are met: • **The provider will document the BMI for renewal:** ○ **BMI less than 27,** ○ **BMI ranging between 27 and 29** ○ **BMI ranging between 30 to 34** ○ **BMI ranging between 35 to 39** ○ **BMI greater than or equal to 40** For Obesity: • ~~The patient is currently engaged in behavioral modification and on a reduced calorie diet~~ • **Per P&T recommendation: 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. • For Wegovy: for patients older than 12 years of age and younger than 18 years of age, the patient has lost greater than or equal to 4% of baseline body weight since starting medication with full dosage titration • For Wegovy and Zepbound: for patients older than 18 years of age, the patient has lost greater than or equal to 5% of baseline body weight since starting medication • The patient is not pregnant For OSA: • The patient has shown improvement in OSA symptoms based on the improvement of apnea hypopnea index
• phentermine/ topiramate (Qsymia) • bupropion/ naltrexone (Contrave) • orlistat (Xenical) • liraglutide (Saxenda) **Weight Loss Agents**	**Updates from May 2025 are in bold. The following questions will be added to the existing PA criteria.** **Automated criteria identifying those beneficiaries with other TRICARE health plan enrollment that is not TRICARE Select or TRICARE PRIM will result in no coverage and a claim denial.** Manual PA criteria apply to all new users of the weight loss drug <u>Manual PA Criteria</u>: Coverage for the weight loss drug is approved if: • **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"** • **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?** ▪ **If yes subject to verification, proceed to the next question** ▪ **If no, coverage is not approved** • **What TRICARE Plan is the patient enrolled in?** ▪ **TRICARE Select – proceed to the next question** ▪ **TRICARE Prime – proceed to the next questions** ▪ **TRICARE For Life–Coverage not approved** • **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.**

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• concizumab-mtci (Alhemo) **Antihemophilic Factors: Non-Factor Agents**	▪ MTF/TMOP/Retail: 30-day supply
• diazoxide choline (Vykat XR) **Metabolic Agents Miscellaneous**	▪ MTF/TMOP/Retail: 30-day supply
• letermovir oral pellets (Prevymis) **Antivirals**	▪ MTF/TMOP/Retail: 30-day supply
• mirdametinib (Gomekli) **Oncologic Agents**	▪ MTF/TMOP/Retail: 30-day supply
• suzetrigine (Journavx) **Pain Agents**	**Updates are in bold and strikethrough** ▪ MTF/TMOP/Retail: ~~30 tablets/fill and no refills~~, **30 tablets/180 days with no refills**
• vimseltinib (Romvimza) **Oncological Agents**	▪ MTF/TMOP/Retail: 60-day supply
• ustekinumab-stab (Steqeyma) • ustekinumab-aauz (Otulfi) • ustekinumab-ttwe (Pyzchiva) • ustekinumab-kfce (Yesintek) • ustekinumab-aekn (Selarsdi) • ustekinumab-ttwe (unbranded) **TIBs: IL-23**	▪ Retail: 1 syringe/vial per fill ▪ MTF/TMOP: 3 syringes/vials per fill (Note these QLs allow for loading doses for pertinent indications)
• mebendazole (Emverm) **Anti-infectives: Antihelmintics**	▪ MTF/TMOP/Retail: 12 tablets per 30 days with no refills
• Dexcom G7 15 Day Sensor **Therapeutic CGM Systems**	▪ Retail: 2 sensors per 30 days ▪ MTF/TMOP: 6 sensors per 90 days
• risdiplam (Evrysdi) tablets **Neurological Agents Miscellaneous**	▪ tablets: MTF/TMOP/Retail: 30 tablets per 30 days ▪ solution: MTF/TMOP/Retail: 36-day supply

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• benz-galantamine (Zunveyl) **Alzheimer's Agents**	• galantamine • Adlarity • galantamine ER • donepezil	• Delayed release (DR Tablet: 5, 10, 15 mg • Dosing: 5 mg orally twice daily	• Treatment of mild to moderate dementia of the Alzheimer's type in adults	• nausea • vomiting • diarrhea • dizziness • headache • decreased appetite	• New prodrug formulation of galantamine for Alzheimer's disease • No new clinical efficacy studies • Provide no clinical advantage over existing agents	• Complete Exclusion • Interim PA
• concizumab-mtci (Alhemo) **Anti-hemophilic Factors: Non-Factor Agents**	• Hemlibra • Idelvion • Altuviiio	• Pen: 60, 150, 300 mg • Dosing: weight-based daily	• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years old with hemophilia A with FVIII inhibitors or hemophilia B with FIX inhibitors	• injection site reaction • urticaria	• Alhemo is the second tissue factor pathway inhibitor (IFPI) antagonist but first one indicated as routine prophylaxis • Phase 3 open-label study demonstrated 86% bleed reduction for patients given Alhemo as routine prophylaxis vs. on-demand treatment only • Alhemo is given once daily while other non-factor agents are given once weekly or less often • Alhemo is an alternative to Hemlibra for hemophilia A patients with inhibitors and offers an option for hemophilia B patients with inhibitors who have limited options	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List
• diazoxide choline (Vykat XR) **Metabolic Agents Miscellaneous -Willi**	• None	• XR tablet: 25/75/150 mg	• Treatment of hyperphagia in patients ≥4 years with Prader-Willi Syndrome	• hypertrichosis • edema • hyperglycemia • rash	• Vykat is the first FDA-approved treatment for hyperphagia in Prader-Willi syndrome • A phase 3 double-blinded study did not demonstrate improvement in the hyperphagia endpoint but did result in statistically significant improvement in those with severe baseline hyperphagia • A phase 3 withdrawal study demonstrated statistically significant worsening of hyperphagia in the placebo group relative to Vykat XR • Vykat is generally well tolerated with mostly grade 1 adverse events • Vykat XR provides an option for hyperphagia associated with this rare disorder	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• hydro-chorothiazide powder 10 mg/mL for oral suspension (Inzirqo) **Diuretic Agents**	• HCTZ tablet • Norliqva solution • Qbrelis Solution • Carospir Suspension	• 10 mg/mL with total volume 80 mL after reconstitution	• Approved for adults and pediatrics with hypertension or edema associated with congestive heart failure, hepatic cirrhosis and renal disease including nephrotic syndrome	• hypokalemia • hyponatremia • hypomagnesemia • hyperglycemia • hyperuricemia • hyperlipidemia • hypotension	• New oral suspension formulation of hydrochlorothiazide (HCTZ) • No clinical efficacy studies were conducted; approval was based on clinical trial data with HCTZ tablets • HCTZ tablets can be crushed and mixed with fluids for patients who cannot swallow • Supplied as 10 mg/mL in 80 mL bottles; typical adult patient will need 50 mg daily and will go through 1 bottle in about 2 weeks • Provides no compelling clinical advantage over existing agents	• NF • PA • MN • TRICARE Maintenance Drug List
• hydroxyurea 100 mg/mL oral solution (Xromi) **Oncologic Agents**	• hydroxyurea capsule • Droxia capsule • Siklos tablet	• solution: 100 mg/mL	• Approved to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients 6 months of age and older with sickle cell anemia with recurrent moderate to severe painful crises	• neutropenia • thrombocytopenia • papular rash	• New oral solution formulation of hydroxyurea for sickle cell disease • Xromi and Siklos can be used in patients who cannot swallow • Xromi is used in pediatrics 6 months and older while Siklos can be used in children 2 years of age or older and in adults • Is not approved for malignancy (e.g., chronic myelocytic leukemia or other cancers • Provides an oral solution formulation for pediatric patients 6 monthsand older	• UF • PA • TRICARE Maintenance Drug List
• letermovir ER oral pellets (Prevymis) **Antivirals**	• letermovir tablets (Prevymis)	• 20 mg or 120 mg ER packet; each carton has 30 packets	• Prophylaxis of cytomegalovirus (CMV) infection and disease in ≥ 6 months of age and weighing ≥ 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) • Prophylaxis of CMV disease in ≥ 12 years of age and weighing ≥ 40 kg who are	• nausea • diarrhea • vomiting • peripheral edema • cough • headache • fatigue • abdominal pain	• New oral pellet formulation of Prevymis for prophylaxis of CMV in adult and pediatric patients ≥ 6 months of age and weighing at least 6 kg who are CMV-seropositive recipients HSCT and prophylaxis of CMV disease in adult and pediatric patients ≥ 12 years of age and weighing at least 40 kg who are kidney transplant recipients at high risk • Can be administered via NG or G tube • Provides an alternative oral dosage formulation for patients who cannot swallow tablets or patients who weigh < 30 kg	• UF • QL • Specialty Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
			kidney transplant recipients at high risk			
• mirdametinib (Gomekli) **Oncologic Agents**	• Koselugo	• Capsu;e: 1, 2 mg • Tab for suspension: 1 mg	• Treatment of patients 2 years of age and older with neurofibromatosis type 1 who have symptomatic plexiform neurofibromas not amenable to complete resection	• rash • diarrhea • nausea • msk pain • vomiting • fatigue	• Second MEK1/2 inhibitor for neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas • Phase 2b open label study demonstrated objective response rate (ORR) in 24 (41%) and 29 (52%) of adults and pediatrics, respectively • Gomekli is available as a tablet for suspension for patients who cannot swallow • Gomekli is an additional treatment option for neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List • Rapid Response Program
• suzetrigine (Journavx) **Pain Agents**	• tramadol tab • oxycodone tab	• Tab: 50mg	• Treatment of moderate to severe acute pain in adults	• pruritis, • muscle spasms • increased CPK • rash	• Journavx is a sodium channel blocker indicated for the treatment of moderate to severe acute pain in adults • Recommended to use for shortest duration; use beyond 14 days has not been studied • Two phase 2 studies demonstrated statistically significant reduced pain scores 48 hours after abdominoplasty and bunionectomy when compared to placebo; baseline populations were predominantly white, young, & female; there is no data regarding special populations of interest such as pregnancy, pediatrics, or geriatrics • Guidelines recommend trial of standard, widely available uniform formulary medications for post operative pain management (e.g. NSAIDs, COX2 inhibitors, gabapentinoids, or acetaminophen) • Provides an additional non-opioid pain treatment for short term use	• UF • QL

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• trazodone 10 mg/mLoral solution (Raldesy) **Anti-depressants And Non-Opioid Pain Syndrome Agents: Serotonin Antagonist and Reuptake Inhibitor**	• Zoloft concentrate • Prozac solution	• Solution: 10mg/mL	• Treatment of major depressive disorder in adults	• edema • blurred vision • syncope • drowsiness • fatigue • diarrhea • nasal congestion • weight loss	• New oral solution formulation of trazodone hydrochloride • No new clinical efficacy studies conducted for approval • Provides an option for patient who cannot swallow trazodone tablet	• NF • PA • MN
• ustekinumab-aekn (Selarsdi) • ustekinumab-aauz (Otulfi) • ustekinumab-kfce (Yesintek) • ustekinumab-stab (Steqeyma) • ustekinumab-ttwe (Pyzchiva) • ustekinumab-ttwe (unbranded) **TIBs: IL-23s**	• Wezlana • Stelara	• SC-pre filled syringe as 45mg/0.5mL, 90mg/1mL: Selarsdi, Otulfi, Yesintek, Steqeyma, Pyzchiva • SC-single dose vial as 45mg/0.5mL: Yesintek	• Adults: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderate to severely active Crohn's, moderate to severely active ulcerative colitis. • ≥ 6 years old: moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, active psoriatic arthritis	indication specific	• Biosimilars to Stelara • ustekinumab-ttwe unbranded is a private label for Quallent Pharmaceuticals • All approved via 351(k); No new clinical studies were completed • Provides no compelling clinical advantage over existing agents	• UF, non-step-preferred ▪ Steqeyma ▪ Otulfi • NF, non-step-preferred ▪ Pyzchiva ▪ Yesintek ▪ Selarsdi • Complete Exclusion: ▪ unbranded (private label) ustekinumab-ttwe • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• vimseltinib (Romvimza) **Oncological Agents**	• Gleevec • Turalio • Tasigna	• Capsule: 14, 20, 30 mg	• Treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity	• hepatoxicity • embryofetal toxicity • reaction to yellow dyes number 5 and number 6 • increased SCr	• Second CSF1 receptor inhibitor approved for symptomatic treatment of TGCT • Phase 3 study demonstrated efficacy in the Romvimza group vs. placebo (40% vs. 0%) • Efficacy of Turalio appears similar to Romvimza • Romvimza has a warning for hepatotoxicity; Turalio has a Boxed Warning and REMS for serious and fatal hepatotoxicity • Romvimza may be taken with or without food; Turalio requires administration with a low-fat meal • Romvimza provides an alternative to Turalio	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List

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

Table 1: TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes*

DoD P&T Meeting	ADD to the TRICARE Maintenance Drug List (if Formulary, Add; 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 2025	**Drug Class Reviews** **Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors** ***Designated UF*** *Retain current status (all agents on the list)* • abemaciclib (Verzenio) • palbociclib (Ibrance) • ribociclib (Kisqali) **Targeted Immunomodulatory Biologics: IL-1, IL-6, and CTLA4-Ig subclasses** ***Designated UF*** *Add or retain current status for all agents on the list* • anakinra (Kineret) *on contingent list* • sarilumab (Kevzara) *on the list* • tocilizumab (Tyenne) *on contingent list* ***Designated NF*** *Add or retain current status for all agents on the list (no reason to exempt from NF TMOP requirement)* • abatacept (Orencia) *on the list* • rilonacept (Arcalyst) *on contingent list* • satralizumab (Enspryng) *on list* • tocilizumab (Actemra) *on list* **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** *Designated UF* • hydroxyurea solution (Xromi) *Designated NF (no reason to exempt from NF TMOP requirement)* • hydrochlorothiazide suspension (Inzirqo)	**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** *Do not add–acute or limited duration of use* • letermovir (Prevymis) • suzetrigine (Journavx) ***Designated NF*** *Exempt from NF TMOP requirement (established general exception for antidepressants* • trazodone oral solution (Raldesy)

***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

DoD 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 2025	**Drug Class Reviews** **Targeted Immunomodulatory Biologics: IL-1, IL-6, and CTLA4-Ig subclasses –** maintain TIBs class as generally suitable for inclusion on the contingent list; retain/add any agent not already on the TDML to the contingent list **Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors –** maintain this subclass as generally suitable for inclusion on the contingent list; retain/add any agent not already on the TMDL to the contingent list **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • concizumab-mtci (Alhemo) • diazoxide choline (Vykat XR) • mirdametinib (Gomekli) • ustekinumab-aauz (Otulfi) • ustekinumab-stba (Steqeyma) • vimseltinib (Romvimza) ***Designated NF*** *No reason to exempt from TMOP requirement* • ustekinumab-aekn (Selarsdi) • ustekinumab-kfce (Yesintek) • ustekinumab-ttwe (Pyzchiva)	

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.

† P&T Committee Administrative Authorities were used to implement some recommendations not requiring UF BAP comment. See the November 2023 Table of Administrative Authorities.

Appendix H—Drugs with Complete Exclusion Status and Formulary Alternatives

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
May 2025	Alzheimer's Agents	• benzgalantamine (Zunveyl)	• galantamine • galantamine ER • ~~Adlarity Patch~~ (D/C'd from market) • donepezil	• 120 days
May 2025	Interleukin-23 Agents	• ustekinumab-ttwe (unbranded private label	• adalimumab (Humira) • ixekizumab (Taltz) • ustekinumab (Stelara) • ustekinumab-stab (Steqeyma) • ustekinumab-aauz (Otulfi) • ustekinumab-auub (Wezlana)	• 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.

Appendix I—DoD P&T Committee Administrative Authority Document

DoD P&T Committee Updates to Approval Authorities

Note that updates are in bold font and strikethrough.

Table 1. Processes and Recommendation/Approval Authorities For the May 2025 DoD P&T Committee Meeting

Process	Function
Administrative (not part of DoD P&T Committee process; Uniform Formulary Beneficiary Advisory Panel (UF BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm5 (Mail Order Pharmacy and Retail **Pharmacies ~~Pharmacy Network~~**) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; **P&T Committee Chair and others as needed**	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing PA requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non-step-preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to PA forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ Implementing temporary PA requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting) **and to institute and/or change existing PAs, as necessary, to comply with governing federal law and policy. (*from the February 2025 meeting)***

	▪ Applying general MN criteria to drugs newly approved by the FDA after August 26, 2015 (previously known as "innovator" drugs), as outlined in the August 2015 DoD P&T Committee meeting minutes. ▪ Designated drugs newly approved by the FDA after August 26, 2015 with no formulary alternatives to adjudicate as UF (Tier 2 co-pay), after consultation with a DoD P&T Committee physician member or MHS specialist prior to formal vote from the DoD P&T Committee. All newly approved drugs, including those that the Pharmacy Operations Division has determined have no formulary alternatives will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the February 2016 DoD P&T Committee meeting minutes. ▪ Establishing temporary specific PA criteria or MN criteria for select drugs newly approved by the FDA after August 26 2015, to be implemented at the time of product launch, after consultation with a DoD P&T Committee physician member or MHS specialist, prior to formal vote by the DoD P&T Committee, as outlined in the February 2016 DoD P&T Committee meeting minutes. All temporary specific PA or MN criteria will be reviewed by the DoD P&T Committee at the next meeting. The temporary specific PA or MN criteria will only be active until the formal P&T Committee process is complete. Implementation of permanent criteria will become effective upon signing of the DoD P&T Committee minutes. All users who have established temporary specific PA or MN criteria will be "grandfathered" when the permanent criteria become effective, unless directed otherwise. ▪ Establishing drug class definitions for maintenance medications as part of the ~~**Expanded MTF/Mail Order Pharmacy Initiative**~~ **TRICARE Maintenance Drug List.** ▪ Exempting NF medications from the requirement for TRICARE Mail Order Pharmacy dispensing where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ Exempting medications or classes of medications previously identified for addition to the ~~**Expanded MTF/Mail Order Pharmacy Initiative**~~ **TRICARE Maintenance Drug List.** from the requirement for Mail Order Pharmacy dispensing in cases where Trade Act Agreement conflicts preclude purchase for use by the Mail Order Pharmacy; for products that will be discontinued from the market; or for products that are not feasible to provide through the Mail Order Pharmacy (e.g., shortages, access requirements). ▪ After consultation with the Chair of the DoD P&T Committee, implementing "brand over generic" authorization and PA criteria for drugs with recent generic entrants where the branded product is more cost effective than the generic formulations. The branded product will continue to be dispensed, and the generic product will only be available upon PA. The branded product will adjudicate at the Tier 1 co-pay at ~~**the**~~ Retail **Pharmacies** ~~**Pharmacy Network**~~ and **the** Mail Order Pharmacy. The "brand over generic" authority will be removed when it is no longer cost effective to the MHS. These actions will be reviewed by the DoD P&T Committee at the next meeting, as outlined in the May 2016 DoD P&T Committee meeting minutes. ▪ Designating "line extension" products to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" drug. Line extensions will be reviewed by the DoD P&T Committee at the next meeting. Line extensions are defined as having the same FDA-approved indication as the parent drug and must be from the same manufacturer. Line extensions

	may also include products where there are changes in the release properties of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm5, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA "health.mil" website. ▪ ~~**Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting.**~~ ▪ Adding or deleting drugs or drug classes from the ~~**Clinical Services**~~ **TRICARE Specialty** Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list ~~**also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies**~~ **is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List**. Addition or deletion of drugs or drug classes from the ~~**Clinical Services**~~ **TRICARE Specialty** Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying or revising manual PA criteria, MN criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs, MNs and/or QLs implemented in these situations will be removed when the situation has resolved. ▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA-approved devices or supplies and determination as to whether a new FDA-approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination **is** made to consider **the device** for coverage, **then the** timeline for review by DoD P&T

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	Committee **will be established**. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. ▪ Designating "line extension" devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication **Complete Exclusion status (not covered**) on the Uniform Formulary, for products ~~**selected for complete exclusion**~~ that provide very little or no clinical effectiveness relative to similar agents, and **formulation of an** implementation plan (including effective date). ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing PA (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as nonformulary (Tier 3 co-pay). ▪ The Director may approve devices or supplies as recommended by the P&T Committee and the UF BAP; however, approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. ▪ Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with PA criteria and implementation plans as recommended by the DoD P&T Committee and UF BAP.
Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to UF BAP for comments)	▪ Establishment of quantity limits for a medication, device or supply or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs, devices or supplies. ▪ Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF).

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	▪ Addition or deletion of drugs or drug classes, devices or supplies on the ~~**Expanded MTF/Mail Order Pharmacy Initiative**~~ **TRICARE Maintenance Drug List** ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver. ▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the ~~**Clinical Services**~~ **TRICARE Specialty** Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. ~~**The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies**~~. **The list Is also used to monitor specialty drug utilization and costs, superseding the previous Specialty Agent Reporting List**.