DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
August 2025

I. CONVENING

The DoD Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on August 6th and 7th, 2025.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

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

B. Clarification of previous meeting minutes

- **Weight Loss Agents**
  - **May 2025—Prior Authorization regulatory and statutory updates:** Implementation of the regulatory changes to the weight loss PA forms and the new PA criteria for the phentermine, benzphetamine, diethylpropion and phendimetrazine immediate release (IR) and sustained release (SR) occurred on August 31, 2025.
  - **May 2024—Weight Loss Agents Quantity Limits (QLs):** QLs also apply to tirzepatide (Zepbound), consistent with what is currently in place for liraglutide (Saxenda) and semaglutide (Wegovy), with implementation occurring on September 15, 2025.
- **May 2025**
  - **Diabetes Non-Insulin: Biguanides—metformin 750 mg IR tablet—** Numerous other more cost-effective generic metformin IR and ER tablets are available. This recommendation was implemented May 30, 2025 using administrative authorities
  - **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. This recommendation was implemented May 30, 2025 using administrative authorities
- **November 2024**

- **Rapid Acting Insulins**—A Joint National Contract was not awarded. No changes were made to the formulary status or step therapy (PAs) as outlined in the meeting minutes.
- **Miscellaneous Ophthalmic Agents**—Clobetasol ophthalmic emulsion was designated with complete exclusion status. The formulary alternative is dexamethasone 0.01% ophthalmic, and not 0.1%.

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 10, 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. Atopy Agents: Interleukin (IL)-13 and IL-31 Subclass

Background—The IL-13 and IL-31 subclasses include four biologic agents, dupilumab (Dupixent), lebrikizumab (Ebglyss), nemolizumab (Nemluvio) and tralokinumab (Adbry). All four agents are indicated for treatment of moderate to severe atopic dermatitis; additionally, Dupixent and Nemluvio are indicated for treatment of prurigo nodularis. Dupixent also has several additional indications.

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 for atopic dermatitis and prurigo nodularis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) the following:

Atopic Dermatitis

- There are no head-to-head trials comparing Dupixent, Adbry, Ebglyss or Nemluvio.
- Guidelines from the American Academy of Dermatology (AAD) (2023) and the American Academy of Allergy, Asthma & Immunology (2023) support the use of multiple systemic and biologic treatments to treat moderate to severe atopic dermatitis refractory to topical treatments.
    - Both Dupixent and Adbry are recommended in the 2023 AAD guidelines with a high certainty for their evidence for efficacy and that they appear safe. Nemluvio and Ebglyss are not yet included in the guidelines due to their more recent FDA approval in November 2024.
    - Topical agents including corticosteroids and calcineurin inhibitors (i.e., tacrolimus and pimecrolimus) are recommended for mild to moderate atopic dermatitis. Topical agents can be used with phototherapy and systemic therapies for maintenance of response or treatment of flares.
- A 2023 network meta-analysis evaluating the four agents along with the oral Janus kinase (JAK) inhibitors in 149 trials with over 28,000 patients concluded the following:
    - Dupixent, Ebglyss, and Adbry are of intermediate effectiveness and have favorable safety profiles.
    - For the Patient Oriented Eczema Measure, Pruritus Numeric Rating Scale, and Dermatology Life Quality Index all four agents were statistically significant when compared to placebo.
    - For the Eczema Area Severity Index, Dupixent, Ebglyss, and Adbry were all statistically significant in relieving symptoms, with Dupixent and Ebglyss also showing clinical significance.
    - In terms of safety, all four agents did not demonstrate a significant increase in frequency of any adverse event. However, Dupixent, Adbry and Ebglyss did show an increased frequency of conjunctivitis, compared with standard care. Dupixent demonstrated a reduced odds of serious adverse events and adverse events leading to discontinuation when compared to placebo.
- Additional literature review included two placebo-controlled trials published in 2024 evaluating Nemluvio and reported statistically significant results for the four rating scales discussed above, with similar outcomes as reported in the 2023 NMA reviewed.

Prurigo Nodularis

- Dupixent and Nemluvio are currently approved to treat prurigo nodularis. A 2021 U.S. expert consensus panel recommends Dupixent or Nemluvio for disease refractory to topical treatments, or for patients with more severe presentation. Topical corticosteroids and topical calcineurin inhibitors are recommended for mild disease. Other supported treatments include methotrexate, azathioprine, mycophenolate, and cyclophosphamide.
- An indirect efficacy analysis between Dupixent and Nemluvio is challenging due to varying inclusion criteria among the trials. The Dupixent data includes two randomized trials over 24 weeks allowing continuation of stable topical treatments, while Nemluvio includes 2 randomized trials over 16 weeks excluding use of topicals.
- For the proportion of patients achieving Investigator Global Assessment scores of 0 to1 (clear to near clearance of lesions), the two Dupixent trials and a single Nemluvio trial achieved a statistically significant proportion of responders compared to placebo. For the endpoint of daily quality of life, all the studies showed that treatment with Dupixent and Nemluvio achieved a statistically significant, similar outcome.
- For the individual prurigo nodularis trials, treatment emergent adverse events occurred in over half of the patients across all trials. A higher proportion of patients had disease flare in the Nemluvio trials compared to those in the Dupixent trials.

Other Factors

- Dupixent carries the most FDA-approved indications (eight). The most recent label updates include bullous pemphigoid in adults and chronic spontaneous urticaria in children down to the age of 12 years. For atopic dermatitis, it is approved for children as young as 6 months of age. The package insert lists more warnings and adverse events compared to other agents in the subclass, including herpes simplex virus infection, conjunctivitis, eosinophilia and arthralgia. It is available in pre-filled syringes and pre-filled pens.
- Adbry and Ebglyss are only indicated for the treatment of atopic dermatitis for adults and children down to 12 years of age. Common adverse events for both include conjunctivitis and herpes simplex virus infection; Adbry can cause eosinophilia. Adbry is available in both an autoinjector and pre-filled syringe, while Ebglyss is supplied as prefilled pens and pre-filled syringes.
- Nemluvio is indicated for atopic dermatitis in adults and children as young as 12 years of age as well as prurigo nodularis for adults. Unique adverse events included in the label include headache, urticaria and myalgia. It

offers the longest dosing frequency of up to 8 weeks and is supplied as a pre-filled pen.

- In terms of therapeutic interchangeability, for efficacy for treating atopic dermatitis, Dupixent, Adbry, Ebglyss and Nemluvio have a high degree of therapeutic interchangeability; for safety, there is a moderate degree of therapeutic interchangeability. For prurigo nodularis, Dupixent and Nemluvio have a high degree of interchangeability for efficacy, and moderate degree of interchangeability for safety.

Overall Conclusion

- For clinical coverage, at least one agent is needed on the formulary to treat atopic dermatitis and prurigo nodularis in order to meet the needs of Military Health System (MHS) beneficiaries.

Relative Cost Effectiveness Analysis and Conclusion—The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 0 absent) designating all four drugs as UF was cost-effective, based on the CMA and BIA.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following:
    - UF
        - dupilumab (Dupixent)
        - lebrikizumab (Ebglyss)
        - nemolizumab (Nemluvio)
        - tralokinumab (Adbry) - *moves from NF to UF*
    - NF: None
    - Complete Exclusion: None
2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Existing PA criteria currently apply to all the drugs. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) updated manual PA criteria as outlined in Appendix C for new users.
    - In general, specialist prescribing is required, and renewal is recommended after one year, documenting improvement in symptoms.
    - Guideline-recommend therapies are required first, including topical treatments and phototherapy for atopic dermatitis, and other therapies, depending on indication (e.g., pulmonary inhalers for asthma and chronic obstructive pulmonary disease for Dupixent; nasal saline irrigation and nasal steroids for nasal polyps).

- The new indications for Dupixent for bullous pemphigoid and chronic spontaneous urticaria were added to the PA.
- For Ebglyss, automated specialist bypass for patients 12 years of age and older when prescribed by a dermatologist, allergist or immunologist was added to bypass the PA. Additionally, an automated drug look back was added for Ebglyss, to allow continuation of coverage by any other prescriber if the patient has received a prescription for Ebglyss in the past 720 days.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QL of a 60-day supply at all points of service for all four drugs. See Appendix D.
4. ***COMMITTEE ACTION: SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS*** —The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) maintaining all the drugs on the Specialty Drug List and maintaining Dupixent and Adbry on the TRICARE Maintenance Drug List; Ebglyss and Nemluvio were not added to the list. See Appendix F for the TRICARE Maintenance Drug List details.
5. ***COMMITTEE ACTION: UF, PA, QLs, SPECIALTY AND TRICARE MAINTENANCE DRUG LISTS, AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. See Appendix G.

B. Diuretics: Mineralocorticoid Receptor Antagonists Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the mineralocorticoid receptor antagonists (MRAs). The subclass is comprised of two generic medications, eplerenone and spironolactone (available in tablets and oral suspension), and branded finerenone (Kerendia). Kerendia was previously reviewed as a new drug in November 2021 and is designated as NF.

In terms of FDA-approved indications, eplerenone and spironolactone are both indicated for treating hypertension, and all three drugs are approved for heart failure. Finerenone is also approved for treating type 2 diabetic chronic kidney disease (CKD). Spironolactone has several additional indications including edema due to nephrotic syndrome or cirrhosis, and primary hyperaldosteronism. The clinical review focused on the place in therapy for type 2 diabetic CKD and heart failure.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) the following:

Efficacy for Type 2 diabetic CKD

- In patients with type 2 diabetes receiving therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), finerenone is approved to reduce the composite endpoint of decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular (CV) death, non-fatal myocardial infarction and heart failure hospitalization, based on the FIDELIO and FIGARO studies.
    - Limitations to the results include the low use (4%) of current guideline-accepted background therapy with sodium-glucose transportor-2 (SGLT-2) inhibitors. Additionally, in the FIDELIO study, the results were driven by the reduction in eGFR; no difference was noted in progression to end-stage kidney disease or the other individual components of the composite endpoint.
- Studies with eplerenone and spironolactone report that both drugs reduce proteinuria, but do not reduce adverse renal outcomes (e.g., progression to end-stage kidney disease). There was a significantly increased risk of hyperkalemia. Overall, the long-term effects of eplerenone and spironolactone on renal outcomes, mortality, and safety for type 2 diabetic CKD remain to be established.
- Finerenone is now included in several clinical practice guidelines to slow the progression of CKD in patients with Type 2 diabetes. However, ACE inhibitors or ARBs remain the mainstay of therapy as first-line treatment. Guidelines also state the SGLT-2 inhibitors are preferred and more-established therapies, before adding finerenone. Guidelines reviewed included, but were not limited to, the following: 2024 American Diabetes Association, 2024 Kidney Disease Improving Global Outcomes, 2025 VA/DoD, and the 2023 United Kingdom National Institute for Clinical Effectiveness.

Efficacy for heart failure

- In July 2025, finerenone received approval for patients with heart failure and preserved ejection fraction (HFpEF) based on the FINEARTS trial. Treatment with finerenone resulted in a 16% risk reduction in the composite of worsening heart failure event and CV death. No significant difference was noted for the individual endpoints of mortality or kidney outcomes. The results were driven by a reduction in heart failure events. As with CKD, the study is limited by low background use of SGLT-2 inhibitors.
- Spironolactone showed a 30% reduction in all-cause death in patients with heart failure and reduced ejection fraction (HFrEF) in the landmark RALES study. Reduced mortality (20% risk reduction) was seen for HFpEF in the TOPCAT study, when the results were limited to North America.

- Eplerenone showed a 15% reduction in all-cause death in patients with heart failure after myocardial infarction (EPHESUS).
- For HFpEF, SGLT-2 inhibitors remain the mainstay of therapy, based on results from several large trials. Other drug classes, including diuretics, eplerenone or spironolactone, sacubitril/valsartan or ARBs are added, based on individual patient clinical presentation (2023 American College of Cardiology.) Finerenone is not specifically mentioned in the guidelines.
- For HFrEF, spironolactone and eplerenone hold a Class I recommendation (strong evidence) for patients with New York Heart Association (NYHA) class II-IV heart failure (2023 American College of Cardiology).

Safety

- Adverse events associated with all three MRAs include hyperkalemia, hypotension, and hyponatremia.
- Finerenone has different receptor affinity than spironolactone, which may account for some differences in the adverse event profile. Lack of head-to-head trials and study design run-in criteria complicates ability to determine if the hyperkalemia risk with finerenone is favorable or unfavorable compared to eplerenone or spironolactone.
- Gynecomastia does not appear to be an issue with eplerenone or finerenone.

Other factors

- MHS providers requested UF placement of finerenone, due to inclusion in national guidelines for T2DM and CKD but acknowledged other guideline-recommended therapies should be used first.

Clinical Coverage

- In order to meet the needs of MHS patients, finerenone should be included on the formulary, despite limitations in clinical trial data.
- Spironolactone oral suspension is required for the pediatric population for edema and heart failure.

Relative Cost Effectiveness Analysis and Conclusion—CMA and BIA were performed. The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 1 absent) that designating finerenone as UF rather than NF would be cost-effective.

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

- eplerenone (Inspra, generics)
- finerenone (Kerendia) - *moves from NF to UF*
- spironolactone (Aldactone, generics)
- spironolactone/hydrochlorothiazide (Aldactazide, generics)
- spironolactone oral suspension (Carospir, generics) - *moves from NF to UF*

- NF – None
- Complete Exclusion – None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria currently apply to Kerendia and for spironolactone oral suspension. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) revising the PA criteria for Kerendia in new users to incorporate feedback from MHS providers for the CKD indication, to modify the safety questions, and to add the new indication for HFpEF based on the inclusion and exclusion criteria from the FINEARTS trial. Other guideline-directed therapies are required first, based on clinical practice guidelines. No changes were recommended for the PA for spironolactone suspension. See Appendix C for the full criteria.
3. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—Spironolactone and eplerenone are not currently included on the list. The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) removing spironolactone oral suspension from the list. Kerendia was not added to the list. See Appendix F.
4. ***COMMITTEE ACTION: UF, PA, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD—***The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (19 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 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 Drug Maintenance List.

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

    - UF
        - acoltremon 0.003% (Tryptyr) ophthalmic solution – Ophthalmic Agent
        - atrasentan (Vanrafia) – Nephrology Agent for Immunoglobulin A Nephropathy (IgAN)
        - avutometinib with defactinib (Avmapki Fakzynja Co-pack) – Oncological Agent for low-grade serous ovarian cancer
        - berdazimer 10.3% topical gel (Zelsuvmi) – Anti-Infective Agent for molluscum contagiosum
        - efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) SC injection– Neurological Agent for generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy (CIDP)
        - ensartinib (Ensacove) – Oncological Agent for non-small cell lung cancer (NSCLC)
        - fitusiran (Qfitlia) – Antihemophilic Agent
        - insulin aspart-szjj (Merilog vial/pen) – Rapid Acting Insulin
        - nilotinib d- tartrate 50, 150, 200 mg capsules (no brand name) – Oncological Agent for Philadelphia chromosome positive chronic myeloid leukemia (Ph^+ CML)
        - taletrectinib (Ibtrozi) – Oncological Agent for NSCLC
        - treprostinil inhalation powder (Yutrepia) – Pulmonary Arterial Hypertension (PAH) Agent
    - NF
        - chlorthalidone 12.5 mg tabs (Hemiclor) – Antihypertensive Agent
        - garadacimab-gxii SC injection (Andembry) – Corticosteroids-immune modulator for Hereditary Angioedema (HAE)
        - hydrocortisone 1 mg/ml solution (Khindivi) – Corticosteroids-immune modulator
        - losartan 10 mg/mL oral suspension (Arbli) – Antihypertensive Agent
        - terazosin 1 mg/ml solution (Tezruly) – Benign Prostatic Hyperplasia (BPH) Agent
        - ustekinumab-srlf (Imuldosa) – Targeted Immunomodulatory Biologics (TIBs) Interleukin (IL)-23s; biosimilar for Stelara

        - ustekinumab (ustekinumab by Janssen) – TIBs IL-23s; unbranded Stelara
    - Complete Exclusion: See Appendix H for additional detail regarding complete exclusion agents and formulary alternatives.
        - acetaminophen 325 mg/ibuprofen 97.5 mg tabs (Combogesic) – Pain Agent
            - Combogesic was recommended for complete exclusion status as it has little to no clinical benefit relative to administering acetaminophen and ibuprofen separately, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include acetaminophen 325 mg and ibuprofen 200 mg.
        - meloxicam 20 mg/rizatriptan 10 mg (Symbravo) – Pain Agent
            - Symbravo was recommended for complete exclusion status as it has little to no clinical benefit relative to administering meloxicam and rizatriptan separately, and the needs of TRICARE beneficiaries are met by alternative agents. Alternatives include meloxicam, rizatriptan, and sumatriptan/naproxen (Treximet).
        - ustekinumab-aekn (unbranded ustekinumab-aekn Selarsdi private label by Teva) – TIBs IL-23s
            - The ustekinumab-aekn 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-auuz (Otulfi), ustekinumab-stab (Stequeyma), and ustekinumab (Stelara).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Andembry, Arbli, Hemiclor, Khindivi, Tezruly, ustekinumab (unbranded Stelara by Janssen) and ustekinumab-slrf (Imuldosa). The MN criteria for NF ustekinumab products will also allow a trial of branded Stelara. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria. See Appendix C for the full criteria.
    - Applying manual PA criteria to new users of the NF ustekinumab products ustekinumab (unbranded Stelara by Janssen) and

ustekinumab-slrf (Imuldosa), 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.

  - Additionally, PA criteria will apply to private label ustekinumab-aekn, until implementation of the complete exclusion status. Providers will need to document why the unbranded private label product is required, rather than using the UF and NF ustekinumab products.

- Applying manual PA criteria to new users of Qfitlia, similar to the PA requirements for other hemophilia agents.
- Applying manual PA criteria to new users of Andembry, Arbli, Avmapki Fakzynja, Ensacove, Ibtrozi, Khindivi, nilotinib d-tartrate 50, 150, 200 mg capsules, Tezruly, Tryptyr, Vanrafia, Vyvgart Hytrulo, Yutrepia, and Zelsuvmi.
- Applying temporary manual PA criteria to new and current users of Combogesic and Symbravo, until implementation of complete exclusion status.

4. ***COMMITTEE ACTION: QLs***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) QLs for Andembry, Avmapki Fakzynja, Ensacove, Hemiclor, Ibtrozi, Imuldosa, nilotinib d-tartrate, Qfitlia, Tryptyr, ustekinumab by Janssen, Vyvgart Hytrulo, and Yutrepia. See Appendix D for the QLs.
5. ***COMMITTEE ACTION: RAPID RESPONSE/SAFETY NET PROGRAM***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) adding Andembry and Khindivi 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 LIST REQUIREMENTS***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 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 LIST, and IMPLEMENTATION PERIOD***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) an effective date of the following:

- **New Drugs Recommended for UF and NF Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.
- **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service; and 2) DHA will send letters to beneficiaries who are affected by the complete exclusion status at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

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

Manual PA criteria were recommended for seven recently marketed drugs 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) **Beta Blockers and Hydrochlorothiazide Combinations—bisoprolol 2.5 mg tablet—**There are other bisoprolol formulations available, including bisoprolol 5 mg tablets (scored), that are more cost-effective than this 2.5 mg strength.

b) **Antianxiety Agents—buspirone (Bucapsol)—**These buspirone capsules are less cost-effective than currently available buspirone tablets. Buspirone tablets are available in the same strengths or can be split to achieve the same strengths as these buspirone capsules.

c) **Antihistamine-1: First Generation and Combos—clemastine 2.68 mg tablets (Clemasz)—**This clemastine tablet is less cost-effective than other clemastine tablets that are available in the same strength.

d) **Pain Agents: NSAIDs—diflunisal 375 mg tablet (Dolobid)—**Numerous other more cost-effective generic NSAIDs are available.

e) **Pain Agents: NSAIDs—flurbiprofen (Lurbipr)—**There are other flurbiprofen 100 mg tablets formulations and other NSAIDs that are more cost-effective than this product.

f) **Antidepressants and Non-opioid Pain Syndrome Agents: SSRIs—escitalopram 10 mg/10 mL dosing cups—**Various other more cost-effective generic escitalopram mg/10 mL solutions are available.

g) **Diabetes Non-Insulin: Biguanides—metformin 625 mg immediate release (IR) tablet—**Numerous other more cost-effective generic metformin IR and extended release (ER) tablets are available.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for bisoprolol 2.5 mg tablets, buspirone capsules (Bucapsol), clemastine (Clemasz), diflunisal (Dolobid) 375 mg tablets, escitalopram 10 mg/10 mL dosing cups, flurbiprofen (Lurbipr), and metformin 625 mg IR tablets in new 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. See Appendix C for the full criteria.

2. New Manual PA Criteria

a) Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists—leuprolide acetate (Lutrate Depot) 22.5 mg—Lutrate Depot is a new formulation similar to other leuprolide products (Lupron Depot, Eligard). It is less cost-effective than the preferred leuprolide (Eligard), so new PA criteria will apply, requiring a trial of Eligard first, similar to Lupron Depot.

COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for Lutrate Depot in new users. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

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

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

a) Atopy—mepolizumab (Nucala)—Nucala is now indicated for the treatment of COPD. The manual PA criteria were updated to allow for this new indication with PA criteria mirroring the COPD criteria for other biologics, requiring use of traditional oral inhalers first.

b) Atopy: Oral JAK-1—upadacitinib (Rinvoq)—The manual PA criteria were updated to allow for the new giant cell arteritis indication. Specialists supported requiring a trial of glucocorticoids and tocilizumab first, for this indication.

c) Endocrine Agents Miscellaneous—osilodrostat (Isturisa)—The manual PA criteria were updated to reflect minor changes in the FDA label and to remove the warnings and precautions language as this drug is restricted to specialists.

d) **Hematological Agents—iptacopan (Fabhalta)—**The manual PA was updated to include the new indication of Complement 3 Glomerulopathy (C3G). In addition, the PA for IgAN was updated to require a trial of Vanrafia or Filspari. The list of formulary alternatives were expanded in the MN criteria, as Fabhalta is currently designated as NF.

e) Immunosuppressives—belimumab (Benlysta)—Benlysta is now indicated in children as young as 5 years old with lupus nephritis. The PA criteria were updated accordingly.

f) Oncological Agents—belzutifan (Welireg)—Welireg received a new indication for locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma. Additionally, the FDA revised the renal cell carcinoma indication to clarify use for a clear cell component. The manual PA was updated to reflect these changes.

g) Psoriasis Agents—roflumilast 0.3% foam (Zoryve)—The manual PA criteria were updated to include the new indication for plaque psoriasis with the PA mirroring standard plaque psoriasis criteria.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Zoryve, Nucala, Benlysta, Isturisa, Welireg, Rinvoq, and the Fabhalta PA and MN updated criteria in new users. Implementation for the PA and MN criteria updates 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) Insulins: Rapid-Acting Agents—glulisine (Apidra) and lispro (Admelog)—Insulin aspart-szjj (Merilog) was added as a preferred agent on the Apidra and Admelog PAs. Additionally, the MN criteria were updated to include Merilog.

b) GI-1 Agent—budesonide oral suspension (Eohilia)—The Eohilia PA was modified to allow use by general surgeons due to MTF provider feedback.

c) Hematological Agents: Platelets—avatrombopag (Doptelet)—The manual PA criteria were updated based on MTF provider feedback, expanding the specialists to allow hematologist and oncologist prescribing in addition to gastroenterologists, regardless of indication.

d) Overactive Bladder (OAB) Agents): Beta-3 Adrenergic Agonists—mirabegron tablets (Myrbetriq) and vibegron (Gemtesa)—Myrbetriq and Gemtesa are beta-3 agonists used to treat OAB. Currently, both drugs

are UF with a PA requiring a trial of generic anticholinergics. Efficacy is similar between anticholinergics and beta-3 agonists. PA automation was added to both PAs, to include specialist bypass for Myrbetriq tablets and an automated lookback for anticholinergics for both Myrbetriq and Gemtesa.

e) **White Blood Cell Stimulants: Filgrastims—filgrastim-sndz (Zarxio)—** Zarxio was moved from step-preferred to non-step-preferred status on the filgrastim PA. This change was due to Zarxio no longer being cost-effective and due to a high degree of therapeutic interchangeability in this biosimilar class.

f) **Weight Loss Agents—semaglutide (Wegovy) and tirzepatide (Zepbound)—** The definition of uncontrolled hypertension was clarified on the Wegovy and Zepbound PAs, based on provider feedback and hypertension professional treatment guidelines. Patients are considered to have uncontrolled hypertension if they do not meet individual blood pressure goal on two or more antihypertensive drugs.

COMMITTEE ACTION: UPDATED MANUAL PA AND MN CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) updates to the manual PA criteria for Apidra, Admelog, Doptelet, Eohilia, Myrbetriq, Gemtesa, Zarxio, Zepbound, and Wegovy and updates to the MN criteria for Apidra, Admelog, and Genotropin 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) **Cardiovascular Agents Miscellaneous—ivabradine (Corlanor)—** Currently, ivabradine (Corlanor) tablets are UF, with cost effective generic formulations now available. There is stable utilization of the drug and a low risk of inappropriate use. The PA will be removed for ivabradine (Corlanor) tablets.

COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) removing the PA criteria for ivabradine (Corlanor) tablets. Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Line Extensions

The P&T Committee clarified the formulary status for 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. Metabolic Agents Miscellaneous—designating **maralixibat (Livmarli)**

tablet with the same formulary status (NF), PA and MN criteria, QL, and Specialty Drug List as the parent Livmarli solution.

2. **Antiretrovirals: Non-nucleoside Reverse Transcriptase Inhibitors**—designating **rilpivirine (Edurant Ped) tablet for oral suspension** with the same formulary status (UF) as the Edurant tablets.

COMMITTEE ACTION: LINE EXTENSION AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) the formulary, QL, PA, MN criteria and Specialty and TRICARE Maintenance Drug Lists for Livmarli tablets and Edurant Ped tablets for oral suspension. Implementation will occur the first Wednesday two weeks after signing of the minutes.

C. Prostate Cancer Agents: CYP-17 Inhibitors—abiraterone acetate (Zytiga)

Abiraterone acetate 250 mg and 500 mg tablets (Zytiga) are available in generic formulations and require administration on an empty stomach. Abiraterone acetate micronized (Yonsa) is only available as a branded agent and is taken without regard to meals. Provider feedback and prostate cancer guidelines suggest that there is a high degree of therapeutic interchangeability between these two products. Yonsa has a tier 1 copay from when the class was last reviewed in February 2019. PA criteria apply to all three abiraterone formulations. At the August 2024 meeting, the PA for Zytiga and generic formulations were given automated PA specialist bypass and drug lookback criteria to allow PA approval if the prescriber is an oncologist, hematologist or urologist and continuation by a non-specialist.

Generic Zytiga 250 mg is now the most cost effective abiraterone formulation, compared with the generic Zytiga 500 mg strength and Yonsa. The following changes were recommended:

- abiraterone acetate 250 mg (Zytiga and generic)
  - Remove PA
- abiraterone acetate 500 mg Zytiga and generic)
  - Remove automated specialist bypass and the automated drug lookback
  - Require a trial of abiraterone acetate 250 mg in new and current users
  - Send letters to current users
- abiraterone acetate micronized (Yonsa)
  - Remove Tier 1 copay
  - Require a trial of generic abiraterone 250 mg in new and current users
  - Send letters to current users

COMMITTEE ACTION: ONCOLOGICAL AGENTS: CYP-17 INHIBITORS PA CRITERIA, TIER 1 COPAY REMOVAL, RAPID RESPONSE PROGRAM, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent)

the following effective dates, as outlined below. Additionally, abiraterone acetate 500 mg (Zytiga and generic) and abiraterone acetate micronized (Yonsa) will be added to the Rapid Response (safety net) program. (See Appendix C).

- *abiraterone acetate 250 mg (Zytiga and generic) PA removal*: an effective date of the first Wednesday 2 weeks after signing of the minutes.
- *abiraterone acetate 500 mg (Zytiga and generic) and abiraterone acetate micronized (Yonsa):* 1) an effective date of the first Wednesday 120 day after signing of the minutes, and that 2) DHA send letters to the patients affected by the PA changes.

VII. BRAND OVER AUTHORIZED GENERIC AUTHORIZATION FOR UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA)

Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease—
Umeclidinium/vilanterol (Anoro Ellipta) inhaler is designated as UF without a PA. An authorized generic has entered the market; however, this product is less cost-effective compared to the branded agent. Therefore, the branded Anoro Ellipta inhaler will continue to be dispensed at all three points of service, and the authorized generic will only be available with prior authorization. The brand Anoro Ellipta will continue to have the Tier 2 copay, as the authorized generic umeclidinium/vilanterol has a Tier 2 copay.

COMMITTEE ACTION: ANORO ELLIPTA BRAND OVER GENERIC REQUIREMENT AND PA CRITERIA IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) requiring brand Anoro Ellipta inhalers over the authorized generic in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The effective date will be the first Wednesday 60 days after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. See Appendix C.

VIII. MHS GENESIS OVER-THE-COUNTER (OTC) LIST UPDATE

Background—Over-the-counter (OTC) products dispensed at MTFs comprise 1) those explicitly included as part of the pharmacy benefit (e.g., diabetic supplies), 2) those added to the pharmacy benefit after P&T Committee review under provisions of 32 CFR 199.21(h)(5) as cost effective and clinically effective compared to other drugs in the same class (e.g., loratadine tabs, cetirizine tabs, fexofenadine, levonorgestrel 1.5 mg, doxylamine 25 mg, naloxone, and norgestrel 0.075 mg), and 3) OTC products on the MHS GENESIS OTC list, which identifies drugs that will adjudicate through the Pharmacy Data Transaction Service under GENESIS and are dispensed only at MTFs.

The MHS GENESIS OTC list was instituted as an operational list to facilitate MHS GENESIS implementation; it was standardized across MTFs by DHA Administrative Instruction 6025.17 (MTF Formulary Policy, 17 July 2023), which states that "Over-the-counter (OTC) agents, on the MHS-GENESIS OTC list, will be made available when ordered by a provider. A subset of OTC medications may be made available to beneficiaries without a prescriber order upon request as part of an OTC-self-care program." The Director, DHA, has authority to expand, limit, or eliminate the MHS GENESIS OTC list.

The P&T Committee discussed concerns regarding prescription volume, personnel resources, and medical appointments associated with dispensing OTC products at MTFs, as well as pros and cons associated with dispensing products on the MHS GENESIS OTC list at MTFs. OTC drugs with no MTF dispensing in the last quarter were evaluated for potential removal from the list.

COMMITTEE ACTION: REMOVAL OF AGENTS ON THE MHS GENESIS OTC—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 0 absent) removing the following OTC products on the MHS GENESIS list with no dispensing over the last 3 months (3QFY25), comprising the following 15 generic code names (GCNs) (products defined at drug/strength/dosage form level), out of 265 GCNs total. Implementation will occur two weeks after signing of the minutes.

- 91071 – piperonyl butoxide/pyrethrins 4%-0.33% shampoo
- 97298 – omega-3 fatty acids/fish oil 340-1000 mg cap
- 52693 – omega-3/DHA/EPA/fish oil 300-1000 mg cap
- 53466 – omega-3/DHA/EPA/fish oil 115-172 mg cap delayed release
- 08380 – lactobacillus acidophilus cap (e.g., Acidophilus)
- 28678 – lactobacillus reuteri 100 mm/5drp drops susp (e.g., Gerber Soothe)
- 41197 – L. acidophilus/pectin, citrus 7.5-100 mg cap (e.g., Acidophilus)
- 36830 – petrolatum, white oint (g) (e.g., Hydrolatum)
- 77729 – mineral oil/petrolatum, white cream (e.g., Dermacerin)
- 52269 – Vit C/E/Zn/copper/lutein/zeaxan 250mg-90mg cap (e.g., Eye Health)
- 28080 – dibucaine 1% ointment
- 78090 – parab/cet alc/stearyl alc/pg/sls cleanser

IX. COMPLETELY EXCLUDED DRUGS DESIGNATED WITH COMPLETE EXCLUSION: ANNUAL REVIEW

Background— P&T Committee reviewed all drugs designated with complete exclusion from the pharmacy benefit program under 32 CFR 199.21(e)(3), which allows the Committee to recommend special Uniform Formulary actions "to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending." This specifically includes "a complete or partial exclusion from the pharmacy benefits

program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD."

Drugs designated with complete exclusion are not available at the MTFs or TMOP points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies. The Committee plans to review complete exclusion status drugs on an annual basis.

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

Two drugs were discussed in detail.

- *Diuretics— furosemide SC injection (Furoscix):* This single-use, on-body infusor administers 80 mg of furosemide over 5 hours. In addition to treating patients with congestion due to New York Heart Association Class II/III heart failure, the FDA indication was expanded to include treatment of adults with edema due to chronic kidney disease, including the nephrotic syndrome. No new clinical trials were conducted for this indication, and no studies are available to show that this device reduces heart failure hospitalizations. Furoscix is not currently mentioned in heart failure clinical practice guidelines. Feedback from cardiologists did not support a clinical need for Furoscix in practice.
- *Miscellaneous Anti-Infectives— omeprazole magnesium, amoxicillin and rifabutin (Talicia):* Talicia is approved to treat *Helicobacter pylori (H. pylori)* infections. The primary difference between this product, which combines all three components in one capsule (to be administered as 4 capsules three times daily), and the individual components taken separately, is that Talicia provides rifabutin 50 mg three times daily, while generic rifabutin is available only as a 150-mg tablet.

  The 2024 American College of Gastroenterology guidelines for treatment of *H. pylori* cite a pharmacokinetic modeling study to suggest that rifabutin 50 mg administered three times daily may have advantages relative to 150 mg administered once daily in terms of duration of time above minimum inhibitory concentration (MIC_{90}) and lower risk of transient myelosuppression. However, it is not clear from the evidence that either effect is clinically relevant, and the optimal dose of rifabutin is unknown. The guidelines suggest rifabutin triple therapy as an option for both treatment-naïve and treatment-experienced patients, with "optimized bismuth quadruple" therapy (proton pump inhibitor, bismuth, tetracycline, and metronidazole) recommended in treatment-naïve patients and patients with a penicillin allergy and suggested in treatment-experienced patients.

  Gastroenterologists and infectious disease providers did not see a need for Talicia to be on the formulary. They preferred optimized bismuth quadruple therapy and stated that they could use the individual components of Talicia instead.

COMMITTEE ACTION: UF RECOMMENDATION FOR DRUGS CURRENTLY DESIGNATED WITH COMPLETE EXCLUSION STATUS—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 1 absent) no changes to the drugs currently designated with complete exclusion status, as the products have little to no clinical benefit relative to other drugs in their respective classes, and the needs of TRICARE beneficiaries are met by alternative agents.

IX. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

A. Fertility Medications—32 CFR 199.4 excludes from coverage "services and supplies related to noncoital reproductive technologies, including but not limited to artificial insemination (including cost related to donors and semen banks), In Vitro Fertilization (IVF) and Gamete Intrafallopian Transfer (GIFT)." PAs currently apply to limit coverage of noncoital reproductive technologies for the following drugs Gonal-F (alpha), Follistim (beta), Bravelle (highly purified), Luveris, Menopur, and Repronex. Additional drugs were identified as requiring PA, due to policy. These drugs include the chorionic gonadotropins (Pregnyl, Novarel, and Ovidrel), GnRH agonists (Lupron), and GnRH antagonists (Cetrotide, Antagon). A PA will be added to these agents for new users. See Appendix C.

B. Pulmonary Arterial Hypertension: Endothelin Receptor Agonists— Pulmonary arterial hypertension (PAH) endothelin receptor agonists (ERAs) as a class require risk evaluation and mitigation strategies (REMS) due to fetal toxicity. These drugs also contain a black box warning. In April 2025, the FDA removed REMS requirements for the following ERAs: ambrisentan (Letairis, generics), macitentan (Opsumit), and macitentan/tadalafil (Opsynvi). A REMS program is still required for bosentan (Tracleer, generics). REMS criteria were removed from the PA criteria for ambrisentan (Letairis, generics), macitentan (Opsumit), and macitentan/tadalafil (Opsynvi). See Appendix C.

C. Growth Stimulating Agents—growth hormone (Genotropin) MN Criteria— Genotropin is a step-preferred growth hormone with a potential supply shortage. The non-step-preferred growth hormone MN criteria require a trial of all step-preferred growth hormone agents. In light of anticipated shortage, the MN criteria were modified to only require three short-acting and two long-acting agents.

D. DoD/VA Continuity of Care List: The DoD/VA Continuity of Care Drug List is a joint list of medications for pain, sleep disorders, psychiatric conditions, and other appropriate conditions that are deemed critical for the transition of an individual from DoD to VA care, as established by Section 715 of the NDAA 2016. Additions, deletions, and clarifications to the list are based on active duty service member prescription utilization patterns, formulary status and clinical considerations, and discussions between DoD and VA subject matter experts. The P&T Committee was notified that no new additions or deletions were

identified for the list during this year's review of FY 24 utilization trends. The list is posted on www.health.mil.

E. Therapeutic Continuous Glucose Monitoring Systems (CGMS)—FreeStyle Libre 2 and FreeStyle Libre 3 sensors market discontinuation in late 2025: The manufacturer intends to transition patients to the newest Libre 2 Plus and Libre 3 Plus systems. As of this meeting, FreeStyle Libre 2 Plus is not yet part of the TRICARE pharmacy benefit due to the UF Beneficiary Advisory Panel pause. (The TRICARE medical benefit is the primary coverage route for the CGMs.) Formulary alternatives include FreeStyle Libre 3 Plus (which is not compatible with the Omnipod systems), or Dexcom G6 or Dexcom G7 (which are compatible with Omnipod systems). Traditional fingersticks are also an option.

F. Benefit Clarification: Keratolytics—urea cream—Topical urea is used as a moisturizer and keratolytic and is available over-the-counter (OTC) and as a legend product but is not FDA approved. The legend-only strengths include urea 35%, 39%, 40%, 41%, 45%, and 47%. MTF dermatologists stated that they only used the OTC and 40% strengths and that the other strengths are not needed clinically. The 40% strength is cost-effective, while the other strengths are less cost-effective. The 41% strength is notably not cost-effective and was addressed with a PA addition at the May 2025 meeting. However, given that these products are not FDA approved, they will be excluded from the TRICARE pharmacy benefit, and the PA recommendation will not be implemented. The cost-effective urea 40% cream will remain available to beneficiaries. These changes align with commercial standards from other health plans. Current users of the 35%, 39%, 41%, 45% and 47% urea formulations will receive letters notifying them of the change, 60 days after signing of the minutes.

G. TPHARM5 Specialty Drug Update: The P&T Committee was updated on the current status of specialty products dispensed through the TMOP under the 5th Generation Pharmacy Services (TPharm5) contract, which has resulted in cost avoidance related to movement of specialty prescriptions to lower cost points of service (MTFs or TMOP), as well as lower TMOP point of service copays and enhanced clinical services for beneficiaries.

XII. ADJOURNMENT—The meeting adjourned at 1430 hours on August 7th. The next meeting will be in November 2025.

Appendix A—Attendance: August 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 Aug 2025 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Complete Exclusion Drugs and Formulary Alternatives

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:

BG Soliz/Signed/Signature on file

Acting Assistant Director
Health Care Administration and
Operations

Date 20 July2026

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen, USPHS	Chief, DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
Ruben Salinas, MD, COL (Ret.) MC, USA	DHA, Family Medicine Physician
MAJ Donald Rees, MC, for 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 Peter Cole, MC	Navy, Physician at Large
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 Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	DHA, Physician at Large
David Nowinski, PharmD, BCOP	DHA, Oncology Pharmacist
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
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Peter Glassman, MD	Department of Veteran's Affairs
Eric Dill, PharmD	Department of Veteran's Affairs
Marsha Peterson	DHA Contracting Officer
Eric Parsons, PharmD	TPharm5 Clinical COR, Pharmacy Benefit Integration Branch
Lt Col Josh Stallings	Defense Logistics Agency
Guests	
COL Thurman Saunders	Deputy, Deputy Assistant Director, Health Care Operations
CAPT Tiffany Cline, MSC	DHA POD Beneficiary Advisory Panel DFO
CPT Ji Yoon Kim, MSC	Army Pharmacist
CDR Katie Jaudon	DHA POD, Direct Car Branch
Hazel Richardson, PharmD	CDC WTCHP
Others Present	
CAPT Scott Raisor, USPHS	Chief, P&T Section, DHA POD Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA POD Formulary Management Branch
Shana Trice, PharmD	DHA POD Formulary Management Branch
CDR Elizabeth Hall, BCPS, USPHS	DHA POD Formulary Management Branch
Maj Angelina Escano, MC	DHA POD Formulary Management Branch
Lt Col Pansy Uberoi	DHA POD Formulary Management Branch
MAJ Kehinde Adesina	DHA POD Formulary Management Branch
Thinh Ha, PharmD	DHA POD Formulary Management Branch
CPT Ji Yoon Kim	DHA POD Formulary Management Branch
Michael Lee, RPh, MBM, MPharm-Econ	DHA POD Formulary Management Branch
David Folmar, RPh, MS, MBA	DHA POD Formulary Management Branch

Appendix A—Attendance

Helen Feinstein, PharmD	DHA POD Formulary Management Branch
Fakhrudin Valibhai, PharmD	DHA POD Pharmacy Benefit Integration Branch
Lt Col Brandy Renner, BSC	DHA Direct Care Branch
Maj Alex Patlovany, BSC	DHA POD Direct Care Brach
LT Sarina Acharya, MSC	Navy Pharmacy Resident San Diego
Col Lisa Seltman, BSC	DHA POD
Tracy Banks	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Stephanie Erpelding	DHA Contracting
Jules Canaley	DHA Contracting
Dwight Bonham	DHA Contracting
Kirk Heyen	DHA Contracting

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity (MN) Criteria
New Drugs MN Criteria	
• chlortalidone 12.5 mg tabs (Hemiclor) **Diuretics**	• No alternative formulary agent: Patient requires a thiazide diuretic and cannot take hydrochlorothiazide 25 mg or cut chlorthalidone 25 mg tablets in half **Formulary alternatives**: chlorthalidone 25 mg tabs, hydrochlorothiazide tabs
• garadacimab injection (Andembry) **Corticosteroids-Immune Modulators**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Use of formulary agents has resulted in therapeutic failure **Formulary alternatives**: C1-inhibitor (Haegarda), C1-inhibitor (Cinryze), lanadelumab (Takhzyro)
• hydrocortisone 1 mg/mL oral solution (Khindivi) **Corticosteroids-Immune Modulators**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents **Formulary alternatives**: generic hydrocortisone 5 mg tablets, prednisone intensol oral solution, hydrocortisone 100 mg act-O-vials
• losartan 10 mg/mL oral suspension (Arbli) **Renin-Angiotensin Antihypertensives**	• No alternative formulary agent: Patient requires a liquid losartan formulation due to a documented medical condition and not due to convenience **Formulary alternatives**: losartan tabs, telmisartan, valsartan
• terazosin 1 mg/mL oral solution (Tezruly) **BPH Agents**	• No alternative formulary agent: Patient requires a liquid alpha blocker formulation due to a documented medical condition and not due to convenience **Formulary alternatives:** tamsulosin, alfuzosin, terazosin caps, doxazosin
• ustekinumab (unbranded Stelara) by Jannsen • ustekinumab-srlf (Imuldosa) **TIBs: IL-23**	• Patient has experienced significant adverse effects from formulary agents • No alternative formulary agent: Patient has tried brand Stelara **Formulary alternatives**: adalimumab (Humira), ixekizumab (Taltz), ustekinumab-stab (Steqeyma), ustekinumab-auuz (Otulfi), ustekinumab-auub (Wezlana), ustekinumab (Stelara)
Other MN Criteria	
• iptacopan (Fabhalta) **Hematological Agents**	**Updates from the August 2025 meeting are in bold** • Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure • **No alternative formulary agent –patient is not able to access an infusion center ~~or patient has C3G glomerulopathy~~**

Appendix B—Table of Medical Necessity Criteria

	Formulary alternatives for PNH pegcetacoplan (Empaveli); **for IgAN: Filspari, Vanrafia, empagliflozin, dapagliflozin**
• glulisine (Apidra) • lispro (Admelog) **Insulins: Rapid-Acting Agents**	**Updates from the August 2025 meeting are in bold** • Use of insulin aspart (Novolog), insulin lispro (Humalog or authorized generic insulin lispro) **and Insulin aspart-szjj (Merilog)** have resulted in therapeutic failure **Formulary alternatives**: insulin aspart (Novolog), insulin lispro (Humalog or authorized generic lispro), **and insulin aspart-szjj (Merilog)**
• growth hormone (Genotropin) **Growth Stimulating Agents**	**Updates from the August 2025 meeting are in bold** • ~~**Use of all step-preferred formulary agents is contraindicated**~~ **Use of 3 short-acting and 2 long-acting step-preferred formulary agents are contraindicated** • Patient has experienced significant adverse effects from ~~**all**~~ **3 short-acting and 2 long-acting** step-preferred formulary agents **Formulary alternatives**: short-acting: somatropin (Norditropin), somatropin (Genotropin), somatropin (Omnitrope), somatropin (Zomacton); long-acting: somatrogon-ghla (Ngenla); somapacitan-beco (Sogroya)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• dupilumab (Dupixent) **Atopy: IL-13, IL-31**	**Updates from the August 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Dupixent Manual PA criteria: Coverage is approved if all criteria are met: For all indications • Non-FDA-approved uses are not approved • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair]) Atopic Dermatitis indication • The patient is at least 6 months of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe or uncontrolled atopic dermatitis • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 6 months to 17 years of age: any topical corticosteroid ▪ For patients 2 years of age and older: topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala] or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires after 12 months Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy Asthma indication • The patient is 6 years of age or older • The drug is prescribed by an allergist, immunologist **or** pulmonologist**~~, or asthma specialist~~** • The patient has one of the following ▪ Moderate to severe asthma with an eosinophilic phenotype, with baseline eosinophils ≥ 150 cells/microliter OR ▪ Oral corticosteroid-dependent asthma with at least 1 month of daily oral corticosteroid use within the past 3 months • For eosinophilic asthma, the patient's asthma must be uncontrolled despite adherence to optimized medication therapy regimen as defined as requiring one of the following; ▪ Hospitalization for asthma in past year OR ▪ Two courses oral corticosteroids in past year OR

	▪ Daily high-dose inhaled corticosteroids with inability to taper off of the inhaled corticosteroids • For eosinophilic asthma, the patient has tried and failed an adequate course (3 months) of two of the following while using a high-dose inhaled corticosteroid: ▪ Long-acting beta agonist (LABA e.g., Serevent, Striverdi), ▪ Long –acting muscarinic antagonist (LAMA e.g. Spiriva, Incruse), or ▪ Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) Non-FDA-approved uses are not approved Prior authorization expires after 12 months Renewal criteria for asthma: 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: • **The patient's disease severity has improved and stabilized to warrant continued therapy** ~~has had a positive response to therapy with a decrease in asthma exacerbations, improvements in forced expiratory volume in one second(FEV1) or decrease in oral corticosteroid use~~ Chronic rhinosinusitis with nasal polyposis indication • The patient is 12 years of age or older • The drug is prescribed by allergist, immunologist, pulmonologist, or otolaryngologist • The patient has chronic rhinosinusitis with nasal polyposis defined by all of the following: • Presence of nasal polyposis is confirmed by imaging or direct visualization AND • At least two of the following: mucopurulent discharge, nasal obstruction and congestion, decreased or absent sense of smell, or facial pressure and pain • Dupixent will only be used as add-on therapy to standard treatments, including nasal steroids and nasal saline irrigation • The symptoms of chronic rhinosinusitis with nasal polyposis must continue to be inadequately controlled despite all of the following treatments: ▪ Adequate duration of at least TWO different high-dose intranasal corticosteroids AND ▪ Nasal saline irrigation AND • The patient has a past surgical history or endoscopic surgical intervention or has a contraindication to surgery • Patients with chronic rhinosinusitis with nasal polyposis must use only the 300 mg strength Non-FDA-approved uses are not approved Prior authorization expires in 12 months Renewal criteria for rhinosinusitis: 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: • **The patient's disease severity has improved and stabilized to warrant continued therapy** • ~~There is evidence of effectiveness as documented by decrease in nasal polyps score or nasal congestion score~~

	Eosinophilic Esophagitis (EoE) indication • The patient is one year of age or older and weighs at least 15 kilograms (approximately 33 lbs) • The drug is prescribed by or in consultation with a gastroenterologist ~~**or allergy/immunology specialist**~~ **allergist or immunologist** • Patient has a documented diagnosis of Eosinophilic Esophagitis (EoE) by endoscopic biopsy • For EoE, the patient has tried and failed an adequate course of both the following: ▪ Proton pump inhibitor (PPI) at up to maximally indicated doses (adults: 20-40 mg twice daily omeprazole equivalent; children: 1-2mg/kg or equivalent), unless contraindicated or clinically significant adverse effects are experienced AND ▪ Topical glucocorticoids [e.g., fluticasone (Flovent), budesonide (Pulmicort)] at up to maximally indicated doses, unless contraindicated, or clinically significant adverse effects are experienced, ~~or in children maximal doses cannot be reached due to concerns for growth suppression or adrenal insufficiency~~ Non-FDA approved uses are not approved Prior authorization expires after 12 months <u>Renewal criteria for EoE: Note that</u> initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met: • ~~Eosinophilic Esophagitis (EoE):~~ **The patients disease severity has improved and stabilized to warrant continued therapy** ~~• For maintenance: patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e):~~ ~~• Reduced intraepithelial eosinophil count; OR~~ ~~• Decreased dysphagia/pain upon swallowing; OR~~ ~~• Reduced frequency/severity of food impaction; OR~~ ~~• Reduced vomiting/regurgitation; OR~~ ~~• Improvement in oral aversion/failure to thrive~~ ~~• For relapse: prior authorization form or chart notes documenting relapse after treatment was discontinued since last approval~~ Prurigo Nodularis Indication: • Patient is 18 years of age or older • The drug is prescribed by an allergist, immunologist, or dermatologist • Patient has a diagnosis of prurigo nodularis • Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk • Patient has experienced pruritus for 6 weeks or longer • Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR • The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed • The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream

	• The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy • **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])** Non-FDA approved uses are not approved ~~Prior authorization does not expire for prurigo nodularis~~ **Prior authorization expires after 12 months** Renewal criteria for prurigo nodularis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met: • ~~Prurigo nodularis:~~ **The patient's disease severity has improved and stabilized to warrant continued therapy** Chronic Obstructive Pulmonary Disease (COPD) indication • Patient is 18 years of age or older • Prescribed by a pulmonologist • Patient has moderate to severe chronic obstructive pulmonary disease (COPD) with both chronic bronchitis and an eosinophilic phenotype (greater than 300 cells/microliter) • Patient has uncontrolled COPD symptoms despite the use of all of the following: long-acting muscarinic antagonists (e.g., tiotropium bromide); long-acting-beta agonists (e.g., formoterol); inhaled corticosteroid (e.g., budesonide) • Medication is being requested for add-on maintenance therapy for management of COPD • **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])** Non-FDA approved uses are not approved Prior authorization expires after 12 months Renewal Criteria for COPD: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy **Chronic Spontaneous Urticaria indication** • **Patient is 12 years of age or older** • **Prescribed by an allergist, immunologist or dermatologist** • **Patient has a diagnosis of chronic spontaneous urticaria with symptoms lasting longer than 6 weeks** • **Patient remains symptomatic despite a trial of at least 4 weeks up to 4 times the standard dosing of a second-generation histamine H-1 antihistamine (i.e., cetirizine, levocetirizine, loratadine, desloratadine, fexofenadine)** • **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])** **Non-FDA approved uses are not approved** **Prior authorization expires after 12 months**

	Renewal criteria for chronic spontaneous urticaria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • **Patient's disease severity has improved and stabilized to warrant continued therapy** **Bullous Pemphigoid indication** • **Patient is 18 years of age or older** • **Prescribed by a dermatologist, allergist, or immunologist** • **Patient has a confirmed diagnosis of bullous pemphigoid** • **Patient has an initial bullous pemphigoid disease area index (BPDAI) score greater than or equal to 24** • **Patient has an initial Peak Pruritus Numeric Rating Scale score of greater than or equal to 4** • **The patient has a contraindication to, intolerability to, or has failed treatment with all the following:** ▪ **One high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream)** ▪ **One oral corticosteroid (e.g., prednisone, prednisolone)** ▪ **Two additional adjuncts (e.g., methotrexate, azathioprine, mycophenolate, cyclophosphamide, doxycycline)** **Non-FDA approved uses are not approved** **Prior authorization expires after 12 months** **Renewal criteria for bullous pemphigoid: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met:** • **Patient's disease severity has improved and stabilized to warrant continued therapy**
• lebrikizumab (Ebglyss) **Atopy: IL-13, IL-31**	**Updates from the August 2025 meeting are in bold** **Automated PA criteria: When the patient is 12 years of age and older AND when prescribed by a dermatologist, allergist or immunologist, prior authorization is not required. Once therapy is initiated by a dermatologist, allergist or immunologist, an automated drug lookback will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days OR** Manual PA criteria apply to all new users of lebrikizumab-lbkz (Ebglyss) if automated criteria are not met Manual PA criteria: Coverage is approved if all criteria are met: Atopic Dermatitis Indication • Patient is 12 years of age or older • Patient's weight is 40 kg or greater • The drug is prescribed by a dermatologist, allergist or immunologist • Patient has diagnosis of moderate to severe atopic dermatitis • Patient has contraindication to, intolerability to, or has failed treatment with ONE medication in EACH of the following categories: ▪ Topical corticosteroids – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) or – For patients 12 to 17 years of age: any topical corticosteroid ▪ Topical calcineurin inhibitors (i.e., tacrolimus, pimecrolimus)

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	• Patient has a contraindication to, intolerability to, inability to access treatment, or patient failed treatment with Narrowband UVB phototherapy • For all indications the patient is not currently receiving another immunobiologic therapy **(e.g., benralizumab [Fasenra], mepolizumab [Nucala}, or omalizumab [Xolair])** Non-FDA approved uses are not approved PA expires after 12 months Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• tralokinumab (Adbry) **Atopy: IL-13, IL-31**	**Note that there were no changes from the August 2025 meeting** Manual PA criteria apply to all new users of Adbry. Manual PA criteria: Adbry is approved if all criteria are met: • Patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 12 to 17 years of age: any topical corticosteroid. ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy • The patient is not currently receiving another immunobiologic therapy (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA-approved uses are not approved Prior authorization expires in 12 months Renewal criteria: Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• nemolizumab (Nemluvio) **Atopy: IL-13, 31**	**Updates from the August 2025 meeting are in bold** Manual PA criteria apply to all new users of nemolizumab (Nemluvio) Manual PA criteria: Coverage is approved if all criteria are met: Prurigo Nodularis Indication: • Patient is 18 years of age or older • Nemluvio is prescribed by an allergist, immunologist, or dermatologist • Patient has a diagnosis of prurigo nodularis • Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk

	• Patient has experienced pruritus for 6 weeks or longer • Patient's prurigo nodularis is not medication-induced or secondary to a non-dermatologic condition OR • The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed • The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroid (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy • The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair]) Non-FDA approved uses are not approved ~~Prior authorization does not expire for prurigo nodularis~~ **Prior authorization expires in 12 months** **Renewal criteria for prurigo nodularis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following criteria are met:** • **Patient's disease severity has improved and stabilized to warrant continued therapy** Atopic Dermatitis Indication: • Patient is 12 years of age or older • The drug is prescribed by a dermatologist, allergist, or immunologist • The patient has moderate to severe atopic dermatitis • The patient has a contraindication to, intolerability to, or has failed treatment with one medication in each of the following categories: ▪ Topical Corticosteroids: – For patients 18 years of age or older: high potency/ class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) – For patients 12 to 17 years of age: any topical corticosteroid ▪ Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with Narrowband UVB phototherapy • **The patient is not currently receiving another immunobiologic (e.g., benralizumab [Fasenra], mepolizumab [Nucala], or omalizumab [Xolair])** Non-FDA approved uses are not approved Prior authorization expires in 12 months Renewal criteria for atopic dermatitis: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the following applies: • Patient's disease severity has improved and stabilized to warrant continued therapy

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• finerenone (Kerendia) **Mineralocorticoid Receptor Antagonists**	**Updates from the August 2025 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Kerendia Manual PA criteria: Kerendia is approved if all criteria are met: • Patient is 18 years of age or older **For Type 2 Diabetes Mellitus and Chronic Kidney Disease** • Kerendia is prescribed by or in consultation with a nephrologist • The patient has a diagnosis of type 2 diabetes mellitus (T2DM) • The patient has documented diabetic kidney disease with albuminuria, defined as ~~one of the following~~ ▪ An estimated glomerular filtration rate (eGFR) of 25-75 AND urinary albumin-to-creatinine ratio of ≥ 30 mg/g ~~OR~~ ~~▪ eGFR 25-60 with albuminuria > 30mg/g plus diabetic retinopathy~~ • Patient has been taking max-dose ACE inhibitor or ARB ~~for at least 4 weeks~~ **or has a contraindication to ACE inhibitor or ARB or is unable to tolerate ACE or ARB** • Patient **is maintained on an** ~~has tried DoDs preferred~~ sodium-glucose-co-transporter 2 (SGLT-2) inhibitor [**e.g., empagliflozin (Jardiance) note that-empagliflozin is TRICARE's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor** • The patient is receiving other appropriate background therapy for diabetes and chronic kidney disease • **Patient's potassium is less than 5 mEq/mL at initiation of therapy** • **Provider agrees to discontinue Kerendia if the patient begins renal replacement therapy** ~~• Patient does not have uncontrolled hypertension (>170/110 mmHg) at initiation of Kerendia therapy~~ ~~• Patient does not have renal artery stenosis~~ ~~• Patient is not concomitantly taking CYP3A4 inhibitors (e.g., ketoconazole, diltiazem, verapamil, clarithromycin, erythromycin, etc) or inducers (e.g., rifampicin, phenobarbital, phenytoin, etc)~~ ~~• Women of child-bearing potential must have a negative pregnancy test, and have received counseling for using 2 forms of contraception~~ **For Heart Failure with Preserved Ejection Fraction (HFpEF)** • **Prescribed by or in consultation with a cardiologist** • **Patient has a documented diagnosis of chronic heart failure (New York Heart Association (NYHA) class II-IV) with a left ventricular ejection fraction (LVEF) greater than 40% and with continued heart failure symptoms** • **Patient is maintained on an SGLT2 inhibitor [e.g., empagliflozin (Jardiance) note that-empagliflozin is TRICARE's preferred SGLT2 inhibitor and does not require PA or dapagliflozin] or has a contraindication to or is unable to tolerate an SGLT2 inhibitor** • **Patient is maintained on other guideline-directed therapy for heart failure** • **Patient's potassium is less than 5 mEq/mL at initiation of therapy** Non-FDA approved uses are not approved including patients undergoing renal transplant Prior authorization does not expire

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• spironolactone oral suspension (Carospir, generic) **Mineralocorticoid Receptor Antagonists**	Manual PA criteria apply to all new users of spironolactone oral suspension (Carospir) Age Edit: PA does not apply to children 12 year of age and younger Manual PA criteria—Coverage is approved if all criteria are met: • The patient has heart failure, hypertension or edema from cirrhosis • The provider must write in why the patient requires CaroSpir and cannot take an aldosterone blocker / potassium-sparing 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 Prior Authorization does not expire
Newly Approved Drug PAs	
• acetaminophen 325 mg/ ibuprofen 97.5 mg (Combogesic) **Analgesics and Combinations**	**Updates from the current PA are in bold** Manual PA criteria apply to all new and current users of acetaminophen and ibuprofen tablets (Combogesic) Manual PA criteria: Coverage is approved if all criteria are met: • **Provider acknowledges that Combogesic 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** • **Provider acknowledges that other formulations of acetaminophen and ibuprofen are available to TRICARE beneficiaries and do not require prior authorization** • Patient is 18 years of age or older • Patient is being treated for short-term mild to moderate acute pain • Provider must document why the patient cannot take formulary alternatives or OTC products ▪ Acceptable responses include: the patient has tried all the listed agents including acetaminophen 325 mg tablet, acetaminophen 500 mg tablet, acetaminophen 160 mg/5ml solution/suspension, ibuprofen 200 mg tablet, ibuprofen 800 mg tablet, ibuprofen 100 mg/5ml solution/suspension Non-FDA approved uses are not approved PA does not expire **until after implementation of complete exclusion status**
• acoltremon 0.003% ophthalmic solution (Tryptyr) **Ophthalmic: Dry Eye**	**Updates from the current PA are in bold and strikethrough** Manual PA criteria apply to all new users of acoltremon 0.003% ophthalmic solution (Tryptyr) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by an ophthalmologist or optometrist • Patient has signs and symptoms of dry eye disease as supported by both of the criteria below: ▪ Positive symptomology screening for dry eye disease from an appropriate measure ▪ At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following:

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	▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is nonpreserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) ▪ 3-month trial of cyclosporine 0.05% (Restasis, generics)~~,~~ **~~cyclosporine 0.09% (Cequa), and lifitegrast (Xiidra)~~** Non-FDA approved uses are not approved PA does not expire
• atrasentan (Vanrafia) **Nephrology Agents Miscellaneous**	Manual PA criteria apply to all new users of Vanrafia Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by a nephrologist • The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN**)** without cellular crescents in more than 25% of sampled glomeruli • Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/gram • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2 • Patient is not currently receiving dialysis or has not undergone kidney transplant • Patient has not received immunosuppressants, including corticosteroids, in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months • Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and is at high risk for disease progression • The patient's baseline liver aminotransferase (AST and ALT) levels are not elevated to greater than 3 times the upper limit of normal • If patient is a female of child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation • If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation Non-FDA approved uses are not approved, including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires in 9 months Renewal criteria: Coverage will be approved indefinitely if all the following apply • Patient has had a response to Vanrafia defined by: ▪ reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR ▪ reduction in proteinuria from baseline AND • Patient's eGFR rate ≥ 30 mL/min/1.73 m2
• avutometinib / defactinib (Avmapki Fakzynja Co-pack) **Oncological Agents**	Manual PA criteria apply to all new users of avutometinib capsules/defactinib tablets (Avmapki Fakzynja Co-Pack) 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 • Patient has recurrent low-grade serous ovarian cancer • The cancer has a KRAS mutation • Patient has tried at least one systemic therapy • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, 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
• berdazimer 10.3% topical gel (Zelsuvmi) **Anti-infectives**	**Updates from the current PA criteria are in bold and strikethrough** Manual PA criteria apply to all new users of berdazimer 10.3% (Zelsuvmi) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 2 years of age or older • Prescribed by a dermatologist • Patient has a diagnosis of molluscum contagiosum which fulfills all the following criteria: ▪ Treatment is not solely due to cosmetic concern ▪ The lesions must be symptomatic (e.g. painful, itchy) • A single lesion will be treated with Zelsuvmi for no more than 12 weeks • Provider must explain why this agent is required and cannot be treated with ALL the following: cryotherapy, AND curettage, AND two additional topical agents ▪ Acceptable responses include the following: Patient has contraindication to, intolerability to, or has failed treatment with cryotherapy, AND curettage, AND two additional topical treatments (e.g. salicylic acid, cantharidin (Ycanth)) Non-FDA approved uses are not approved. PA expires after 3 months. Renewal PA criteria: **No renewal allowed. When the PA expires, the next fill/refill will require submission of a new PA** ~~Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for 3 months for continuation of therapy if all the criteria are met:~~ ~~• Patient has documentation of positive clinical response defined as clearance or reduction in number of lesions with Zelsuvmi treatment~~ ~~• Patient requires ongoing treatment of molluscum contagiosum lesions which must be symptomatic (e.g. painful, itchy)~~ ~~• Prescribed by a dermatologist~~
• chlorthalidone 12.5 mg tabs (Hemiclor) Diuretics	**Updates from the current PA are in bold** Manual PA criteria apply to all new users of Hemiclor Manual PA criteria: Coverage is approved if all criteria are met • **Provider acknowledges that generic chlorthalidone 25 mg and 50 mg tablets can be split or crushed and are available to TRICARE beneficiaries without Prior Authorization** • Patient is 18 years of age or older • Patient has hypertension **or edema from congestive heart failure, hepatic cirrhosis, or renal disease**

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	• Provider must write in why the patient requires Hemiclor and cannot take a loop diuretic AND a thiazide diuretic in a tablet formulation ▪ Acceptable responses: Patient has tried and failed chlorthalidone 25 mg and 50 mg tablets or hydrochlorothiazide 25 mg tablets. Non-FDA-approved uses are not approved PA does not expire
• efgartigimod alfa-fcab injection (Vyvgart Hytrulo) **Miscellaneous Neurological Agent**	**Updates from the current PA criteria are in bold** Manual PA criteria apply to all new users of efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by a neurologist • Patient is being treated for chronic inflammatory demyelinating polyneuropathy OR • Patient is being treated for generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AchR) antibody positive • For patients being treated for generalized myasthenia gravis: ▪ Patient had insufficient response or intolerance to pyridostigmine AND ▪ Patient had insufficient response or intolerance to glucocorticoid sparing therapy such as azathioprine, mycophenolate, cyclosporine, or tacrolimus • Patient is not receiving concomitant neonatal Fc receptor antagonists or other C5 inhibitors with Vyvgart Hytrulo **including but not limited to the following: efgartigimod injection for intravenous use (Vyvgart), eculizumab (Soliris), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), or zilucoplan (Zilbrysq)** Non-FDA approved uses are not approved PA expires in 6 months <u>Renewal criteria:</u> Note that initial TRICARE PA approval required for renewal. Coverage will be approved indefinitely if the following applies: • The patient's disease severity has improved and stabilized to warrant continued therapy
• ensartinib (Ensacove) **Oncological Agent**	Manual PA criteria apply to all new users of ensartinib (Ensacove) <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist or oncologist • Patient has locally advanced or metastatic non-small cell lung cancer (NSCLC) • Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected by an FDA-approved test • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation: to facilitate approval, please list the diagnosis, guideline version, and page number _____ Other non-FDA approved uses are not approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• fitusiran injection (Qfitlia) **Antihemophilic Factors**	**Updates from the current PAg are in bold** Manual PA criteria apply to all new users of fitusiran (Qfitlia) 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 or without factor VIII inhibitors or hemophilia B with or without factor IX inhibitors • Patient is not concurrently receiving factor VIII or factor IX therapy after initial transition period unless for the treatment of breakthrough bleeding • **For patients with hemophilia A, patient has had an inadequate response, intolerance, or contraindication to emicizumab-kxwh (Hemlibra)** Non-FDA approved uses are not approved PA does not expire
• garadacimab injection (Andembry) **Corticosteroids Immune Modulators**	**Updates from the current PA are in bold** Manual PA criteria apply to all new users of garadacimab (Andembry) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 12 years of age or older • The patient has a diagnosis of hereditary angioedema (HAE) • Andembry is prescribed for prophylaxis to prevent attacks of hereditary angioedema • Prescribed by an allergist, immunologist, rheumatologist, or HAE specialist • The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., **two or more~~2~~** HAE attacks/month, or laryngeal attacks, etc.) • The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly) • The patient has had an inadequate response, adverse reaction, or contraindication to all of the following: ▪ One C1-inhibitor (e.g., Cinryze, Haegarda, Berinert, Ruconest) ▪ One Kallikrein inhibitor (e.g., Takhzyro, Orladeyo) Non-FDA-approved uses not approved Prior Authorization does not expire
• hydrocortisone 1mg/mL oral solution (Khindivi) **Corticosteroids-Immune Modulators**	**Updates from the current PA are in bold** Manual PA criteria apply to all new of hydrocortisone oral solution (Khindivi) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is at least 5 years of age • Patient is not **older ~~greater~~** than 18 years of age • Provider acknowledges that the following products are available without a prior authorization: 5 mg generic hydrocortisone tablets, **hydrocortisone 100 mg act-O-vials**, and prednisone Intensol oral solution. Please consider changing the prescription to one of these agents • Patient is using **Khindivi** as replacement therapy for adrenocortical insufficiency • Provider acknowledges that the patient's dosing regimen requires small doses of hydrocortisone and cannot accurately split the dose using 5 mg hydrocortisone tablets

Appendix C—Table of Prior Authorization (PA) Criteria

	• **Provider must explain why this agent is required and patient cannot take generic hydrocortisone tablets, Alkindi Sprinkle, hydrocortisone 100 mg act-O-vials, and prednisone Intensol oral solution. Blank write in _____** ▪ **Acceptable response: patient requires a g-tube** Non-FDA approved uses are not approved PA does not expire
• losartan 10 mg/mL oral suspension (Arbli) **Renin Angiotensin Antihypertensives**	Manual PA criteria apply to all new users of losartan oral suspension (Arbli) Automated PA Criteria: Age Edit: PA not required if patient is 12 years of age and younger Manual PA Criteria: Coverage is approved if all criteria are met: • Provider must write in why the patient requires Arbli oral suspension and cannot take losartan tablets ▪ Acceptable response: Patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience Non-FDA approved uses are not approved PA does not expire
• meloxicam 20 mg/ rizatriptan 10 mg tabs (Symbravo) **Migraine Agents: Triptans**	**Updates from the current meeting are in bold** Manual PA criteria apply to all new and current users of meloxicam and rizatriptan (Symbravo) Manual PA criteria: Coverage is approved if all criteria are met: • **Provider acknowledges that Symbravo 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** • **Provider acknowledges that other formulations of triptans are available to TRICARE beneficiaries and do not require prior authorization including eletriptan, sumatriptan, rizatriptan** • Patient is 18 years of age or older • Patient is being treated for acute treatment of migraine with or without aura • Provider must document why the patient cannot use rizatriptan tablet and meloxicam tablet. ▪ Acceptable responses include: the patient has had an adverse reaction to an excipient in either rizatriptan tablet and/or meloxicam tablet that would not be likely to occur with Symbravo Non-FDA approved uses are not approved. PA does not expire **until after implementation of complete exclusion status**

• nilotinib d-tartrate 50 mg, 150 mg and 200 mg caps (no brand name)
 	
Oncological Agents
	Manual PA criteria apply to all new users of nilotinib tartrate capsule
	Manual PA criteria: Coverage is approved if all criteria are met:
	• Provider acknowledges Prior Authorization is not required for Tasigna capsules. Please consider changing the prescription to Tasigna.
	• Prescribed by or in consultation with a hematologist or oncologist
	• Patient is 18 years of age or older
	• Patient has a diagnosis of either:
	  ▪ Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase OR
	  ▪ Chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib

Appendix C—Table of Prior Authorization (PA) Criteria

	• The patient has tried nilotinib tartrate tablet (Danziten) and had an adverse reaction to an excipient that would not be likely to occur with nilotinib tartrate capsule • The diagnosis is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval please list the diagnosis, guidelines version and page number:_____ Other non-FDA approved uses are not approved except as noted above PA does not expire
• taletrectinib (Ibtrozi) **Oncological Agents**	Manual PA criteria apply to all new users of taletrectinib (Ibtrozi) 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 • Patient has locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) • 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
• terazosin 1 mg/mL oral solution (Tezruly) **BPH Agents**	Manual PA criteria apply to all new users of terazosin oral solution (Tezruly) Manual PA criteria: Coverage is approved if all criteria are met: • Provider must write in why the patient requires Tezruly and cannot tolerate the terazosin capsules ▪ 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
• treprostinil inhalation powder (Yutrepia) **PAH Agents**	Manual PA criteria apply to all new users of treprostinil inhalation powder (Yutrepia) Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by or in consultation with a cardiologist or a pulmonologist • Patient has WHO Group 1 pulmonary arterial hypertension (PAH) OR WHO Group 3 pulmonary hypertension with interstitial lung disease (PH-ILD) • Patients with WHO Group 1 PAH have had a right heart catheterization • Documentation was provided to confirm that patient had the procedure and confirmed diagnosis of WHO Group 1 PAH Non-FDA approved uses are not approved PA does not expire
• ustekinumab (ustekinumab by Janssen) • ustekinumab-srlf (Imuldosa) **TIBs: IL-23**	**Updates from the August meeting are in bold** Manual PA criteria apply to all new users of ustekinumab (ustekinumab by Janssen) and ustekinumab (Imuldosa) Manual PA Criteria: Coverage is approved if all criteria are met: • 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 Stequeyma, 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**
• ustekinumab-aekn (unbranded Selarsdi private label) **TIBs: IL-23**	Manual PA criteria apply to all new users of ustekinumab-aekn (unbranded Selarsdi) <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that this unbranded ustekinumab aekn 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-aekn (unbranded Selarsdi) 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 unbanded ustekinumab-ttwe **Non-FDA approved uses are not approved**

Appendix C—Table of Prior Authorization (PA) Criteria

	~~**PA expires in 120 days, when the complete exclusion status is implemented**~~ **PA does not expire until after implementation of complete exclusion status**
Utilization Management PAs	
• bisoprolol 2.5 mg tablet **Beta Blockers and Hydrochlorothiazide Combinations**	Manual PA criteria apply to all new users of bisoprolol 2.5 mg tablet. Manual PA criteria: bisoprolol 2.5 mg tablet is approved if all criteria are met: • Provider acknowledges other formulations of bisoprolol tablets are available without prior authorization. • Provider must explain why the patient requires bisoprolol 2.5 mg tablet and cannot take the cost-effective generic bisoprolol 5 mg 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 bisoprolol formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• buspirone capsules (Bucapsol) **Antianxiety Agents**	Manual PA criteria apply to all new users of buspirone capsules (Bucapsol). Manual PA criteria: buspirone (Bucapsol) is approved if all criteria are met: • Provider acknowledges other formulations of buspirone tablets are available without prior authorization. • Provider must explain why the patient requires buspirone capsules (Bucapsol) and cannot take the cost-effective generic buspirone tablet 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 buspirone formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• clemastine (Clemasz) **Antihistamine-1: First Generation and Combos**	Manual PA criteria apply to all new users of clemastine (Clemasz). Manual PA criteria: clemastine (Clemasz) is approved if all criteria are met: • Provider acknowledges other formulations of clemastine are available without prior authorization. • Provider must explain why the patient requires clemastine (Clemasz) and cannot take the cost-effective generic clemastine 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 clemastine formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• diflunisal (Dolobid) 375 mg tablet **Pain Agents: NSAID**	Manual PA criteria apply to all new users of diflunisal 375 mg tablets (Dolobid). Manual PA criteria: diflunisal (Dolobid) is approved if all criteria are met: • Provider acknowledges other formulations of diflunisal are available without prior authorization. • Provider must explain why the patient requires diflunisal 375 mg tablets (Dolobid) and cannot take the cost-effective generic diflunisal 250 mg or 500 mg 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 diflunisal formulations Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• flurbiprofen (Lurbipr) **Pain Agents: NSAIDs**	Manual PA criteria apply to all new users of flurbiprofen (Lurbipr). Manual PA criteria: flurbiprofen (Lurbipr) is approved if all criteria are met: • Provider acknowledges other formulations of flurbiprofen are available without prior authorization. • Provider must explain why the patient requires flurbiprofen (Lurbipr) and cannot take the cost-effective generic flurbiprofen 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 flurbiprofen formulations Non-FDA-approved uses are not approved Prior authorization does not expire
• metformin 625 mg IR tablet **Diabetes Non-Insulin: Bigaunides**	Manual PA criteria apply to all new users of metformin 625 mg IR tablet. Manual PA criteria: metformin 625 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 625 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
• leuprolide acetate (Lutrate Depot) 22.5 mg (3 month) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	Manual PA criteria apply to all new users of Lupron Depot, **Lutrate Depot**, and leuprolide acetate (no brand name) Manual PA criteria: Coverage is approved if all criteria are met: • If patient is 18 years of age or younger, PA is not approved if indication is gender dysphoria • For patients 18 years of age or older, or for younger patients using for other indications besides gender dysphoria, proceed with the following questions: ▪ Provider is aware leuprolide acetate SQ (Eligard) is the preferred leuprolide product and does not require PA ▪ Patient has tried and failed or has not been able to tolerate Eligard PA does not expire
• mepolizumab (Nucala) **Atopy**	**Updates from the August 2025 meeting for COPD are listed below** Note that there were no changes to the PA criteria for eosinophilic asthma, eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyps and hyper-eosinophilic syndrome (HES) Manual PA criteria apply to all new users of Nucala Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by a pulmonologist • Patient has moderate to severe COPD and an eosinophilic phenotype (>150 cells/ul) • Patient has uncontrolled COPD symptoms despite the use of long-acting muscarinic antagonists (e.g., tiotropium bromide); long-acting-beta agonists (e.g., formoterol); or inhaled corticosteroid (e.g., budesonide) • Medication is being requested for add-on maintenance therapy for management of COPD

Appendix C—Table of Prior Authorization (PA) Criteria

	Non-FDA approved uses are not approved PA expires following 12 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient's disease severity has improved and stabilized to warrant continued therapy
• upadacitinib (Rinvoq) **Atopy: Oral JAK-1**	**Updates from the August 2025 meeting for Giant Cell Arteritis are listed below**. Note that there were no changes to the current Rinvoq criteria for the other indications (rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, Crohn's Disease, ankylosing spondylitis, or atopic dermatitis) Manual PA criteria apply to all new users of upadacitinib (Rinvoq). 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 rheumatologist • Patient has a diagnosis of giant cell arteritis • Patient has tried and failed, or has a contraindication to, or has had an adverse reaction to both of the following: ▪ glucocorticoid ▪ tocilizumab (Tyenne; Actemra) • Patient is not receiving other targeted immunomodulatory biologics with Rinvoq Non-FDA approved uses are not approved PA does not expire
• osilodrostat (Isturisa) **Endocrine Agents Miscellaneous**	**Updates from August 2025 are in bold and strikethrough.** Manual PA is required for all new users of Isturisa. Manual PA Criteria: Isturisa is approved if all criteria are met: • Patient is 18 years of age of older • Patient has documented diagnosis of **endogenous hypercortisolemia with** Cushing's disease • Patient has persistent or recurrent Cushing's disease despite ~~**pituitary**~~ surgery OR • Patient in whom ~~**pituitary**~~ surgery is not indicated • Drug is prescribed by an endocrinologist, oncologist, or neurosurgeon • ~~**Provider agrees to correct hypokalemia or hypomagnesemia prior to starting Isturisa**~~ • ~~**Provider agrees to obtain baseline electrocardiogram (ECG) prior to starting Isturisa and use with caution in patients with risk factors for QTc prolongation**~~ • ~~**Patient will be monitored closely for hypocortisolism and potentially life threatening adrenal insufficiency. Dosage reduction or interruption may be necessary**~~ • ~~**Patient will be monitored for hypokalemia, worsening of hypertension, edema, and hirsutism**~~ Non-FDA-approved uses are not approved. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• iptacopan (Fabhalta)
 	
Hematological Agents
	Updates from the August 2025 meeting are in bold.
	Note that there are no changes recommended to the current PA criteria for PNH.
	Manual PA criteria apply to all new users of Fabhalta
	• **All indications**
	  • **Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and REMS requirements**
	  • **Patient is not receiving C3 or C5 inhibitors with Fabhalta, including but not limited to the following: eculizumab (Soliris), ravulizumab (Ultomiris), danicopan (Voydeya), or pegcetacoplan (Empaveli)**
	  • **Patient is 18 years of age or older**
	• **Complement 3 glomerulopathy (C3G)**
	  • **Prescribed by a nephrologist**
	  • **The patient has a diagnosis of C3G confirmed by biopsy**
	  • **Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gram**
	  • **Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2**
	  • **Patient has not undergone kidney transplant**
	  • **Patient is on maximally tolerated RAS inhibitor (ACE/ARB)**
	  • **Patient has not received complement inhibitors within the past 6 months**
	  • **Corticosteroids (prednisone doses less than or equal to 7.5 mg/day) or mycophenolate are allowed if the patient has been stable on these therapies for 90 days.**
	• Paroxysmal Nocturnal Hemoglobinuria (PNH)
	  • Prescribed by a hematologist or oncologist
	  • Patient has a documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
	  • Patient has tried and failed treatment with a C5 inhibitor for three months(e.g., eculizumab (Soliris), ravulizumab (Ultomiris)), and has residual anemia
	• IgAN
	  • Prescribed by a nephrologist
	  • The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli
	  • Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/gram
	  • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m2
	  • Patient is not currently receiving dialysis or has not undergone kidney transplant
	  • Patient has not received immunosuppressants, including corticosteroids in the past 90 days and is not expected to need immunosuppressants in the next 6 months
	  • Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and an SGLT-2 inhibitor (e.g., empagliflozin, dapagliflozin) and is at high risk for disease progression

	• Patient has failed therapy with, or has a contraindication to, or has had intolerable adverse effects with Filspari **or Vanrafia** • Patient will not use Fabhalta concomitantly with Filspari **or Vanrafia** Non-FDA approved uses are not approved including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schoenlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires after 9 months 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: • For IgAN • Patient has had a response to Fabhalta defined by • reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR • reduction in proteinuria from baseline • Patient's eGFR rate ≥ 30 mL/min/1.73 m2 • For PNH: • Patient has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, or reductions in hemolysis • **For Complement 3 glomerulopathy (C3G), patient has had a response to Fabhalta defined by:** • **Reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR** • **Reduction in proteinuria from baseline AND** • **Patient's eGFR rate ≥ 30 mL/min/1.73 m2**
• belimumab (Benlysta) **Immunosuppressives**	**Updates from the August 2025 meeting are in bold and strikethrough** Manual PA Criteria apply to all new users of belimumab (Benlysta), including patients currently receiving the IV formulation of Benlysta Manual PA criteria: Coverage is approved for Benlysta if all of the following are met: • Benlysta is prescribed by or in consultation with a specialty provider for systemic lupus erythematosus (SLE): rheumatologist, cardiologist, neurologist, nephrologist, immunologist, or dermatologist • The patient is ~~**18**~~ **5** years of age or older ~~**for active lupus nephritis or the patient is 5 years of age or older for SLE**~~ • Must have one of the following documented diagnoses: ▪ Active, autoantibody positive (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) SLE ▪ Class III, IV, or V active lupus nephritis • For SLE, the patient is concurrently taking standard therapy (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination)

Appendix C—Table of Prior Authorization (PA) Criteria

	• For active lupus nephritis, patient is concurrently receiving either mycophenolate mofetil or cyclophosphamide followed by azathioprine • The patient does not have severe active central nervous system lupus • The patient is not taking concomitant biologics (e.g., rituximab) Off-label uses are not approved Prior Authorization expires in 2 years. Renewal PA Criteria: Benlysta will be approved on a yearly basis if all of the following are met: • For SLE, treatment with Benlysta has shown documented clinical benefit (i.e., improvement in number/frequency of flares, improvement in in Safety of Estrogen in Lupus Erythematosus National Assessment – SLE Disease Activity Index (SELENA-modified SLEDAI) score, improvement/stabilization of organ dysfunction, improvement in complement levels/lymphocytopenia, etc.) • The patient is concurrently taking standard therapy for SLE (e.g., hydroxychloroquine, systemic corticosteroid and/or immunosuppressives either alone or in combination) • The patient does not have severe active central nervous system lupus • The patient is not taking concomitant biologics (e.g., rituximab)
• belzutifan (Welireg) **Oncological Agents**	**Updates from August 2025 are in bold** Manual PA criteria apply to all new users of Welireg Manual PA criteria: Welireg is approved if all criteria are met: • Welireg is prescribed by or in consultation with a hematologist/oncologist • **Patient is 12 years of age or older and has locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL) OR** • Patient is 18 years of age or older • The patient has von Hippel-Landau disease and requires therapy for associated renal cell carcinoma (RCC), CNS hemangioblastomas or pancreatic neuroendocrine tumors (pNET) not requiring **immediate** surgery OR • The patient has advanced renal cell carcinoma (RCC) **with a clear a cell component** following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) • 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, other than noted above PA does not expire
• roflumilast 0.3% foam (Zoryve) **Psoriasis Agents**	**Updates from the August 2025 meeting for plaque psoriasis are listed below**. Note that there were no changes to the PA criteria for the seborrheic dermatitis indication. Manual PA criteria apply to all new users of Zoryve foam. 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 dermatologist • Patient has a diagnosis of plaque psoriasis • The patient must have tried for at least 2 weeks and failed, have a contraindication to, or have had an adverse reaction to both of the following:

	▪ A topical corticosteroid – For patients 18 years of age or older: high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) OR – For patients 12-17 years of age: any topical corticosteroid ▪ A topical vitamin D analog (e.g. calcipotriene foam) Non-FDA approved uses are NOT approved PA does not expire
• glulisine (Apidra) • lispro (Admelog) **Insulins: Rapid-Acting Agents**	**Updates from the August 2025 meeting are in bold.** Automated PA Criteria: The patient has filled a prescription for insulin aspart (Novolog), insulin lispro (Humalog or authorized generic lispro), and **insulin aspart-szjj (Merilog)** at any MHS pharmacy point of service (MTFs, retail pharmacies or TRICARE Mail Order Pharmacy) during the previous 720 days. Manual PA criteria: if automated criteria are not met, Apidra or Admelog is approved if all criteria are met: • Provider acknowledges Novolog, Humalog and the authorized generic insulin lispro, and **Merilog** are TRICARE's preferred rapid-acting insulins. If the prescription is for Novolog, Humalog or the authorized generic insulin lispro, or **Merilog**, prior authorization is not required. • The patient has diabetes AND ▪ The patient has tried and failed insulin aspart (Novolog) AND ▪ The patient has tried and failed insulin lispro (Humalog or authorized generic insulin lispro) AND ▪ **The patient has tried and failed insulin aspart-szjj (Merilog)** OR • The patient is using an insulin pump/continuous subcutaneous insulin infusion (CSII) and is stabilized on insulin glulisine (Apidra) or insulin lispro (Admelog) Non-FDA-approved uses are not approved PA does not expire
• budesonide oral suspension (Eohilia) **GI-1 Agent**	**Updates from the August 2025 meeting are in bold.** Manual PA criteria apply to all new users of Eohilia Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by a gastroenterologist, allergy/immunology specialist, or **general surgeon** • Patient has a documented diagnosis of eosinophilic esophagitis (EoE) by endoscopic biopsy • Patient has tried and had an inadequate response, intolerance, or contraindication to a Proton Pump Inhibitor Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• avatrombopag (Doptelet) **Hematological Agents: Platelets**	**Updates from the August 2025 meeting are in bold and strikethrough.** Manual PA is required for new users of Doptelet. Manual PA Criteria: Doptelet is approved if all criteria are met: • **Drug is prescribed by or in consultation with a gastroenterologist or hematologist/oncologist** Liver Disease Indication • Patient is 18 years of age or older • ~~**Drug is prescribed by or in consultation with a gastroenterologist**~~ • Patient is diagnosed with liver disease that has caused severe thrombocytopenia (platelet < 50 x 109/L) • Patient is scheduled to undergo a procedure with a moderate to high bleeding risk within 10-13 days after starting avatrombopag • Patient has no evidence of current thrombosis • The patient has tried, failed, has a contraindication to, or is expected to have an intolerance to lusutrombopag (Mulpleta)? OR ITP Indication • Patient is 18 years of age or older with a diagnosis of chronic immune thrombocytopenia (ITP) and has failed to adequately respond to previous therapy • ~~**Drug is prescribed by or in consultation with a hematologist/oncologist**~~ • Patient has tried and failed Nplate or Promacta OR Has a contraindication to both Nplate and Promacta OR Is expected to have an adverse effect to both Nplate and Promacta that would not be anticipated by Avatrombopag • Doptelet is not being used concomitantly with other chronic ITP therapy Non-FDA-approved uses are not approved. For thrombocytopenia associated with liver disease: PA expires in 60 days. New PA required per prescription fill For ITP: PA does not expire.
• mirabegron tablets (Myrbetriq) **Overactive Bladder Agents: Beta-3 Adrenergic Agonists**	**Updates from the August 2025 meeting are in bold.** PA Criteria apply to all new users of Myrbetriq. **Automated PA Criteria: The patient has filled a prescription for oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine within the last 720 days. OR** **Automated PA Criteria: When prescribed by a urologist, urogynecologist, or geriatrician prior authorization is not required. Once therapy is initiated by a urologist, urogynecologist, or geriatrician an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.** Manual PA criteria: **If automated criteria are not met,** coverage of Myrbetriq is approved if all criteria are met: • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 1 generic antimuscarinic medication (oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such central nervous

	system effects due to comorbid conditions, advanced age, or other medication • The patient's estimated creatinine clearance (CrCl)/glomerular filtration rate (eGFR) is ≥15 mL/min/1.73m^2 Non-FDA-approved uses are not approved. Prior authorization does not expire.
• vibegron (Gemtesa) **Overactive Bladder Agents: Beta-3 Adrenergic Agonists**	**Updates from the August 2025 meeting are in bold.** PA Criteria apply to all new users of Gemtesa. **Automated PA Criteria: The patient has filled a prescription for oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine within the last 720 days.** Manual PA criteria: **If automated criteria are not met,** coverage of Gemtesa is approved if all criteria are met: • The patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency • The patient has tried and failed behavioral interventions to include pelvic floor muscle training in women, and bladder training, • The patient has had a 12-week trial with 1 generic antimuscarinic medication (oxybutynin, tolterodine, trospium, solifenacin, darifenacin, or fesoterodine) and had therapeutic failure OR • The patient has experienced central nervous system adverse events with oral OAB medications OR is at increased risk for such central nervous system effects due to comorbid conditions, advanced age, or other medication • The patient's estimated creatinine clearance (CrCl)/glomerular filtration rate (eGFR) is ≥15 mL/min/1.73m^2 Non-FDA-approved uses are not approved. Prior authorization does not expire.
• filgrastim-sndz (Zarxio) **White Blood Cell Stimulants: Filgrastims**	**Updates from the August 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of filgrastim-sndz (Zarxio) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that tbo-filgrastim (Granix)~~,~~ **and** filgrastim-aafi (Nivestym)**~~, and filgrastim-sndz (Zarxio)~~** are the preferred filgrastims and are available without a PA. Please consider changing the prescription to a formulary preferred medication. Note: Granix and Nivestym are available at the generic (Tier 1) copay at the TRICARE Mail Order and Retail Pharmacies. • Prescribed by or in consultation with a hematologist or oncologist • Patient has experienced an inadequate treatment response or intolerance to tbofilgrastim Granix)~~,~~ **and** filgrastim-aafi (Nivestym)**~~, and filgrastim-sndz (Zarxio)~~** and is expected to respond to filgrastim (Neupogen)**,** filgrastim-ayow (Releuko), filgrastim-txid (Nypozi), or **filgrastim-sndz (Zarxio).** PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• semaglutide (Wegovy) • tirzepatide (Zepbound) **Weight Loss Agents**	**Updates from August 2025 are in bold for the definition of uncontrolled hypertension** 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? ▪ 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; 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: ▪ Obesity ▪ Diabetes or impaired glucose tolerance ▪ Obstructive sleep apnea ▪ Osteoarthritis ▪ Metabolic syndrome ▪ Dyslipidemia ▪ Hypertension ▪ Metabolic dysfunction-associated steatohepatitis (MASH) ▪ Established cardiovascular disease with a history of stroke ▪ Established cardiovascular disease with a history of myocardial infarction ▪ 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 ▪ 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 a patient not meeting blood pressure goal on 2 or more antihypertensives)** 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 <u>Renewal PA Criteria</u>: Note that 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 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
• abiraterone acetate (Zytiga and generic) 500 mg **Oncological Agents: CYP-17 Inhibitors**	**Updates from the August 2025 meeting are in bold and strikethrough.** ~~**Automated PA Criteria: When prescribed by a hematologist, oncologist, or urologist prior authorization is not required. Once therapy is initiated by a hematologist, oncologist, or urologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.**~~ Manual PA criteria applies to all **new and current** users of Zytiga 500 mg: Manual PA coverage**, ~~if automated criteria are not met~~:** Coverage approved if all criteria are met: ~~**• If the physician is a hematologist, oncologist or urologist, PA is approved OR**~~ ~~**• If the prescriber is not a hematologist, oncologist or urologist and if the drug prescribed in consultation with a hematologist/oncologist or urologist, then continue with the questions below:**~~ • Patient is 18 years of age or older • **Prescribed by or in consultation with a hematologist/oncologist** • **Provider acknowledges that abiraterone 250 mg strength is available without a PA** • **If the prescription is for abiraterone 500 mg strength, please state why the patient cannot take multiple of the 250 mg strength _____, then continue with the PA criteria below** ▪ **Acceptable responses: Patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in generic abiraterone 250 mg** • Patient has documented diagnosis of non-localized disease including: ▪ metastatic castration-resistant prostate cancer (mCRPC), OR ▪ metastatic castration-sensitive prostate cancer (mCSPC), OR ▪ regional disease (TxN1M0) • Patient must receive concomitant therapy with prednisone • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog for example: Eligard, Lupron, Orgovyx, Trelstar, or Zoladex concomitantly OR have had a bilateral orchiectomy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval If so, please list the diagnosis, guideline version, and page number: _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• abiraterone acetate micronized (Yonsa) **Oncological Agents: CYP-17 Inhibitors**	**Updates from the August 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all **new and current** users of Yonsa. 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 an oncologist or urologist • Provider is aware that Yonsa may have different dosing and food effects than other abiraterone acetate products (medication errors and overdose warning) • **Provider acknowledges that abiraterone 250 mg (generic Zytiga) is available without a PA and at a Tier 1 copay** • **Please explain why patient cannot take the preferred generic abiraterone** ▪ **Acceptable response: Patient has experienced a serious allergic reaction (i.e. hives/anaphylaxis) to an excipient in generic abiraterone or patient is unable to comply with the fasting requirements with generic abiraterone** • Patient has documented diagnosis of non-localized disease including: ▪ Metastatic castration-resistant prostate cancer (mCRPC) ▪ Metastatic castration-sensitive prostate cancer (mCSPC) ▪ Regional disease (TxN1M0) OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. ~~**If so, the provider must list the diagnosis**~~ **To facilitate approval, please list the diagnosis, guideline version, and page number**:_____. • Patient must receive concomitant therapy with methylprednisolone • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy Other non-FDA-approved uses are NOT approved except as noted above PA does not expire.
• umeclidinium/vilanterol (authorized generic for Anoro Ellipta) **Pulmonary-2 Agents: Chronic Obstructive Pulmonary Disease**	Manual PA criteria apply to new and current users of umeclidinium and vilanterol authorized generic at all points of service Manual PA criteria: umeclidinium and vilanterol authorized generic is approved if all criteria are met: • Provider acknowledges that the brand Anoro Ellipta is TRICARE's preferred product over authorized generic umeclidinium and vilanterol • The provider must document a patient-specific justification as to why the brand Anoro Ellipta cannot be used in this patient. _____ (fill-in the blank). ▪ Acceptable reasons include the patient has had an adverse reaction to an excipient in brand Anoro Ellipta that would not be likely to occur with the authorized generic product
• chorionic gonadotropin, human (Pregnyl, Novarel) • choriogonadotropin alfa (Ovidrel) **Follicle Stimulating Hormone (FSH) Luteinizing Hormone (LH) Fertility Agents**	**Sex edit: PA does not apply to males** Manual PA is required for **new users**. Manual PA Criteria: PA is approved if all criteria are met: • Fertility agent is not being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer. The TRICARE family planning benefit outlined in the Code of Federal Regulations does not include services and supplies related to noncoital reproductive technology Prior Authorization expires after 1 year; provider must fill out a new PA.

Appendix C—Table of Prior Authorization (PA) Criteria

• leuprolide acetate **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	**Updates from the August 2025 meeting are in bold.** Manual PA criteria apply to all **new users** of Lupron Depot, Lutrate Depot, and leuprolide acetate (no brand name) Manual PA criteria: Coverage is approved if all criteria are met: • If patient is 18 years of age or younger, PA is not approved if indication is gender dysphoria • For patients 18 years of age or older, or for younger patients using for other indications besides gender dysphoria, proceed with the following questions • **Fertility agent is not being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer. The TRICARE family planning benefit outlined in the Code of Federal Regulations does not include services and supplies related to noncoital reproductive technology** • Provider is aware leuprolide acetate SQ (Eligard) is the preferred leuprolide product and does not require PA • Patient has tried and failed or has not been able to tolerate Eligard **PA does not expire**
• ganirelix acetate (Fyremadel, Antagon) • cetrorelix acetate (Cetrotide) **FSH-LH Fertility Agents**	Manual PA is required for new users. Manual PA Criteria: PA is approved if all criteria are met: • Fertility agent is not being prescribed for use in conjunction with a noncoital reproductive technology, including but not limited to artificial insemination, in vitro fertilization, or gamete intrafallopian transfer. The TRICARE family planning benefit outlined in the Code of Federal Regulations does not include services and supplies related to noncoital reproductive technology Prior Authorization expires after 1 year; provider must fill out a new PA.
• ambrisentan (Letairis) • macitentan (Opsumit) **Pulmonary Arterial Hypertension: Endothelin Receptor Agonists**	**Updates from the August 2025 meeting are in bold and strikethrough.** **Manual PA criteria apply to all new users of ambrisentan and macitentan** Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed or in consultation with cardiologist or a pulmonologist • Patent has a documented diagnosis of WHO group 1 PAH • Patient has had a right heart catheterization with documentation provided • Results of right heart catheterization confirm diagnosis of WHO Group 1 PAH • ~~**If patient is a female, then prescriber is enrolled in Risk Evaluation and Mitigation Strategy (REMS) program**~~ • Female patient is not pregnant • Females of childbearing age are using adequate contraception up to 1 month after therapy • Patient has no history of LTF elevations on previous ERA therapy accompanied by symptoms of liver toxicity or increases in bilirubin > 2x upper limit of normal • Patient does not have moderate or severe liver impairment (e.g., Child-Pugh Class B or C) Non-FDA approved uses are not approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• macitentan/tadalafil (Opsynvi) **Pulmonary Arterial Hypertension: Endothelin Receptor Agonists**	**Updates from the August 2025 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of macitentan and tadalafil (Opsynvi). Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed or in consultation with cardiologist or a pulmonologist • Patient has had a right heart catheterization with documentation provided • Results of right heart catheterization confirm diagnosis of WHO Group 1 PAH • Patient has WHO Functional Class II or III PAH • ~~**If patient is a female, then prescriber is enrolled in Risk Evaluation and Mitigation Strategy (REMS) program**~~ • Female patient is not pregnant • Females of childbearing age are using adequate contraception up to 1 month after therapy • Provider must describe why the patient requires a fixed dose combination and cannot take the individual components separately (write-in) ▪ Acceptable responses include the following: the patient cannot swallow tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience Non-FDA approved uses are not approved PA does not expire

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• acoltremon 0.003% ophthalmic solution (Tryptyr) **Ophthalmic: Dry Eye**	▪ MTF/TMOP/Retail: 60 single dose vials (1 carton)/30 days supply
• avutometinib/ defactinib (Avmapki Fakzynja Co-pack) • ensartinib (Ensacove) • nilotinib d tartrate capsule **Oncological Agents**	▪ MTF/TMOP/Retail: 60-day supply
• **c**hlorthalidone 12.5 mg tabs (Hemiclor) **Diuretics**	▪ Retail: 30 tabs/30 days ▪ MTF/TMOP: 90 tabs/90 days
• efgartigimod alfa-fcab injection (Vyvgart Hytrulo) **Miscellaneous Neurological Agent**	▪ MTF/TMOP/Retail: 60-day supply
• fitusiran injection (Qfitlia) **Antihemophilic Factors**	▪ MTF/TMOP/Retail: 60-day supply
• garadacimab-gxii (Andembry) **Corticosteroids-immune modulators**	▪ MTF/TMOP/Retail: 30-day supply
• taletrectinib (Ibtrozi) Oncological Agents	▪ MTF/TMOP/Retail: 30-day supply
• treprostinil inhalation powder (Yutrepia) **Pulmonary Arterial Hypertension**	▪ MTF/TMOP/Retail: 30-day supply
• ustekinumab (ustekinumab by Janssen) • ustekinumab-srlf (Imuldosa) **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)
• liraglutide (Saxenda) • semaglutide (Wegovy) • **tirzepatide (Zepbound)** **Weight Loss Agents**	▪ Retail: 30 day supply ▪ MTF/TMOP: 60-day supply

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• acetaminophen 325 mg/ ibuprofen 97.5 mg (Combogesic) **Analgesics and Combinations**	• acetaminophen • ibuprofen	• aceta-minophen 325 mg with ibuprofen 200 mg tablets dosed 3 tablets PO Q6h PRN	• Short-term management of mild to moderate acute pain in adults	Adverse Drug Reactions (ADRs) ≥2% • nausea • vomiting • headache • dizziness • somnolence	• Fixed dose combination acetaminophen and ibuprofen prescription product • Ibuprofen component contains lower dose than OTC ibuprofen • No new clinical efficacy studies • Unanimous agreement from providers that Combogesic is not needed on the formulary • Provides no compelling clinical advantage over existing agents	• Complete Exclusion
• acoltremon 0.003% ophthalmic solution (Tryptryr) **Ophthalmic: Dry Eye**	• Cyclosporine (generic Restasis) • Xiidra • Miebo • Vevye	• Dosing: Instill one drop in each eye BID	• Treatment of the signs and symptoms of dry eye disease	ADRs ≥50% • instillation site pain	• New mechanism of action, but does not appear to confer any advantages over other available dry eye disease products • Two phase 3 studies demonstrated more patients in the Tryptyr group had a ≥10 mm increase in the Schirmer tear test sign from baseline at Day 14 vs. vehicle • Two phase 3 studies had mixed results for improvement in the symptoms measure, with only one study showing statistically significant difference from vehicle • Provides another option with a different mechanism of action for dry eye disease	• UF • PA • QL • Specialty Drug List
• atrasentan (Vanrafia) **Nephrology Agents Miscellaneous**	• Fabhalta • Tarpeyo • Filspari	• 0.75 mg tablets; bottles #30 tabs • Dosing: 0.75 mg PO QD with or without food	• Reduce proteinuria in adults with primary IgAN at risk of rapid disease progression	ADRs ≥5% • peripheral edema • anemia	• Fourth FDA-approved drug to reduce proteinuria in adults with immunoglobulin A nephropathy (IgAN) • The ALIGN Phase 3 study showed benefit in reducing proteinuria, in the surrogate outcome of the mean change in urinary protein to creatinine ratio (UPCR) from baseline vs. placebo with a geometric mean difference of 36% • Disadvantages include that full approval is contingent on confirmatory trial completion • Advantages are that patients can remain on ACE/ARB therapy and it does not have a REMS program • The formulary alternative Filspari has a REMS for pregnancy risk and concomitant ACE/ARBs are not allowed; however Filspari	• UF • PA • 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	Clinical Summary	Recommendation
					has a confirmed trial showing slowed kidney decline. • Safety profile of Vanrafia has fluid retention and anemia as most common adverse effects • Vanrafia provides a therapeutic alternative to Fabhalta and Filspari for IgAN	
• avutometinib/ defactinib (Avmapki Fakzynja Co-pack) **Oncological Agents**	• Mekinist	• 0.8 mg avutometinib capsules/200 mg defactinib tablets • Avutometinib: 3.2 mg PO twice weekly (Day 1 and Day 4) x first 3 weeks of each 4-week cycle. Defactinib: 200 mg PO BID x first 3 cycles of each 4-week cycle	• Treatment of adults with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy	ADRs ≥25% • ↑ CPK, ↑ bilirubin, ↑ TGs, • nausea, fatigue • ↑ AST. ↑ALT, ↑ alk phos • diarrhea, vomiting • ↓ HgB, ↓ platelets, ↓ lymphocytes, ↓ neutrophils • musculoskeletal pain, edema • abdominal pain, dyspepsia, stomatitis • dermatitis, acneiform, pruritus • vitreoretinal disorders, visual impairment	• Avmapki Fakzynja Co-Pack is recommended for low grade serous carcinoma, for KRAS-mutated tumors as “Useful in Certain Circumstances” (category 2A) per NCCN guidelines • Phase 2 open label study demonstrated a confirmed Objective Response Rate of 44%, with the duration of response ranging from 3.3 to 31.1 months • Monitoring is necessary for rhabdomyolysis and ocular, skin, and liver toxicities • Avmapki Fakzynja Co-Pack is new therapy for a cancer type that typically does not respond well to chemotherapy	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List
• berdazimer 10.3% topical gel (Zelsuvmi) **Anti-Infectives: Misc**	• hydroxyurea capsule • Droxia capsule • Siklos tablet	• 10.3% gel supplied as two tubes: Tube A contains berdazimer gel and Tube B contains hydrogel	• Treatment of molluscum contagiosum in patients ≥1 year of age	• application site reactions	• A phase 3 study demonstrated a statistically significant clearance of lesions at Week 12, compared to vehicle • A network meta-analysis indicates cantharidin 0.7% (Ycanth, medical benefit) is a top-ranked treatment, while Zelsuvmi ranks mid-range for treatments that achieve complete clearance of lesions compared to placebo • Zelsuvmi is overall well tolerated with localized skin reactions as common adverse events • Provides an additional treatment option for a condition that typically self-resolves	• UF • PA

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• chlorthalidone 12.5 mg tabs (Hemiclor) **Diuretics**	• chlorthalidone 25 & 50 mg tabs • azilsartan • HCTZ 25mg • Inzirqo liquid	• 12.5 mg tablets • Dosing: 12.5 mg or 25 mg PO QD (Max daily dose = 100 mg)	• Treatment of hypertension in adults, to lower blood pressure	• electrolyte abnormalities • metabolic disturbances	• Contains ½ the dose (12.5 mg) of chlorthalidone 25 mg (1950 original approval) • No clinical efficacy studies; approved via 505(b)(2) pathway using data from the original chlorthalidone • Branded chlorthalidone (Thalitone-1988 original approval) is also available in 15 mg and 25 mg tabs; with enhanced bioavailability • FDA-approval is limited to adults with hypertension; not approved for pediatrics • Chlorthalidone does have cardiovascular (CV) outcomes data from the landmark ALLHAT and SHEP trials • Hemiclor provides no clinical advantage other than providing a lower dose of chlorthalidone; the original chlorthalidone 25 mg can be cut in half or crushed, despite not being scored, or branded Thalitone 15 mg can be used	• NF • PA • MN • QL
• efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) **Neurologic Agents Misc**	• Rystiggo • Zilbrysq	• Pre-filled syringe: efgartigimod alfa (1,000 mg) and hyaluronidase (10,000 U) per 5 mL	• Treatment of adults with generalized myasthenia gravis (MG) who are anti-acetylcholine receptor antibody positive • Treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP)	• injection reaction • respiratory infection • headache • UTI	• Vyvgart Hytrulo is self-administered via SC injection; the original formulation is IV • For MG, a single open label study demonstrated comparable pharmacodynamic effect of efgartigimod SQ to the IV formulation • For CIDP, a single randomized withdrawal study demonstrated a statistically significant reduced hazard ratio for risk of deterioration with Vvygart vs. placebo • Alternative treatment with complement inhibitors (Soliris, Ultomiris and Zilbrysq) include a black boxed warning for serious infections and require REMS monitoring • Vyvgart Hytrulo does not include black box warnings or REMS requirements • Vyvgart Hytrulo provides another option for the treatment of these rare disorders	• 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	Clinical Summary	Recommendation
• ensartinib (Ensacove) **Oncological Agent**	• Alecensa • Alunbrig • Lorbrena • Xalkori	• 25 mg, 100 mg capsules • Dosing: 225 mg PO QD	• Treatment of adults with anaplastic lymphoma kinase (*ALK*)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) who have not previously received an ALK-inhibitor	ADRs ≥20% • rash • musculoskeletal pain • constipation • pruritus • cough • nausea • edema • vomiting • fatigue • pyrexia	• Sixth targeted FDA-approved therapy for the treatment of non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK) rearrangements • Phase 3 open label study demonstrated Progression Free Survival (PFS) of 25.8 months vs. 12.7 months for Xalkori • NCCN guidelines recommend Alecensa, Alunbrig, Ensacove, and Lorbrena as first-line "Preferred" therapies for ALK-rearrangement positive NSCLC • Therapeutic alternative to the other approved ALK inhibitor therapies for this indication	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List
• fitusiran injection (Qfitlia) **Antihemophilic Factors**	• Hemlibra • Alhemo • Hympavzi	• 20 mg/0.2 mL solution (vials) • 50 mg/0.5 mL auto-injector pens • Dosing: 50 mg q 2 months, followed by dose and/or interval adjustment to maintain anti-thrombin (AT) activity between 15-35%	• Prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years with hemophilia A or B with or without factor VIII or IX inhibitors	ADRs >10% • viral infections • nasopharyngitis • bacterial infections	• First-in-class antithrombin-lowering agent, and first agent indicated as routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years of age who have hemophilia A or B **with or without inhibitors** ▪ Alhemo is indicated as routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients ≥ 12 years of age with hemophilia A or B **with or without** inhibitors ▪ Hympavzi is similar to Alhemo but FDA-approved in patients **without** inhibitors ▪ Hemlibra is indicated for routine prophylaxis to reduce or prevent the frequency of bleeding episodes in adults and pediatric patients ages **newborn** and older with **hemophilia A with or without inhibitors** • Phase 3 open label study, Qfitlia demonstrated 71% reduction in annualized bleeding rate (ABR) versus clotting factor concentrates (CFCs) on-demand in patients without inhibitors and 73% reduction in ABR versus bypassing agents (BPA) on-demand in patients with inhibitors	• 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	Clinical Summary	Recommendation
					• Blackbox warnings for thrombotic events and gallbladder disease • Offers the fewest doses for any prophylactic treatment with as few as six injections per year, and it is given subcutaneously • Qfitlia offers an alternative to Alhemo, Hemlibra and Hympavzi for either hemophilia A or B with or without inhibitors	
• garadacimab-gxii (Andembry) **Corticosteroids-Immune-modulator**	• Haegarda • Orladeyo	• Single dose prefilled autoinjector or prefilled syringe: 200mg/1.2 mL	• Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥12 years	• nasopharyngitis • abdominal pain	• Indicated for prophylaxis of HAE attacks • A single phase 3 trial demonstrated a statistically significant reduction in the number of attacks per month compared to placebo • An indirect network meta-analysis demonstrated that prophylactic HAE treatments (Andembry, Haegarda, Orladeyo, Takhzyro) were statistically significant in reducing the rate of attacks compared with placebo; additionally, all treatments were statistically significantly in reducing the rate of attacks treated with on-demand therapy compared with placebo • Andembry has a mild adverse event profile, with common events to include nasopharyngitis and abdominal pain • Offers an additional pharmacologic option for prophylaxis of this condition	• NF • PA • MN • QL • Specialty Drug List • TRICARE Maintenance Drug List • Rapid Response program
• hydrocortisone 1mg/mL oral solution (Khindivi) **Corticosteroids-Immune Modulators**	• hydrocortisone oral granules (Alkindi Sprinkle) • hydrocortisone tablets (Cortef, generics)	• 1 mg/mL oral solution	• Replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency	Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain	• Oral solution formulation of hydrocortisone for use as replacement therapy in pediatric patients ≥ 5 years of age with adrenocortical insufficiency • No new clinical efficacy studies; approved via 505(b)(2) pathway • Oral solution must be refrigerated and contains a warning regarding systemic adverse reactions due to inactive ingredients • Alkindi Sprinkle can also be used in patients who cannot swallow or achieve required dose with hydrocortisone tablets, but Khindivi can be used in a g-tube while Alkindi Sprinkle cannot	• NF • PA • MN • Specialty Drug List • TRICARE Maintenance Drug List • Rapid Response program

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
					• Provides little compelling clinical advantage over existing agents	
• insulin aspart-szjj (Merilog vial/pen) **Insulins: Rapid Acting Agents**	• insulin aspart (Novolog) • insulin lispro (Humalog) • insulin aspart (Lyumjev)	• 100 units/mL (U-100) • Vial: 10 mL multiple-dose vial • Pen: 3 mL single-patient-use SoloStar prefilled pen	• Improve glycemic control in adults and pediatric patients with diabetes mellitus	• hypoglycemia	• Biosimilar to Novolog • Approved via 351(k); No new clinical studies were completed • Available as 10 ml single dose vials and 3 ml SoloStar prefilled pen • Merilog can inject up to 80 units/dose • Novolog can be given via continuous SC infusion pump or intravenously. It can also be mixed with other insulins while Merilog has not yet received this indication • Merilog has not received interchangeability status from the FDA • Provides no compelling clinical advantage over existing agents	• UF • TRICARE Maintenance Drug List
• losartan 10 mg/mL oral suspension (Arbli) **Renin-Angiotensin Antihypertensive**	• Inzirqo • Norliqva • Qbrelis • Carospir	• 10mg/ml • Dosing: 50 mg PO QD	• HTN in adults and children ≥ 6 years of age to lower blood pressure • ↓ risk of stroke in patients with HTN and LV hypertrophy • Diabetic nephropathy with ↑ serum creatinine and proteinuria in T2DM and history of HTN	ADR >2% • dizziness • upper respiratory infection • nasal congestion • back pain.	• 1st ready-to-use oral suspension formulation of the ARB losartan • No clinical efficacy studies; approved via 505(b)(2) pathway using data from Cozaar • Losartan tablets can be crushed and mixed into a suspension; compounded formulations are often available in 2.5 mg/mL, but Arbli is 10 mg/mL. Risk of 4-fold dosing error • Provides no compelling clinical advantage over generic losartan tablets or other angiotensin receptor blockers (ARBs)	• NF • PA • MN • TRICARE Maintenance Drug List
• meloxicam 20 mg /rizatriptan 10 mg tabs (Symbravo) **Migraine Agents: Triptans**	• Treximet • meloxicam • rizatriptan	• 20 mg meloxicam and 10 mg rizatriptan • Dosing: One tablet PO PRN (max: 1 tablet per day)	• Acute treatment of migraine with or without aura in adults	• dizziness • somnolence	• Fixed dose combination of a non-steroidal anti-inflammatory drug (NSAID) and triptan • Clinical data demonstrated a statistically significant achievement of headache pain freedom and most bothersome symptom freedom at 2 hours vs placebo • Guidelines recommend switching to a triptan for migraines not responding to analgesics or NSAIDs • Provides no compelling clinical advantage over existing agents	• Complete Exclusion

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events	Clinical Summary	Recommendation
• nilotinib tartrate capsules (no brand name) **Oncologic Agents**	• nilotinib 71mg and 95 mg tabs (Danziten) • nilotinib capsules (Tasigna)	• Capsule: 50, 150, or 200 mg	• Adults with newly diagnosed Philadelphia chromosome positive chronic myeloid lukemia (Ph+ CML) in chronic phase • Adult with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib	• nausea • rash • headache • fatigue • pruritus • vomiting • diarrhea • cough • constipation • arthralgia • nasopharyngitis • pyrexia • night sweats	• Nilotinib tartrate capsules are a new formulation of nilotinib containing the tartrate salt • No new clinical efficacy studies; approved via 505(b)(2) • Provides no compelling clinical advantage over existing agents	• UF • PA • QL • Specialty Drug List • TRICARE Maintenance Drug List
• taletrectinib (Ibtrozi) **Oncological Agents**	• Xalkori • Rozlytrek • Augtyro • Lorbrena	• 200mg capsules • Dosing: 600 mg PO QD	• Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	ADR ≥20% • diarrhea • nausea • vomiting • dizziness • rash • constipation • fatigue	• Fourth tyrosine kinase inhibitor (TKI) for ROS1-positive NSCLC; after Augtyro, Rozlytrek and Xalkori • Phase 2 open label, single arm studies demonstrated efficacy in both ROS1 treatment-naïve and ROS1 previously-treated patients • Based on indirect comparisons in the TKI-naïve population: Ibtrozi has numerically higher objective response rates (ORR) at 88% compared with Augtyro at 79%, Rozlytrek at 68% and Xalkori at 72% • NCCN guidelines state Ibtrozi, Augtyro, Rozlytrek, and Xalkori are all “preferred” first-line options for NSCLC with ROS1 rearrangement; however, the guidelines note that only Ibtrozi, Rozlytrek, or Augtyro are preferred for patients with brain metastases compared with Xalkori • Alternative to other FDA-approved kinase inhibitors, especially Augtyro or Rozlytrek, for the treatment of ROS1-positive NSCLC	• 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	Clinical Summary	Recommendation
• terazosin 1 mg/mL oral solution (Tezruly) **BPH Agents**	• terazosin • tamsulosin • silodosin • Cardura	• 1 mg/ml • Dosing: 1mg QHS	• Treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adult males • Treatment of hypertension alone or with other antihypertensive agents in adults	ADRs ≥5% • asthenia • back pain • headache • palpitations	• First oral solution formulation of terazosin • No new clinical efficacy studies • Provides an option for those who cannot swallow tablets • *Note the manufacturer discontinued marketing in February 2026*	• UF • PA • Specialty Drug List • TRICARE Maintenance Drug List
• treprostinil inhalation powder (Yutrepia) **Pulmonary Arterial Hypertension**	• Tyvaso • Ventavis • Orenitram • Uptravi	• 26.5 mcg, 53 mcg, 79.5 mcg, 106 mcg inhalation powder contained in capsules • Dosing: 26.5 mcg given 3 to 5 times daily	• Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise ability • Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability	ADRs ≥10% • cough • headache • throat irritation • dizziness	• Third inhaled treprostinil product FDA-approved for PAH • No efficacy data; approved via 505(b)(2) based on nebulized treprostinil (Tyvaso) data) • Supporting phase 3 open-label trial demonstrated tolerability • FDA-approval is limited to increased exercise capacity in PAH WHO Group 1 – does not alter disease course • All treprostinil products are also approved for PH-ILD • Second orally inhaled prostacyclin powder via disposable inhaler; powder is supplied in a capsule as opposed to a cartridge (Tyvaso dry powder inhaler - DPI) • Yutrepia administration requires 12 steps with potential for error (e.g., swallowing capsules instead of using the inhaler), compared to the 3-step process with Tyvaso DPI cartridges • Inhalation powder offers convenience to the patient, as nebulized products require additional time to administer and clean, but more complicated than Tyvaso DPI • Provides a therapeutic alternative to Tyvaso and Tyvaso DPI, but complicated delivery system	• 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	Clinical Summary	Recommendation
• ustekinumab (ustekinumab by Janssen) • ustekinumab-srlf (Imuldosa) • ustekinumab-aekn (ustekinumab-aekn unbranded Selarsdi private label) **TIBs: IL-23s**	• Wezlana • Stelara • Humira • Taltz	• 45 mg/0.5 mL, 90 mg/mL single-dose prefilled syringe	• Adults: moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy • Active psoriatic arthritis (PsA) • Moderately to severely active Crohn's disease (CD) • Moderately to severely active ulcerative colitis. • Pediatrics ≥ 6 years old: moderate to severe Ps who are candidates for phototherapy or systemic therapy • PsA	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 • The P&T Committee has concluded that biosimilar products are therapeutically interchangeable with other biosimilars and the reference product	• NF, after step ▪ Imuldosa ▪ ustekinumab-Janssen • Complete Exclusion: ▪ unbranded (private label) ustekinumab-aken • PA • MN • 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)
Aug 2025	**Drug Class Reviews** **Atopy: IL-13, IL-31 agents** ***Designated UF*** *Retain current status on the TMDL* • dupilumab (Dupixent) • tralokinumab (Adbry) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • insulin aspart-szjj (Merilog) ***Designated NF*** *Add – no reason to exempt from NF TMOP requirement)* • chlorthalidone 12.5 mg tabs (Hemiclor) • losartan 10 mg/mL oral suspension (Arbli) • terazosin 1 mg/mL solution (Tezruly)	**Drug Class Reviews** **Atopy: IL-13, IL-31 agents** ***Designated UF*** *Do not add–not cost advantageous to government* • lebrikizumab (Ebglyss) • nemolizumab (Nemluvio) **Diuretics: Mineralocorticoid Receptor Antagonists** ***Designated UF*** *Do not add–not cost advantageous to government* • finerenone (Kerendia) spironolactone oral susp (Carospir) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** *Do not add–not cost advantageous to government* • acoltremon 0.003% (Tryptyr) *Do not add–short duration* • berdazimer 10.3% (Zelsuvmi)

***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)
Aug 2025	**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • atrasentan (Vanrafia) • avutometinib; defactinib (Avmapki Fakzynja Co-pack) • efgartigimod alfa-fcab (Vyvgart Hytrulo) • ensartinib (Ensacove) • fitusiran (Qfitlia) • nilotinib tartrate 50,150,200 mg caps (unbranded; Cipla) • taletrectinib (Ibtrozi) • treprostinil oral inhalation (Yutrepia) ***Designated NF*** *No reason to exempt from TMOP requirement* • garadacimab-gxii (Andembry) • hydrocortisone 1 mg/mL solution (Khindivi) • ustekinumab-srlf (Imuldosa) • ustekinumab (unbranded; Janssen)	

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—Complete Exclusion Drugs and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Products designated with Complete Exclusion	Formulary Alternatives	Implementation
August 2025	Pain Agents	• acetaminophen 325 mg and ibuprofen 97.5 mg tablets (Combogesic)	• acetaminophen (OTC) • ibuprofen 200 mg	• 120 days
August 2025	Migraine Agents	• meloxicam 20 mg /rizatriptan 10 mg (Symbravo) tablets	• meloxicam • rizatriptan • sumatriptan/ibuprofen (Treximet)	• 120 days
August 2025	Interleukin-23 Agents	• ustekinumab-aekn private label	• adalimumab (Humira) • ixekizumab (Taltz) • ustekinumab (Stelara) • ustekinumab-stab (Steqeyma) • ustekinumab-auuz (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.