DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
August 2024

I. CONVENING

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

II. ATTENDANCE

The attendance roster is listed in Appendix A.

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

B. Clarification of previous meeting minutes

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

III. REQUIREMENTS

All clinical and cost evaluations for new drugs, including newly approved drugs reviewed according to 32 Code of Federal Regulations (CFR) 199.21(g)(5), and full drug class reviews included, but were not limited to, the requirements stated in 32 CFR 199.21(e)(1) and (g)(5). All completely excluded pharmaceutical agents were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3). When applicable, patient-oriented outcomes are assessed. All uniform formulary (UF), basic core formulary (BCF), nonformulary (NF), and completely excluded pharmaceutical agent recommendations considered the conclusions from the relative clinical effectiveness and relative cost-effectiveness determinations, and other relevant factors including those outlined in Section 702 of the National Defense Authorization Act (NDAA) for fiscal year (FY) 2018, permanently codified at 10 USC 1074g (a)(10). Medical Necessity (MN) criteria were based on the clinical and cost evaluations and the conditions for establishing MN for a NF medication.

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

IV. UF DRUG CLASS REVIEWS

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

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

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

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

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

Clinical Practice Guidelines

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

Efficacy

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

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

Safety

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

Other Factors

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

Overall Clinical Conclusion

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

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (19 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that acalabrutinib (Calquence) is the most cost effective BTKi agent, followed by zanubrutinib (Brukinsa), ibrutinib (Imbruvica), and pirtobrutinib (Jaypirca).
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the agents in accordance with the formulary recommendation below demonstrated significant cost avoidance for the MHS.

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

   - UF
     - acalabrutinib (Calquence)
     - ibrutinib (Imbruvica)
     - pirtobrutinib (Jaypirca)
     - zanubrutinib (Brukinsa)
   - NF - None
   - Completely Excluded - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Existing PA criteria currently apply to all four drugs. For the Imbruvica tablet formulation, further justification is required on the PA to state why the capsules cannot be used first. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) the changes below. See Appendix C for the full criteria.

   - For all four BTKi drugs, the PA criteria were streamlined in the sections pertaining to FDA-indications and safety monitoring.
   - For Imbruvica, the current criteria preferring the capsules over the tablets was removed.
   - For Calquence and Brukinsa, if the prescribing physician specialty is identified as an oncologist or hematologist during adjudication, no PA will be required. The provider's specialty is identified through an automated system that searches for specific specialty information in the claim. This will hereafter be referred to as automated specialist bypass. Manual PA will also allow approval solely based on the prescribing physician being identified as an oncologist or hematologist. Additionally, for prescriptions initially written by an oncologist or hematologist, an automated drug lookback for Calquence or Brukinsa will allow PA approval if the patient has received the drug in the past 720 days, to allow continuation of therapy for prescriptions subsequently written by non-specialists.

3. ***COMMITTEE ACTION: QUANTITY LIMITS—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current QLs for all agents. See Appendix D for the full QLs.

4. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (19 for, 0

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

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

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

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

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

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

Statins

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

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

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

Non-statins and Combinations

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

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

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

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

For the statins

- The committee reviewed the CMA results for atorvastatin, atorvastatin oral suspension (Atorvaliq), fluvastatin, lovastatin ER (Altoprev), lovastatin, pitavastatin calcium (Livalo, generics), pitavastatin magnesium (Zypitamag), pravastatin, rosuvastatin, rosuvastatin sprinkle (Ezallor), simvastatin oral suspension (Flolipid), and simvastatin.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the statin agents in accordance with the formulary recommendation below demonstrated benefit to the MHS.

For the non-statins and combinations

- The committee reviewed the CMA results for amlodipine/atorvastatin, bempedoic acid (Nexletol), bempedoic acid/ezetimibe (Nexlizet), ezetimibe, ezetimibe/rosuvastatin (Roszet, generics), and ezetimibe/simvastatin.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the non-statin and combination agents in accordance with the formulary recommendation below demonstrated cost-avoidance for the MHS.

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

   Statins

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

   Non-statins and Combinations

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

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

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

Statins

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

Non-statins and Combinations

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

2. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current MN criteria for Altoprev, Livalo, Zypitamag, Atorvaliq, Ezallor, and FloLipid.

3. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 1 absent) maintain Nexletol, Nexlizet, Altoprev, Atorvaliq, Ezallor, Zypitamag, ad FloLipid; and removing Livalo, Vytorin, and Lescol XL. See Appendix F.

4. ***COMMITTEE ACTION: UF, PA, MN, TRICARE MAINTENANCE DRUG LIST PROGRAM and IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent)

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

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (20 for, 0 opposed, 0 abstained, 0 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the August 2024 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:
    - UF
        - diazepam buccal film (Libervant) – Anticonvulsants – Antimania Agents
        - elafibranor (Iqirvo) – Gastrointestinal-2 Agents
        - mavorixafor (Xolremdi) – Hematological Agents
        - mycophenolate mofetil 200 mg/mL oral suspension (Myhibbin) – Immunosuppressives
        - naloxone 4 mg nasal spray (Rextovy) – Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists
        - resmetirom (Rezdiffra) – Gastrointestinal-2 Agents
        - sotatercept-csrk (Winrevair) – Pulmonary Arterial Hypertension Agents
        - tocilizumab-aazg syringe (Tyenne) – Targeted Immunomodulatory Biologics (TIBS): Non-Tumor Necrosis Factor Inhibitors
        - tovorafenib (Ojemda) – Oncological Agents
    - NF
        - adalimumab-ryvk (Simlandi) – TIBS: Tumor Necrosis Factor Inhibitors
        - danicopan (Voydeya) – Hematological Agents
        - givinostat (Duvyzat) – Corticosteroids-Immune Modulators
        - macitentan/tadalafil (Opsynvi) – Pulmonary Arterial Hypertension Agents

        - sitagliptin/metformin authorized generic (Zituvimet) – Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors
        - spesolimab-sbzo syringe (Spevigo) – TIBS: Miscellaneous Interleukins
    - Complete exclusion
        - adalimumab (Cordavis brand of Humira) – TIBS: Tumor Necrosis Factor Inhibitors

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) MN criteria for Simlandi, Voydeya, Duvyzat, Opsynvi, Zituvimet authorized generic, and Spevigo. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria (see Appendix C for the full criteria):
    - Applying manual PA criteria to new users of the oncology/hematology drugs Voydeya, Xolremdi, and Ojemda; and for new users of Iqirvo, Duvyzat, Rezdiffra, and Winrevair.
    - Applying manual PA criteria to new and current users of Opsynvi, requiring a trial of the individual components separately.
    - Applying manual PA criteria to new users of Spevigo requiring a trial of Humira and Cosentyx first.
    - Applying manual PA criteria to new users of Tyenne requiring a trial of Humira for moderate to severely active RA and active polyarticular juvenile idiopathic arthritis (pJIA) first. Additionally, a trial of Tyenne will be required before the originator Actemra formulation in new users (see the UM section on page 15).
    - Applying manual PA criteria to new and current users of the Humira biosimilar Simlandi, similar to what is in place for the other Humira biosimilars. A trial of the Humira branded product is required first as per the February 2023 P&T Committee meeting minutes.
    - Applying manual PA criteria to new users of Zituvimet authorized generic, requiring a trial of Januvia, similar to the other NF, non-step-preferred DPP-4 inhibitors in the class.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) QLs for Duvyzat, Iqirvo, Libervant, Ojemda, Opsynvi, Rextovy, Rezdiffra, Simlandi, Spevigo, Tyenne, Voydeya, Winrevair, and Xolremdi. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: TRICARE MAINTENANCE DRUG LIST REQUIREMENTS***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding or exempting the drugs listed in Appendix F to/from the TRICARE Maintenance Drug List program for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the TRICARE Maintenance Drug List program which includes the NF medications subject to the mail requirement.

6. ***COMMITTEE ACTION: UF, MN, PA, QL, TRICARE MAINTENANCE DRUG LIST and IMPLEMENTATION PERIOD***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding an effective date of the following:

    - **New Drugs Recommended for UF, NF and Completely Excluded Status:** An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

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

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

COMMITTEE ACTION: EFLAPEGRASTIM-XNST (ROLVEDON) PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) PA criteria in new users of eflapegrastim-xnst (Rolvedon) prefilled syringe, requiring use of the step-preferred WBC stimulants first. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full PA criteria.

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

Manual PA criteria were recommended for six recently marketed drugs produced by a sole manufacturer which contain active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators and cannot be reviewed for formulary status. Numerous cost-effective formulary alternatives are available that do not require prior authorization.

a) **Endocrine Agents Miscellaneous—lanreotide 120 mg/0.5 mL syringe—**Other versions of lanreotide 120 mg/0.5 mL syringe are available, including Somatuline Depot, that are more cost-effective than this version made by a sole manufacturer.

b) **Pain Agents: Pain Topical—lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V)—**Numerous other more cost-effective lidocaine 5% patches are available. BCF status does not apply to these specific formulations.

COMMITTEE ACTION: NEW PA CRITERIA FOR DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5) AND IMPLEMENTATION PLAN—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for lanreotide 120 mg/0.5 mL syringe, lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V in new and current users, due to the significant cost differences compared with other available alternative agents. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for several drugs, due to new FDA-approved indications and expanded age ranges. The updated PA criteria outlined below will apply to new users. See Appendix C for full criteria.

a) **Atopy: Oral JAK-1—upadacitinib (Rinvoq)—**The manual PA were updated to allow for use in polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older and to expand the psoriatic arthritis indication to include pediatric patients 2 years of age and older. Both indications are for use in patients who have had an inadequate response or intolerance to one or more tumor necrosis factor inhibitors. A trial of Humira will be required for both indications.

b) **Atopy—benralizumab (Fasenra)**—The manual PA criteria for Fasenra were expanded to include patients 6 years of age or older with severe asthma with an eosinophilic phenotype.

c) **TIBs: Non-TNFs—vedolizumab (Entyvio)—**The manual PA criteria were updated to allow use of Entyvio to treat Crohn's Disease in adults.

d) **TIBs: Non-TNFs—sarilumab (Kevzara)—**Kevzara is now indicated for the treatment of active polyarticular JIA in patients who weight at least 63 kg. The manual PA were updated to reflect this new indication.

e) **Metabolic Agents Miscellaneous—maralixibat (Livmarli)—**The manual PA criteria were updated to allow for use in patients 12 months of age and older with cholestatic pruritus due to Progressive Familial Intrahepatic Cholestasis.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the manual PA criteria for Rinvoq, Fasenra, Entyvio, Kevzara, and Livmarli in new users. Implementation will be effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

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

a) **Corticosteroids-Immune Modulators: Adrenocorticotrophic Hormones—corticotropin (Acthar Gel SelfJect)—**The manual PA criteria were updated to exclude use of the new Acthar Gel SelfJect formulation for the treatment of infantile spasms, as it is not FDA approved for this indication.

b) **Antiemetic-Antivertigo Agents—doxylamine/pyridoxine (Diclegis, Bonjesta)—**The PA was updated to inform prescribers that the more cost-effective OTC doxylamine is available under the TRICARE pharmacy benefit without a copay at the MTF and retail points of service; a prescription is required for coverage.

c) **Oncological Agents—trametinib (Mekinist), dabrafenib, (Tafinlar), neratinib (Nerlynx), vemurafenib (Zelboraf), venetoclax (Venclexta), nilutamide (Nilandron), belzutifan (Welireg), tucatinib (Tukysa), glasdegib (Daurismo), erdafitinib (Balversa) and Prostate Cancer drugs—abiraterone (generic and Zytiga), enzalutamide (Xtandi), darolutamide (Nubeqa), and apalutamide (Erleada)—**Based on a review of MHS data and feedback from providers, several oncology PA were reviewed in order to standardize and streamline the criteria. Future meetings will address the other oncology PAs.

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

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

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

d) **TIBs: Non-TNFs—anakinra (Kineret)—**The manual PA criteria for Kineret were updated to allow for treatment of adult-onset Still's Disease (AOSD) without requiring a trial of Humira. This update is based on the approved indication in Europe, updates from the 2024 British Society of Rheumatology treatment recommendations of AOSD, available clinical data, and specialist feedback.

e) **Sleep Disorders: Wakefulness Promoting Agents—solriamfetol (Sunosi)—**The manual PA criteria were updated to allow for alternative treatments and prescribing providers for patients with obstructive sleep apnea and excessive daytime sleepiness. This update is based on review of current guidelines and literature, as well as specialist feedback. Additional edits were made to better align the Sunosi PA with existing PA criteria in the class.

f) **Sleep Disorders: Wakefulness Promoting Agents—pitolisant (Wakix)—**The manual PA criteria were updated to allow use in children as young as 6 years for the updated indication of narcolepsy with excessive daytime sleepiness. Additional edits were made to better align the Wakix PA with existing PA criteria in the class.

g) **TIBs: TNFs—adalimumab (Humira)—**At the May 2023 meeting, automated specialist bypass PA criteria were added to Humira to allow for rheumatologists to bypass PA requirements, which was implemented on May 15, 2024. At this meeting, the automated specialist bypass was expanded to include dermatologists and gastroenterologists. Additionally, the manual PA criteria were expanded to allow for off-label use of Humira for generalized pustular psoriasis (GPP) in children and adults based on guidelines and provider feedback.

h) **TIBs: Non-TNFs—secukinumab (Cosentyx)—**Similar to Humira, the manual PA criteria for Cosentyx were updated to allow for off-label use of Humira for generalized pustular psoriasis (GPP) in children and adults based on guidelines and provider feedback.

i) **TIBs: Non-TNFs—tocilizumab (Actemra)—**The manual PA and MN criteria for Actemra were updated due to the recent availability of a cost-effective tocilizumab biosimilar (see new drugs section on page 11). The PA updates require a trial of the biosimilar tocilizumab-aazg (Tyenne) prior to Actemra. Other updates were made to standardize the PA, consistent with what was done with other TIBs (e.g., removing the monitoring and counseling questions). The Actemra MN criteria were updated to include adding Tyenne as a formulary alternative.

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

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

B. Line Extensions

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

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

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

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

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

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

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

- **Mirabegron (Myrbetriq):** requiring brand Myrbetriq tablets over the generics in new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Myrbetriq tablets. The effective date will be no later than 60 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.
- **Topiramate ER (Trokendi XR):** For Trokendi XR, the removal of the Tier 1 copay and brand over generic PA criteria will take place no later than 60 days after the signing of the minutes.

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

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

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

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

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

> ***COMMITTEE ACTION: HCV DAAs MAVYRET PA REMOVAL, PA UPDATED CRITERIA, QLs, AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the PA criteria for Epclusa, Harvoni, Zepatier, Sovaldi and Vosevi, with an implementation of the first Wednesday 60 days after signing of the minutes at all points of service.
>
> The Mavyret PA removal and QL limits increases for Mavyret, Epclusa, Harvoni, Zepatier, Sovaldi and Vosevi will be implemented the first Wednesday two weeks after the signing of the minutes at all points of service. The PA and QL changes will increase beneficiary access under the TRICARE pharmacy benefit and reduce provider administrative time. See Appendix C and D for the full criteria.

IX. PROCESS FOR EVALUATING BIOSIMILARs AND BIOLOGICS

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

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

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

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

The Committee concluded the following regarding biologics and their biosimilars.

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

1. ***COMMITTEE ACTION: CLINICAL EFFECTIVENESS***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:
    - The clinical conclusions as stated above will apply to all biosimilar products.
    - Reference biologics and their biosimilar products are interchangeable.
    - The DoD P&T Committee agrees to accept these conclusions as the clinical effectiveness review for all future biosimilar agents.

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

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

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

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

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

XI. COMPLETELY EXCLUDED DRUGS: ANNUAL REVIEW

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

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

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

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

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

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

XII. MISCELLANEOUS ITEMS FOR INFORMATION BRIEFED TO THE COMMITTEE

A. DoD/VA Continuity of Care List

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

B. Pharmacy Benefit Management Clarification

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

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

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

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

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

XIII. ADJOURNMENT

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

Appendix A—Attendance: August 2024 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—TRICARE Maintenance Drug List Status of Medications Designated Formulary or Nonformulary during the August 2024 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Completely Excluded Agents and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

☐ concurs with the recommendations, except for the following:

[redacted]

Matthew Case
RDML, USN
Acting Assistant Director, Health Care Administration
28 October 2024
Date

Appendix A—Attendance

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

Appendix A—Attendance

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

Appendix A—Attendance

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

Appendix B—Table of Medical Necessity Criteria

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

Appendix B—Table of Medical Necessity Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

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

	• The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy ***For patients at high risk for ASCVD*** • **The patient has LDL >190 mg/dL or** • **Patient has diabetes and LDL <190 mg/dL or** • **Patients with LDL 70 to 189 mg/dL and an estimated 10-year risk for ASCVD >7.5% or** • **Patients with LDL < 190 mg/dL and evidence of significant subclinical atherosclerosis defined as:** ▪ **Significant atherosclerotic plaque observed in an asymptomatic patient on any of the following diagnostic studies: coronary artery calcification noted on computed tomography (CT) studies, including calcium scoring, cardiac CT coronary angiography, chest CT for ruling out pulmonary embolism, chest CT for lung cancer screening, or diagnostic chest CT; carotid plaque noted on carotid ultrasound or angiography; or abnormal ankle-brachial index or plaque noted on peripheral arterial angiography. AND** • **The patient must have tried either atorvastatin 40-80 mg or rosuvastatin 20-40 mg, OR** • **The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR** • **If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy, AND** • **The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.** *For **~~both HeFH and ASCVD~~ all uses***: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: • Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. • Contraindication to statin ▪ The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) *For all **~~FDA-approved~~** indications* • ~~Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD.~~ • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: • 140 mg every 2 weeks, or • 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. PA does not expire

• atorvastatin 20 mg/5 mL suspension (Atorvaliq) • rosuvastatin sprinkle (Ezallor Sprinkle) • simvastatin oral suspension (Flolipid) • pitavastatin calcium (Livalo, generics) • pitavastatin magnesium (Zypitamag) **Antilipidemic-1s: Statins**	Note no changes were made to the existing PA criteria.
Newly Approved Drug PAs	
• adalimumab-ryvk (Simlandi) **TIBS: Tumor Necrosis Factor Inhibitors (TNFs)**	Manual PA criteria apply to all new and current users of the Humira biosimilar <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations • Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient ▪ Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Humira biosimilar • If patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease ▪ If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older ▪ If indication is moderate to severe Crohn's disease patient must be 6 years of age or older AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease • If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa ▪ If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease ▪ If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months • Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira

	• Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed) • Patient is not receiving other targeted immunomodulatory biologics with Humira, including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER) Non-FDA approved uses are NOT approved, except if indication is approved for Humira, it is approved for a biosimilar PA does not expire
• danicopan (Voydeya) **Hematological Agents**	Manual PA criteria apply to all new users of danicopan (Voydeya). <u>Manual PA criteria</u>: Coverage is approved if all criteria are met: • Prescribed by a hematologist/oncologist • Patient is 18 years of age or older • Patient has documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) • Patient has tried and failed monotherapy with a C5 inhibitor for six months (e.g., eculizumab, ravulizumab), and has residual anemia • Patient will receive C5 inhibitor therapy (eculizumab, ravulizumab) concurrently with Voydeya • Provider is aware of all monitoring requirements, screening precautions, importance of medication adherence, and Risk Evaluation and Mitigation Strategies (REMS) requirements • Patient is not receiving C3 or Complement Factor B inhibitors with Voydeya, including but not limited to the following: iptacopan (Fabhalta), or pegcetacoplan (Empaveli) Non-FDA approved uses are NOT approved PA expires after 6 months then annually <u>Renewal Criteria</u>: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for another year if all the criteria are met: • Patient ~~meets initial criteria,~~ has documentation of positive clinical response including increase in or stabilization of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis.

Appendix C—Table of Prior Authorization (PA) Criteria

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

	• 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**
• mavorixafor (Xolremdi) **Hematological Agents**	Manual PA criteria apply to all new users of mavorixafor (Xolremdi). Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 12 years of age or older • Prescribed by an immunologist or hematologist • Patient has diagnosis of WHIM syndrome • Patient's diagnosis has been confirmed by genotype variant of CXCR4 • Patient has absolute neutrophil count (ANC) ≤ 400 cells/microliter Non-FDA approved uses are NOT approved PA expires after 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all the criteria are met: • Patient has documentation of positive clinical response defined as one of the following: ▪ improvement in absolute neutrophil count (ANC) ▪ decrease in infections
• resmetirom (Rezdiffra) **GI-2 Agents**	**Updates from the current PA criteria are in bold and strikethrough** Manual PA criteria apply to all new users of resmetirom (Rezdiffra). 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 hepatologist or gastroenterologist • Patient has biopsy-proven non-alcoholic steatohepatitis (NASH) OR • Patient has fibrosis stage of F2 or F3 **diagnosed with appropriate assessment (e.g., FibroScan, MRI-PDFF)**~~confirmed by imaging (e.g., VCTE, MRI-PDFF)~~ • **The patient has metabolic risk factors that are managed by standard of care (e.g., lifestyle modifications, glucagon-like peptide 1-receptor agonists (semaglutide, tirzepatide), or statins)** Non-FDA approved uses are NOT approved. ~~PA does not expire~~. **PA expires in 1 year** **Renewal Criteria: Initial TRICARE approval is required for renewal. Rezdiffra is approved for an additional year if all criteria are met:** • **Patient has documentation of positive clinical response to include improvement in fibrosis or stabilization of fibrosis AND** • **Patient has continued consultation with a hepatologist or gastroenterologist**

Appendix C—Table of Prior Authorization (PA) Criteria

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

	• **Patient has had an inadequate response to non-biologic systemic therapy. (For example – cyclosporine, methotrexate, acitretin, isotretinoin, systemic glucocorticoids, or mycophenolate)** • Patient has generalized pustular psoriasis and is not currently experiencing a flare as defined by a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 0 or 1 • Patient has history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past **while on biologic suppressive maintenance therapy** • ~~Patient has negative TB test result in past 12 months (or TB is adequately managed)~~ • **Coverage is NOT provided for concomitant use with other TIBs including, but not limited to: certolizumab (Cimzia), etanercept (Enbrel), infliximab (Remicade), ustekinumab (Stelara), secukinumab (Cosentyx), ixekizumab (Taltz), guselkumab (Tremfya), tildrakizumab (Ilumya), risankizumab (Skyrizi)** **Non-FDA approved uses are NOT approved** **PA expires in 1 year** **Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved for an additional year if all the criteria are met:** • **Patient has had a documented reduction in generalized pustular psoriasis symptoms or** • **Patient has had a reduction in generalized pustular psoriasis flares.**
• tocilizumab-aazg syringe (Tyenne) **TIBS: Non-Tumor Necrosis Factor Inhibitors**	**Updates from the current PA criteria are in bold and strikethrough** **Manual PA criteria apply to all new users of tocilizumab-aazg (Tyenne)** Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira • **The patient has had an inadequate response to Humira OR** • **The patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR** • **The patient has a contraindication to Humira AND** • Patient has moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs ~~AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5~~ UNL OR • Patient has active polyarticular Juvenile Idiopathic Arthritis (pJIA) OR • Patient **has a diagnosis for which adalimumab is not approved** including ~~AND greater than 18 years of age~~ ▪ Giant cell arteritis OR ▪ Systemic sclerosis-associated lung disease ~~then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ OR ▪ Patient has systemic Juvenile Idiopathic Arthritis (sJIA) OR ▪ If "other" diagnosis, ~~does patient have a contraindication to Humira?~~ **please provide appropriate literature-based support documentation for the indication and utilization** ○ ~~If yes and if moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ○ ~~If yes and If giant cell arteritis OR systemic sclerosis associated lung disease then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~

	~~• Patient has not tried Humira AND less than 18 years of age but greater than 2 years of age~~ ~~▪ Patient has systemic Juvenile Idiopathic Arthritis (sJIA)~~ ~~• Patient has evidence of negative TB test result in the past 12 months or TB is adequately managed~~ • Patient is not receiving other targeted immunomodulatory biologics with Tyenne **Non-FDA approved uses are NOT approved, except as noted above.** **PA does not expire**
• tovorafenib (Ojemda) **Oncological Agents: N/A**	Manual PA criteria apply to all new users of tovorafenib (Ojemda). Manual PA criteria: Coverage is approved if all criteria are met: • Prescribed by or in consultation with a hematologist/oncologist • Patient has pediatric low-grade glioma • Patient has relapsed or refractory disease • Tumor is positive for one of the following: BRAF fusion, BRAF rearrangement, BRAF V600 mutation • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. To facilitate approval, please list the diagnosis, guideline version and page number _____. Other non-FDA approved uses are NOT approved except as noted above PA does not expire
Utilization Management Updated PAs	
• eflapegrastim-xnst (Rolvedon) **White Blood Cell Stimulants**	**Updates from the August 2024 meeting are in bold** Manual PA criteria apply to all new users of pegfilgrastim (Neulasta) and pegfilgrastim (Neulasta OnPro, and **eflapegrastim-xnst (Rolvedon)** Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) are the TRICARE preferred pegfilgrastims and are available without a prior authorization. • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient requires use of an on-body injector (Neulasta OnPro) because the patient/caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration OR • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) and is expected to respond to the requested medication PA does not expire
• lanreotide 120 mg/ 0.5 mL syringe **Endocrine Agents Miscellaneous**	Manual PA criteria apply to all new and current users Manual PA criteria: Lanreotide acetate 120 mg injection is approved if all criteria are met: • Provider acknowledges that this drug has been identified as having cost-effective alternatives and Somatuline Depot is available without prior authorization. • Provider must explain why the patient cannot use the 120 mg Somatuline Depot brand. ▪ Acceptable responses include if the patient has a hypersensitivity to an excipient in the brand that is not found in the generic Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• lidocaine 5% patch (Tridacaine I, II, and III, Lidocan IV and V) **Pain Agents: Pain Topical**	**Updates from the August 2024 meeting are in bold.** Manual PA criteria apply to all new and current users of lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III, **Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, Tridacaine III**). Manual PA criteria: lidocaine 5% patch (DermacinRx Lidocan, Lidocan II, Lidocan III) is approved if all criteria are met: • Provider acknowledges other formulations of lidocaine 5% patch are available without prior authorization. • Provider must explain why the patient requires DermacinRx Lidocan, Lidocan II, Lidocan III, **Lidocan IV, Lidocan V, Tridacaine I, Tridacaine II, or Tridacaine III** and cannot take the cost-effective generic lidocaine 5% formulations. ▪ Acceptable responses include that the patient has failed a trial of at least 3 other preferred generic lidocaine 5% patches; examples of failure include a documented allergy to an inactive ingredient or the patch not adhering to skin Non-FDA-approved uses are not approved Prior authorization does not expire
• upadacitinib (Rinvoq) **Atopy: Oral JAK-1**	**Updates from the August 2024 meeting are in bold and strikethrough.** Note that there were no changes to the current Rinvoq criteria for the other indications (RA, PsA, Ulcerative Colitis, Ankylosing Spondylitis, or Atopic Dermatitis – see the August 2022 P&T Committee meeting minutes for the full criteria) Manual PA apply to all new users of Rinvoq Manual PA criteria: Rinvoq is approved if all criteria are met: • **Patient is 2-17 years of age and either:** ▪ **Patient is being treated for active polyarticular juvenile idiopathic arthritis OR** ▪ **Patient is being treated for psoriatic arthritis** • Provider acknowledges that Humira is the Department of Defense preferred targeted biologic agent for approved indications • Patient has had an inadequate response to Humira OR • Patient has experienced an adverse reaction to Humira and that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira AND For all indications • ~~Patient has no evidence of active TB infection within the past 12 months~~ • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

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

	• Patient tried and failed or had an inadequate response to infliximab (Remicade) • Patient has had an inadequate response to nonbiologic systemic therapy (for example– methotrexate, aminosalicylates (e.g., sulfasalazine, mesalamine), corticosteroids, immunosuppressants (e.g., azathioprine), etc. • Patient has received induction dosing with two intravenous doses of vedolizumab (Entyvio) OR patient has been receiving intravenous vedolizumab (Entyvio) and achieved clinical response or remission beyond week 6 • Patient will not be receiving any other targeted immunomodulatory biologics with vedolizumab including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi) or upadacitinib (Rinvoq ER) Non-FDA approved uses are NOT approved PA does not expire
• sarilumab (Kevzara) **TIBs: Non-TNFs**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Kevzara Manual PA criteria: Kevzara is approved ~~for Polymyalgia Rheumatica~~ if all criteria are met: • ~~Patient is greater than or equal to 18 years of age~~ • Kevzara is prescribed by or in consultation with a rheumatologist • Provider acknowledges Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira • Patient has a diagnosis of: ▪ Moderately to severely active rheumatoid arthritis AND - Had inadequate response **or intolerance** to one or more disease-modifying antirheumatic drug (DMARD) ▪ **Active polyarticular juvenile idiopathic arthritis (pJIA) and weighs 63 kg or more AND** - **Had inadequate response or intolerance to one or more disease-modifying antirheumatic drug (DMARD)** ▪ Polymyalgia Rheumatica (PMR) (No trial of Humira required) AND - Patient has tried and/or failed ONE systemic corticosteroid; OR the patient is not a candidate for corticosteroid therapy • ~~Patient does not have platelets less than 150,000/mm3 or liver transaminases above 1.5 times upper limit of normal (UNL)~~ • ~~Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed)~~ • Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR Non-FDA-approved uses are not approved PA for non-PMR indications approved indefinitely.

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

• trametinib (Mekinist) **Oncological Agents**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Mekinist. Manual PA criteria: Coverage will be approved if: • **Prescribed by or in consultation with a hematologist/oncologist** • **Monotherapy for treatment** of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation in BRAF-inhibitor treatment naïve patients • Combination with dabrafenib (Tafinlar) for the treatment of patients with: ▪ ~~Treatment (alone or in combination with dabrafenib [Tafinlar]) of~~ unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation ▪ **Adjuvant treatment of patients of melanoma with BRAF-V600E or BRAF-V600K mutation and involvement of lymph node(s), following complete resection** ▪ ~~In combination with dabrafenib (Tafinlar), for the treatment of patients with~~ metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation ▪ ~~Combination with dabrafenib (Tafinlar) for~~ locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options ▪ ~~For the treatment of adult and pediatric patients 1 year of age and older with~~ unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options ▪ ~~In combination with dabrafenib (Tafinlar), For the treatment of pediatric patients 1 year of age and older with l~~ow-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy • Coverage not approved as a single agent in patients who have received prior BRAF inhibitor therapy • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so,~~ please list the diagnosis, **guideline version, and page number**: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• dabrafenib (Tafinlar) **Oncological Agents**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Tafinlar. Manual PA criteria: Coverage will be approved if: • **Prescribed by or in consultation with a hematologist/oncologist** • Single agent for treatment of unresectable or metastatic melanoma with BRAF V600E ~~or BRAF V600K~~ mutation • In combination with trametinib (Mekinist) for the treatment of patients with: ▪ ~~in the treatment of~~ unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations ~~OR~~ ▪ **Adjuvant treatment of patients of melanoma with BRAF-V600E or BRAF-V600K mutation and involvement of lymph node(s), following complete resection**

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ ~~In combination with trametinib (Mekinist), for the treatment of patients with~~ metastatic non-small cell lung cancer (NSCLC) with BRAF V600E Mutation ▪ ~~Combination with trametinib (Mekinist) for~~ **l**ocally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options ▪ ~~For the treatment of adult and pediatric patients 1 year of age and older with~~ unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options ▪ ~~In combination with trametinib (Mekinist), for the treatment of pediatric patients 1 year of age and older with~~ low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• neratinib (Nerlynx) **Oncological Agents: Breast Cancer**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Nerlynx. Manual PA criteria: Coverage will be approved if**:** • **Prescribed by or in consultation with a hematologist/oncologist** • Patient is greater than or equal to 18 years of age • As a single agent for extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, following adjuvant trastuzumab based therapy ~~• Patient has early stage HER2 overexpressed/amplified breast cancer AND~~ ~~• Following adjuvant trastuzumab based therapy (preferably less than 1 year, but no more than 2 years after completion) OR~~ • **Used in combination with capecitabine for advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer following two or more prior anti-HER2-based regimens** ~~▪ Patient has a Advanced or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer~~ **following** ~~AND Patient has received two or more prior anti-HER2-based regimens in the metastatic setting OR~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____.~~AND~~ ~~• Counseled on significant adverse event profile AND~~ ~~• Co-prescribed antidiarrheal to mitigate for at a minimum 2 months AND~~ Non-FDA-approved uses are not approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• vemurafenib (Zelboraf) **Oncological Agents: Melanoma**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Zelboraf. Manual PA criteria: Coverage will be approved if: • **Prescribed by or in consultation with a hematologist/oncologist** • Documented diagnosis of unresectable or metastatic melanoma with BRAF V600E mutation AND **melanoma that is NOT wild-type BRAF** • ~~Detected by an FDA-approved test (Cobas 4800) OR~~ • Patient has Erdheim-Chester Disease with BRAF V600 mutation • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA-approved uses are not approved, **except as noted above** PA does not expire
• venetoclax (Venclexta) **Oncological Agents: Non-BTKI for Chronic Lymphocytic Leukemia**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to new users of Venclexta <u>Manual PA Criteria</u>: Coverage for Venclexta is approved if all criteria are met: • Drug is prescribed by or in consultation with a hematologist/oncologist • Age greater than or equal to 18 years • Venclexta will be used **for** ~~in one of the following contexts:~~ ▪ ~~Frontline therapy for~~ chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) ~~without del(17p)/TP53 mutation~~ - ~~Patient fits one of the following categories:~~ • ~~Frail patient with significant comorbidity (not able to tolerate purine analogues)~~ • ~~Patient is greater than or equal to 65 years of age with significant comorbidity~~ • ~~Patient is less than 65 years of age~~ - ~~Will be combined with obinutuzumab (Gazyva) infusion~~ ▪ ~~Relapsed/refractory therapy for CLL/SLL without del(17p)/TP53 mutation~~ - ~~Patient fits one of the following categories:~~ - ~~Frail patient with significant comorbidity (not able to tolerate purine analogues)~~ - ~~Patient is greater than or equal to 65 years of age with significant comorbidity~~ - ~~Patient is less than 65 years of age~~ ▪ ~~Frontline or relapsed/refractory therapy for CLL/SLL with del(17p)/TP53 mutation~~ ▪ ~~Patient has newly diagnosed~~ acute myeloid leukemia (AML**) in combination with azacitidine, decitabine, or low-dose cytarabine if**: and is a candidate for intensive remission induction therapy ~~and meets the following criteria:~~ - ~~Age greater than or equal to 60 years~~ - Unfavorable-risk cytogenetics ~~(exclusive of AML with myelodysplasia-related changes)~~ - ~~Patient is greater than or equal to 60 years of age and~~ has newly diagnosed AML and is not a candidate for**, or declines**, intensive remission induction therapy - ~~Patient is greater than or equal to 60 years of age and~~ completed lower-intensity induction therapy for AML with a response

	- Patient has relapsed refractory AML • ~~Will titrate to therapeutic dose in consideration of tumor lysis syndrome (TLS)~~ • ~~Provider is aware of the drug interactions and dose modifications recommended in the package insert~~ • ~~Will prophylax and monitor for tumor lysis syndrome (TLS) (based on tumor burden-defined risk)~~ • ~~Will monitor for neutropenia~~ • ~~Will monitor for signs and symptoms of infection~~ • ~~Will not administer live attenuated vaccines prior to, during, or after treatment with Venclexta until B-cell recovery occurs.~~ • ~~If the patient is female, she is not pregnant or planning to become pregnant~~ • ~~Female patients will not breastfeed~~ • ~~Male patients have been informed of risk of infertility~~ • ~~Female patients of reproductive potential will use effective contraception during treatment and for at least 30 days after discontinuation~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA approved uses are NOT approved**, except as noted above** PA does not expire
• nilutamide (Nilandron) **Oncological Agents: Prostate 1**	**Updates from the August 2024 meeting are in bold.** Manual PA criteria applies to all new users of Nilandron. Manual PA criteria**:** Coverage will be approved if: • **Prescribed by or in consultation with a hematologist/oncologist or urologist** • Patient has a contraindication to bicalutamide or flutamide OR • Patient experienced significant adverse effects from bicalutamide or flutamide • Patient experienced therapeutic failure with bicalutamide or flutamide OR • Patient has a diagnosis of metastatic prostate cancer (Stage D2) disease and the patient has undergone orchiectomy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA-approved uses are not approved, except as noted above PA does not expire
• belzutifan (Welireg) **Oncological Agents**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Welireg Manual PA criteria: Welireg is approved if all criteria are met: • **Welireg is prescribed by or in consultation with a hematologist/oncologist** • Patient is 18 years of age or older • ~~Welireg is prescribed by or in consultation with an oncologist~~

	• The patient has von Hippel-Landau disease and requires therapy for associated renal cell carcinoma (RCC), CNS hemangioblastomas or pancreatic neuroendocrine tumors (pNET) not requiring surgery OR • The patient has advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) ~~• Female patients of childbearing age are not pregnant, confirmed by ( ) HCG~~ ~~• Female patients will not breast feed during treatment and for at least 3 weeks after the cessation of treatment~~ ~~• Both male and female patients of childbearing potential agree to use effective nonhormonal contraception during treatment and for at least 1 week after cessation of therapy if female; and for 3 months if male~~ ~~• Male patients have been informed of the risk of infertility~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA approved uses are not approved, other than noted above PA does not expire
• tucatinib (Tukysa) **Oncological Agents: Breast Cancer**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA is required for all new users of Tukysa. Manual PA Criteria: Tukysa is approved if all criteria are met: • Medication is prescribed by or consultation with a hematologist/oncologist • Patient is 18 years of age or older • The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting AND Tucatinib will be used in combination with trastuzumab ~~(Herceptin)~~ and capecitabine ~~(Xeloda)~~ OR • The patient has a confirmed diagnosis of RAS wild-type, HER2-positive, unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy AND tucatinib will be used in combination with trastuzumab ~~• Provider agrees to monitor for hepatotoxicity~~ ~~• Patient has been counseled on risk of diarrhea~~ ~~• Female patients of childbearing age are not pregnant confirmed by ( ) HCG~~ ~~• Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment~~ ~~• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of therapy~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

• abiraterone (generic and Zytiga) **Oncological Agents: CYP-17 Inhibitors**	**Updates from the August 2024 meeting are in bold and strikethrough.** **<u>Automated PA Criteria</u>: When prescribed by a hematologist, oncologist, or urologist prior authorization is not required. Once therapy is initiated by a hematologist, oncologist, or urologist an automated drug look back will apply, allowing continuation of coverage by any other prescriber if the patient has received the requested medication in the past 720 days.** Manual PA criteria applies to all new users: **Manual PA coverage, if automated criteria are not met**: Coverage approved if all criteria are met: • **If the physician is a hematologist, oncologist or urologist, PA is approved OR** • **If the prescriber is not a hematologist, oncologist or urologist and if the drug is prescribed in consultation with a hematologist/oncologist or urologist, then continue with the questions below:** • Patient is 18 years of age or older • Patient has documented diagnosis of non-localized disease including: ▪ metastatic castration-resistant prostate cancer (mCRPC), OR ▪ metastatic castration-sensitive prostate cancer (mCSPC), OR ▪ regional disease (TxN1M0) • Patient must receive concomitant therapy with prednisone • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog ~~for example: Eligard,Lupron, Orgovyx, Trelstar, or Zoladex concomitantly~~ OR have had a bilateral orchiectomy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire
• enzalutamide (Xtandi) **Oncological Agents: 2nd-Gen Antiandrogens**	**Updates from the August 2024 meeting are in bold and strikethrough.** **Note: For metastatic castration-sensitive prostate cancer (mCSPC) abiraterone acetate is listed as a category 1 recommendation for either doublet or triplet therapy. Abiraterone acetate is available as part of the Tricare benefit as a Tier 1 agent and available without a PA for hematologists, oncologists and urologists.** Manual PA criteria apply to new users of Xtandi <u>Manual PA Criteria</u>: Xtandi is approved if all criteria are met: • Medication is prescribed by or in consultation with a hematologist/oncologist or urologist • Patient is greater than or equal to 18 years of age • Patient has documented diagnosis of: ▪ metastatic **or non-metastatic** castration resistant-prostate cancer (~~m~~CRPC) OR ~~▪ non-metastatic castration-resistant prostate cancer (nmCRPC)~~ ~~If used in (nmCRPC) patient must have: PSADT less than or equal to 10 months~~ ▪ OR metastatic castration-sensitive prostate cancer (mCSPC)

	▪ OR non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis • ~~Patient with CRPC or mCSPC must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy~~ • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Other non-FDA approved uses are NOT approved, except as noted above PA does not expire
• darolutamide (Nubeqa) **Oncological Agents: 2nd-Gen Antiandrogens**	**Updates from the August 2024 meeting are in bold and strikethrough.** **Note: For metastatic castration-sensitive prostate cancer (mCSPC) abiraterone acetate is listed as a category 1 recommendation for either doublet or triplet therapy. Abiraterone acetate is available as part of the Tricare benefit as a Tier 1 agent and available without a PA for hematologists, oncologists and urologists.** Manual PA is required for all new users of Nubeqa <u>Manual PA Criteria</u>: Nubeqa is approved if all criteria are met: • Drug is prescribed by or in consultation with a hematologist/oncologist or urologist AND • Patient is 18 years of age or older AND • Note that Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. The patient is required to try Xtandi first. OR. Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Nubeqa AND • Patient has diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) ~~AND~~ • ~~The patient has had a negative CT scan of abdomen/pelvis and/or negative bone scan AND~~ • ~~Prostate-specific antigen doubling time (PSADT) is 10 months OR~~ • Patient has a diagnosis of metastatic ~~hormone~~ **castration**-sensitive prostate cancer (m~~H~~**C**SPC) in combination with docetaxel • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Other non-FDA approved uses are not approved, except as noted above PA does not expire
• apalutamide (Erleada) **Oncological Agents: 2nd-Gen Antiandrogens**	**Updates from the August 2024 meeting are in bold and strikethrough.** **Note: Abiraterone acetate is available as part of the Tricare benefit as a Tier 1 agent and available without a PA for hematologist, oncologist, and urologists.** Manual PA is required for all new users of Erleada <u>Manual PA Criteria</u>: Erleada is approved if all criteria are met: • ~~Xtandi is the Department of Defense's preferred 2nd Generation Antiandrogen Agent. Has the patient tried Xtandi? OR Does the patient have or have they had a contraindication/inadequate response/adverse reaction to Xtandi that is not expected to occur with requested agent~~

	• Drug is prescribed by or in consultation with an oncologist or urologist • Age 18 years or older • Provider acknowledges Xtandi is the Department of Defense's preferred 2nd-Generation Antiandrogen Agent. • The patient is required to try Xtandi first. OR. Patient has a contraindication or has had an inadequate response or adverse reaction to Xtandi that is not expected to occur with Erleada AND • Patient has documented diagnosis of: ▪ non-metastatic castration-resistant prostate cancer (nmCRPC), ~~AND PSADT ≤ 10 months~~ ▪ ~~Negative CT scan of abdomen/pelvis and/or negative bone scan, AND~~ ▪ metastatic castration-sensitive prostate cancer (mCSPC) • Patient must be receiving a gonadotropin-releasing hormone (GnRH) analog concomitantly OR have had a bilateral orchiectomy • Other non-FDA-approved uses are NOT approved • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. **To facilitate approval** ~~If so~~, please list the diagnosis, **guideline version, and page number**: _____. Non-FDA approved uses are NOT approved, except as noted above Prior authorization does not expire
• anakinra (Kineret) **TIBs: Non-TNFs**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of anakinra (Kineret). <u>Manual PA Criteria</u>**:** Kineret is approved if all criteria are met: • Pediatric patients (all ages) with: ▪ Neonatal-Onset Multisystem Inflammatory Disease (NOMID), a subset of Cryopyrin Associated Period Syndrome (CAPS). (Trial of Humira not required). ▪ Systemic Juvenile Idiopathic Arthritis (sJIA) (Trial of Humira not required). ▪ Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (Trial of Humira not required). • **Patient is 18 years of age or older with:** ▪ **Adult-Onset Still's Disease (AOSD) with active systemic features of moderate to high disease activity (Trial of Humira not required) OR** ▪ Moderate to severe active rheumatoid arthritis AND - Prescriber is aware that Humira is the Department of Defense's preferred targeted immune biologic for approved indications - The patient has a contraindication to Humira (adalimumab), an inadequate response to Humira, OR an adverse reaction to Humira that is not expected to occur with the requested agent - The patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) • ~~The patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ • Coverage is NOT provided for concomitant use with other TIBs including, but not limited to the following: adalimumab (Humira), etanercept (Enbrel), certolizumab (Cimzia), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab-rzaa (Skyrizi), or upadacitinib (Rinvoq ER) **Non-FDA-approved uses are not approved** **Prior authorization does not expire**

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

	• ~~Below criteria applies to all patients (regardless of age):~~
	  ▪ ~~Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this?~~
	  ▪ ~~Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~
	Coverage for non-FDA-approved uses not listed above: Please provide the diagnosis and rationale for treatment. Supportive evidence will be considered.
	Prior authorization does not expire.
	• Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (~~Remicade~~), apremilast (Otezla), ustekinumab (~~Stelara),~~ abatacept (Orencia), anakinra (Kineret), tocilizumab (~~Actemra~~), tofacitinib (Xeljanz/Xeljanz XR), rituximab (~~Rituxan~~), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER).

• secukinumab (Cosentyx)
 	
TIBs: Non-TNFs
	Updates from the August 2024 meeting are in bold and strikethrough.
	Manual PA criteria apply to all new users of secukinumab (Cosentyx).
	Automated PA Criteria: The patient has filled a prescription for adalimumab (Humira), at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 180 days. AND
	Manual PA Criteria: If automated criteria are not met, Cosentyx is approved if all criteria are met.
	• Humira is the Department of Defense's preferred targeted biologic agent. The patient must have tried Humira AND: The patient had an inadequate response to Humira OR the patient experienced an adverse reaction to Humira that is not expected to occur with the requested agent OR the patient has a contraindication to Humira
	• Coverage approved for patients 18 years of age or older with one of the following diagnosis/indication:
	  ▪ Active psoriatic arthritis (PsA)
	  ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
	  ▪ Active ankylosing spondylitis (AS)
	  ▪ Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
	  ▪ Moderate to severe hidradenitis suppurativa (HS)
	  ▪ **Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past**
	• OR Coverage approved for pediatric patients 6-17 years of age with diagnosis of:
	  ▪ Moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
	• OR Coverage approved for pediatric patients 4-17 years of age with diagnosis of:
	  ▪ Active enthesitis-related arthritis (ERA)
	• OR Coverage approved for pediatric patients 2-17 years of age with diagnosis of:
	  ▪ Active PsA
	• **OR Coverage approved for pediatric patients 12-17 years of age with diagnosis of:**
	  ▪ **Generalized pustular psoriasis (GPP) with a history of at least two generalized pustular psoriasis flares of moderate-to-severe intensity in the past**

Appendix C—Table of Prior Authorization (PA) Criteria

	• Below criteria applies to all patients unless noted: ▪ Patient has had an inadequate response to non-biologic systemic therapy. (For example - methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressant's [e.g. azathioprine], antibiotics, anti-androgens, etc.) (Note: AS, nr-axSpA, ERA indications do not apply) ▪ Patient has had an inadequate response to at least two NSAIDs over a period of at least two months (Note: applies to AS and nr-axSpA indication ONLY) ~~▪ Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed)~~ ▪ May not be used concomitantly with other TIBs agents**, including but not limited to TNF inhibitors, IL-1, IL-6, IL-17, IL-23, IL-36, JAK inhibitors** Non-FDA-approved uses are not approved**, except as noted above.** Prior Authorization does not expire
• tocilizumab (Actemra) **TIBs: Non-TNFs**	**Updates from the August 2024 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users tocilizumab (Actemra) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges the Department of Defense's preferred targeted immune biologic is Humira. Has the patient tried Humira? ▪ Patient had inadequate response OR experienced adverse reaction OR has contraindication to Humira • **Provider acknowledges the Department of Defense's preferred tocilizumab is Tyenne. Has the patient tried Tyenne?** ▪ **Patient had inadequate response OR experienced adverse reaction OR has contraindication to Tyenne** • Patient has tried Humira: ▪ Moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs ~~AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ▪ Active polyarticular Juvenile Idiopathic Arthritis (pJIA) • Patient has not tried Humira **and has a diagnosis for which adalimumab is not approved:** AND greater than 18 years of age: ▪ Giant cell arteritis ~~OR~~ ▪ Systemic sclerosis-associated lung disease ~~then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ~~▪ If diagnosis "other" does patient have a contraindication to Humira?~~ ~~If yes and if moderate to severely active RA then has patient has inadequate response to at least 1 or more DMARDs AND patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ~~If yes and If giant cell arteritis OR systemic sclerosis associated lung disease then patient has platelets greater than 100,000/mm3 or liver transaminase less 1.5 UNL~~ ~~• Patient has not tried Humira AND less than 18 years of age but greater than 2 years of age~~ ▪ Patient has systemic Juvenile Idiopathic Arthritis (sJIA)

	~~• Patient has evidence of negative TB test result in the past 12 months or TB is adequately managed~~ • Patient is not receiving other targeted immunomodulatory biologics with tocilizumab Non-FDA approved uses are NOT approved**, except as noted above.** PA does not expire
• mirabegron (Myrbetriq) **Overactive Bladder Agents: Beta-3 Adrenergic Agonists**	**Updates from the August 2024 meeting are in bold.** Manual PA criteria applies **to new and current users of mirabegron generic at all points of service** <u>Manual PA criteria</u> – mirabegron generics are approved if all criteria are met: The following will be added to the existing PA criteria • **Provider acknowledges that the brand Myrbetriq tablet is the preferred product over generic mirabegron and is covered at the lowest copayment, which is the generic formulary copayment for non-Active-Duty patients, and at no cost share for Active-Duty patients. (Although Myrbetriq is a branded product, it will be covered at the generic formulary copayment or cost share)** • **Please provide a patient-specific justification as to why the brand Myrbetriq cannot be used in this patient. _____ (fill-in the blank).** ▪ Reasons to allow the generic mirabegron would be the patient has had an adverse reaction to an excipient in brand Myrbetriq that would not be likely to occur with the generic mirabegron
• sofosbuvir/velpatasvir (Epclusa) **Hepatitis C Agents: Direct Acting Antivirals**	**Updates from the August 2024 meeting are in bold and ~~strikethrough~~.** PA criteria: Epclusa is approved if all criteria are met:*Note: The branded agent on the top of this form is the preferred agent for TRICARE. If the authorized generic of Epclusa is required, please stop filling out this form and complete the separate PA form specific for the authorized generic product. **Note: Mavyret does not require prior authorization** <u>**Automated PA Criteria**</u>**: When prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician, PA is approved.** <u>Manual PA Criteria</u>: **If automated criteria are not met for gastroenterologist, hepatologist infectious disease physician or liver transplant physician specialist prescribing, coverage is approved if all criteria are met:** ~~• Patient is 3 years of age or older~~ ~~• Patient has laboratory evidence of chronic HCV~~ ~~• What is the HCV genotype~~ • **If the physician is a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician, PA is approved OR** • **If the prescriber ~~physician~~ is not a gastroenterologist, hepatologist, infectious diseases physician or a liver transplant physician ~~or and if the drug is prescribed in consultation with a specialist~~, then continue with the questions below.** ~~• Prescribed by a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician OR~~ • **Patient has a detectable hepatitis C viral load AND** ▪ **Patient is not cirrhotic OR** ▪ **Patient is cirrhotic with non-genotype 3 hepatitis c virus (HCV) infection OR** ▪ **Patient is cirrhotic with genotype 3 HCV infection and the prescription is prescribed by or in consultation with a gastroenterologist,**

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

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

Appendix D—Table of Quantity Limits (QL)

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

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

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

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• adalimumab (Cordavis brand of Humira) TIBs: Tumor Necrosis Factor Inhibitors	• adalimumab (Humira) • Other adalimumab biosimilars	• Prefilled pen: 40 mg/0.8 mL • Prefilled syr.: 10 mg/0.1 mL 20 mg/0.2 mL 40 mg/0.4 mL 80 mg/0.8 mL • Dosing: varies based on indication	• rheumatoid arthritis • juvenile idiopathic arthritis • arthritis • psoriatic arthritis • ankylosing spondylitis • adult Crohn's disease • ulcerative colitis • plaque psoriasis • hidradenitis suppurativa • uveitis	ADRs (>10%): • infection (e.g., upper respiratory, sinusitis) • injection site reactions • headache • rash	• AbbVie entered agreement to supply Cordavis with co-branded Humira • No new clinical data • CVS Health launched subsidiary named Cordavis to work with manufacturers to commercialize and/or co-produce biosimilar products • Provides no compelling clinical advantage over existing agents	• Completely Excluded • Interim PA
• adalimumab-ryvk (Simlandi) TIBs: Tumor Necrosis Factor Inhibitors	• adalimumab (Humira) • Other adalimumab biosimilars	• Autoinjector: 40 mg/0.4 mL • Dosing: varies based on indication	• rheumatoid arthritis • juvenile idiopathic arthritis • arthritis • psoriatic arthritis • ankylosing spondylitis • adult Crohn's disease • ulcerative colitis • plaque psoriasis • hidradenitis suppurativa • uveitis	ADRs (>10%): • infection (e.g., upper respiratory, sinusitis) • injection site reactions • headache • rash	• Simlandi only comes in a high concentration formulation that is interchangeable with the reference product • This formulation is citrate free and latex free • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF, non-step-preferred • PA • MN • QL • TRICARE Maintenance Drug List
• danicopan (Voydeya) Hematological Agents	• iptacopan • pegcetacoplan • eculizumab (med benefit) • ravulizumab (med benefit)	• Tablet: 100mg 150mg • Dosing: 150 mg to 200 mg PO TID	• Add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH)	ADR (≥10%) • headache	• Oral complement Factor D inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) that controls extravascular hemolysis and intravascular hemolysis; when used with Soliris or Ultomiris as add-on therapy • Voydeya controls C3 mediated **extravascular** hemolysis whereas Soliris and Ultomiris are complement C5 inhibitors that only inhibit terminal complement-mediated **intravascular** hemolysis in patients with PNH • Fabhalta and Empaveli both control both C3b-mediated **extravascular** hemolysis and terminal complement-mediated **intravascular** hemolysis	• NF • PA • MN • QL • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					• Voydeya is add-on therapy while Fabhalta and Empaveli are monotherapy • Phase 3 study demonstrated Voydeya plus Soliris or Ultomiris to be superior to placebo plus Soliris or Ultomiris in increasing the hemoglobin level from baseline to Week 12 • No head-to-head study versus monotherapy agents (i.e., Empaveli or Fabhalta) • Provides an add-on option to Soliris or Ultomiris for extravascular and intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria (PNH)	
• diazepam (Libervant) Anticonvulsant – Antimania Agents	• Diastat (generic) • Valtoco	• Film - Buccal: 5 mg 7.5 mg 10 mg 12.5 mg 15 mg • Dosing: weight based dosing	• Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age	ADR (≥4%) • headache • somnolence	• Another formulation of diazepam for acute treatment of intermittent, stereotypic episodes of frequent seizure activity in patients with epilepsy 2 to 5 years of age • Libervant was FDA approved through the 505(b)(2) pathway, no new clinical data • Other diazepam formulations for this indication include a rectal gel and a nasal spray • Provides a buccal rescue option for seizure disorders	• UF • QL
• elafibranor (Iqirvo) Gastrointestinal-2 Agents	• urso-deoxycholic acid • obeticholic acid • benzfibrate	• Tablet: 80 mg • Dosing: 80 mg PO QD w/wo food	• Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA	ADR (5%) • weight gain • diarrhea • abdominal pain • nausea • vomiting • arthralgia • constipation • muscle injury • fracture • GERD • dry mouth • weight loss • rash	• Iqirvo is a peroxisome proliferator-activated receptor (PPAR) agonist approved for the adult treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) for those with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA • A single phase 3 study demonstrated a statistically significant achievement in desired biochemical response in patients treated with Iqirvo compared to placebo • Accelerated approved is based on reduction of alkaline phosphatase • Currently lacking long-term data on survival or prevention or liver transplant	• UF • PA • QL • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					• Provides an additional pharmacologic treatment option for adults with this progressive rare disease	
• givinostat (Duvyzat) Corticosteroids -Immune Modulators	• prednisone • deflazacort • vamorolone	• Oral susp: 8.86 mg/ml • Dosing: based on body weight PO BID with food	• Treatment of Duchenne Muscular Dystrophy (DMD) in patients 6 years of age and older	ADR (≥10%) • nausea • vomiting • diarrhea • abdominal pain • thrombocytopenia • elevated triglyceride • pyrexia	• Duvyzat is histone deacetylase inhibitor approved for the treatment of Duchenne Muscular Dystrophy (DMD) in patients 6 years of age and older. • A single phase 3 study demonstrated statistically significant less decline in the 4-stair climb time at 18 months in patients treated with Duvyzat compared with placebo. o Clinical significance of this primary outcome and its therapeutic benefit on long term DMD disease progression is currently unclear • Provides another treatment option for this rare disorder	• NF • PA • MN • QL • TRICARE Maintenance Drug List
• macitentan/ tadalafil (Opsynvi) Pulmonary Arterial Hypertension Agents	• Opsumit 10mg and tadalafil 20mg • ambrisentan • Adempas, • Uptravi	• Film: 10 mg–20 mg 10 mg–40 mg • Dosing: 10 mg-20 mg QD w/wo food	• Chronic treatment of pulmonary arterial hypertension (PAH, WHO Group 1) in adult patients of WHO functional class (FC) II-III	ADR (≥10%) • edema/ fluid retention (21%) • anemia (19%) • headache/ migraine (18%)	• First fixed-dose combination product for PAH comprised of a PDE-5 inhibitor (tadalafil – available as a generic) with an endothelin receptor agonist (macitentan (Opsumit) – patent expiration in Dec 2025) • Phase 3 study demonstrated that combination therapy achieved a higher treatment effect compared to each individual agent alone: no head-to-head trials with any other PAH drug • Only surrogate outcomes available (reduction in pulmonary vascular resistance); no data available that shows the fixed dose combination reduces clinical outcomes (e.g., mortality) • Other than the convenience of reducing tablet burden, provides no compelling clinical advantage over current PAH drug on the formulary	• NF • PA • MN • QL • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• mavorixafor (Xolremdi) Hematological Agents	• n/a	• Capsule: 100 mg • Dosing: based on body weight PO daily	• Patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes	ADR (≥10%) • thrombocytopenia • pityriasis • rash • rhinitis • epistaxis • vomiting • dizziness	• FDA-approved to treat WHIM syndrome, which is a rare immunodeficiency disorder • Phase 3 study demonstrated favorable effectiveness over placebo in increasing ANC from baseline • Provides an alternative option to supportive care to treat WHIM syndrome	• UF • PA • QL • TRICARE Maintenance Drug List
• Myco-phenolate mofetil (Myhibbin) Immuno-suppressive	• generic mycophenolate suspension	• Oral Susp: 200 mg/ml • Dosing: adult: 1 to 1.5 gm PO BID ped: 600 mg/m^2 to 900 mg/m^2 PO BID. Max dose: kidney transplant: 2 g/day for heart/liver transplant: 3 g/day	• Prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants	ADR (≥20%) • diarrhea • leukopenia • infection • vomiting • higher frequency of certain types of infections	• Another oral solution formulation of mycophenolate mofetil that is ready to use versus generic formulation that must be reconstituted by the pharmacist • CellCept is available generically and available as capsules, tablets, oral suspension and SDV for IV use • Shares same boxed warning as CellCept and Myfortic • Myhibbin and CellCept cannot be used interchangeably with Myfortic DR tablets without physician supervision • No new clinical data • Provides no compelling clinical advantage over existing agents	• UF
• naloxone (Rextovy) Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists	• Opvee • Narcan • Zimhi • Kloxxado • generic naloxone nasal sprays	• Nasal spray: 4 mg • Dosing: single spray intranasally. May repeat q2-5 minutes as needed	• An opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and pediatric patients	ADR (≥3%) • oral paresthesia • headache	• Another intranasal formulation of the opioid antagonist, naloxone, for emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and pediatric patients • No new clinical studies • Provides no compelling clinical advantage over existing agents	• UF • QL • Tier 1 Co-pay

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• resmetirom (Rezdiffra) Gastrointestinal-2 Agents	• Ocaliva • Wegovy • Zepbound	• Tablets: 60 mg 80 mg 100 mg • Dosing: varies based on actual body weight	• Treatment of adults with noncirrhotic nonalcoholic steatohepatitis with moderate to advanced liver fibrosis	ADRs (>5%) • diarrhea • nausea • pruritus • vomiting • constipation • abdominal pain • dizziness	• First agent approved with diet and exercise for the treatment of non-cirrhotic NASH with moderate to advanced fibrosis in adults • Phase 3 study demonstrated significantly more patients with NASH with moderate to advanced fibrosis receiving Rezdiffra vs. placebo met at least one of the dual primary endpoints at Week 52 • MAESTRO-NAFLD-OLE study aims to determine long term efficacy and safety following additional 52-weeks of open label study • Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial o Provides an option for non-cirrhotic NASH with moderate to advanced fibrosis in adults	• UF • PA • QL • TRICARE Maintenance Drug List
• sitagliptin/ metformin (Zituvimet AG) Diabetes Non-Insulin: Dipeptidyl Peptidase 4 (DPP-4) Inhibitors	• Janumet • Janumet XR • Kazano • Jentadueto • Kombiglyze XR	• Tablet: 50-1000 mg 50-500 mg • Dosing: 1 tab daily w/food	• Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	ADRs (≥5%) • diarrhea • upper respiratory tract infection • headache	• Another formulation of sitagliptin and metformin • No new clinical studies; approved via 505(b)(2) • Provides no compelling clinical advantage over existing agents	• NF, non-step-preferred • PA • MN
• sotatercept-csrk (Winrevair) Pulmonary Arterial Hypertension Agents	• tadalafil • Opsumit • Ambrisentan • Adempas, • Uptravi	• Single dose vial: 45 mg 60 mg • Dosing: Starting dose 0.3 mg/kg SC with target dose 0.7 mg/kg SC Q3W	• Treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events	ADRs (≥10%) • headache • epistaxis • rash • telangiectasia • diarrhea • dizziness • erythema	• PAH therapy with a new mechanism of action that targets the imbalance between pro-proliferative and antiproliferative signaling to regulate vascular proliferation • The STELLAR trial showed addition of Winrevair to background PAH therapy significantly improved exercise capacity (by showing a clinically relevant increase in 6MWD) and WHO functional class • Secondary endpoint showed a reduction in the composite risk of death or clinical worsening for patients with WHO Group 1 PAH receiving	• UF • PA • QL • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
					background PAH therapies, but the trial was not powered to address mortality • May be self-administered after appropriate training (SC injection q 21 days); considerable monitoring is required for the first 5 doses due to the potential for decreased Hgb and platelet counts • Mild bleeding and telangiectasias are additional adverse events with Winrevair that are not reported with other PAH therapies • Winrevair is not yet addressed in PAH clinical practice guidelines • Winrevair will likely be used as an add-on to dual PAH therapy in patients who are experiencing a suboptimal response or disease progression • Long-term data are needed to show durability of effect	
• spesolimab-sbzo (Spevigo) TIBs: Non-TNFs	• adalimumab (Humira) • secukinumab (Cosentyx)	• Prefilled syr.: 150 mg/ml • Dosing: loading dose of 600 mg followed by 300 mg SC every 4 weeks	• Treatment of general pustular psoriasis (GPP) in adult and pediatric 12 years of age and older and weighing at least 40 kg	ADRs (≥9%): • injection site reaction • urinary tract infection • arthralgia • pruritus	• Spevigo SC is the first medication FDA approved for the treatment of generalized pustular psoriasis when not experiencing a flare • Spevigo IV is approved for treatment of generalized pustular psoriasis flares • Phase 2b study demonstrated moderate improvement with FDA approved dose of Spevigo SC vs. placebo for the primary endpoint of time to generalized pustular psoriasis flare • There is an ongoing 5-year open label extension trial which will further explore the long-term efficacy and safety of Spevigo • Spevigo is associated with the risk of infection and infusion-related reactions • Non-biologics and biologics previously used off-label in USA, several biologics approved in other countries, overall data limited • Provides an option for a rare, potentially life-threatening disorder	• NF non-step-preferred • PA • MN • QL • TRICARE Maintenance Drug List

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

Generic (Trade) UF Class	Comparators	Strength/ Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
• tocilizumab-aazg (Tyenne) TIB: Non-Tumor Necrosis Factor Inhibitors	• Actemra • Kineret • Humira • Kevzara	• Prefilled syr.: 162 mg/0.9 mL • Dosing: 162 mg SC QW or Q2W or Q3W depending on diagnosis and weight	• Actemra biosimilar	ADRs (≥5%): • URI • nasopharyngitis • headache • HTN • increased ALT • injection site reactions	• 2nd biosimilar of Actemra and is available as intravenous and subcutaneous formulations • First biosimilar formulation for the subcutaneous pharmacy benefit • No new clinical data • Actemra has an extra SC indication for slow rate of decline in pulmonary function in adult patients with SSc-ILD, however, this can be extrapolated to Tyenne • Tyenne and Actemra are both available in pre-filled syringes and pre-filled autoinjectors • Provides no compelling clinical advantage over existing agents	• UF, non-step-preferred • PA • QL • TRICARE Maintenance Drug List
• tovorafenib (Ojemda) Oncological	• Tafinlar and Mekinist	• Tablets: 100 mg • Oral Susp: 25 mg/ml • Dosing: 380 mg/m^2 based on BSA PO QW	• Treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement or BRAF V600 mutation	ADRs (≥30%): • rash • hair color changes • fatigue • viral infection • vomiting • headache • hemorrhage • pyrexia • dry skin • constipation • nausea • dermatitis acneiform • URI	• Sole agent FDA-approved for the treatment of patients with relapsed or refractory pediatric LGG, harboring a BRAF fusion or rearrangement or a BRAF V600 mutation • Phase 2 single arm study demonstrated ORR of 51% when Ojemda was used as a third- or fourth-line systemic therapy • Tafinlar + Mekinist are FDA-approved for BRAF V600E mutation-positive LGG only • Guidelines do not yet address Ojemda's role in therapy • Ongoing study assessing use as first line therapy for LGG • Provides an option for relapsed or refractory pediatric LGG, harboring a BRAF fusion or rearrangement or a BRAF V600 mutation	• UF • PA • QL • TRICARE Maintenance Drug List

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

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

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

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

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

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

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

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: October 28, 2024

Two weeks after signing: November 13, 2024

30 days after Signing: November 27, 2024

60 days after signing: January 8, 2025

90 days after signing: January 29, 2025

120 days after signing: February 26, 2025

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

Appendix H—Completely Excluded Agents and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Completely Excluded Products	Formulary Alternatives	Implementation
August 2024	TIBs:	• adalimumab Cordavis brand of Humira	• other adalimumab biosimilars	• 2 weeks

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 32 CFR 199.21(e)(3).

Drugs recommended for complete exclusion will not be available at the MTFs or TMOP points of service. Beneficiaries will be required to pay the full out-of-pocket cost for the complete exclusion agents at the Retail points of service.

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