DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
November 2023

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on November 1st and 2nd, 2023.

II. ATTENDANCE AND PREVIOUS MEETING CLARIFICATION

The attendance roster is listed in Appendix A.

A. Approval of August 2023 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the August 2023 DoD P&T Committee meeting on October 30, 2023.

B. Clarification of previous meeting minutes

- **August 2023**
  - **Specialty Drugs and the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI)—Luteinizing Hormone-Releasing Hormones (LHRH)-Agonists/Antagonists—**In addition to the prostate cancer LHRH drugs, the endometriosis and fibroids, and central precocious puberty LHRH drugs are also maintained on the EMMPI program, as outlined in Appendix F, Table 1 in the August 2023 P&T Committee meeting minutes.
  - **Section 703 drug: tidezolid (Sivextro)—**tidezolid (Sivextro) 200 mg tablets were originally recommended for nonformulary (NF) status with PA and medical necessity (MN) criteria, as the manufacturer (Nabriva Therapeutics) was not in compliance with FY08 NDAA, Section 703, permanently codified at 10 USC 1074g(f). Another manufacturer has purchased Sivextro and is working on complying with Section 703. As a result, Sivextro will remain UF, without PA criteria.
- **May 2023**
  - **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors Agents—adalimumab (Humira)—**The prior authorization (PA) criteria for Humira were updated to allow for approval if the prescriber specialty is Rheumatology. The implementation was delayed from the original implementation date of August 30, 2023. DoD continues to work with the pharmacy benefits manager (PBM) contractor on implementation, based on the P&T Committee recommendations.

- **Over-the-counter (OTC) Naloxone Nasal Spray (OTC Narcan Nasal)—**OTC Naloxone was added to the UF at the May 2023 P&T meeting, although the product did not launch until October 2023. (Refer to the May 2023 P&T Committee minutes for additional information). As of October 5th, prescription claims were processing at Retail Network pharmacies at a $0 copay, with a Tier 1 copay applied at the Mail Order Pharmacy. As per the PBM contractor, a prescription is still required at this time, due to operational limitations.
- **Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI)—**The new drug fezolinetant (Veozah) was not added to the program.
- **Advair HFA brand over generic PA and Tier 1 copay—**The brand over generic PA requirement for fluticasone/salmeterol HFA generic formulations and Tier 1 copay for brand Advair HFA were not implemented (refer to the Utilization Management section on pp 17-18 for additional information).

III. REQUIREMENTS

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

NF medications are generally restricted to the mail order program in accordance with 10 USC 1074g (a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (a)(9), added by Section 702(c)(2) of the NDAA 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

IV. UF DRUG CLASS REVIEWS

A. Migraine Agents-Calcitonin Gene-Related Peptide (CGRP) Antagonist Prophylaxis Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the injectable CGRP antagonists. The drugs in the subclass include erenumab (Aimovig),

fremanezumab (Ajovy), and galcanezumab (Emgality). The products are administered once monthly for prevention of episodic and chronic migraine. Emgality has an additional formulation approved for treating cluster headache. The class was previously reviewed for formulary placement in February 2019.

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

CGRP antagonists vs. oral preventive therapies

- The 2021 American Headache Society consensus statement (which was updated from 2012/2015), encourages use of oral medications including antiepileptics (e.g., valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol) and antidepressants (e.g., amitriptyline, nortriptyline) as first-line treatment options for migraine headache prevention. Injectable CGRP antagonists are recommended after trials of two different oral preventive medications administered at target therapeutic doses for a minimum of 8 weeks.
- There was no new data to change the conclusion from a 2018 network meta-analysis that the evidence is inadequate to distinguish the net health benefit between treatment with the CGRP inhibitors versus oral preventive therapies (e.g., amitriptyline, topiramate, or propranolol).

CGRP antagonist vs. CGRP antagonist

- Although there are still no published head-to-head trials comparing erenumab, fremanezumab, or galcanezumab, there does not appear to be clinically relevant differences in efficacy, based on indirect comparisons from network-meta-analyses for episodic and chronic migraine.
- The 2018 network meta-analysis evaluated the reduction in monthly migraine days for preventive treatment and concluded the three injectable CGRP medications had similar effectiveness and are more effective than the oral CGRPs. *(Note that the oral CGRPs Qulipta, Nurtec ODT and Ubrelvy were not included in this class review.)*

Safety

- The CGRP antagonists have a relatively mild side effect profile, with injection site reactions the most commonly reported adverse event. Injection site reactions occurred at an incidence of 5.6% with Aimovig, 18% to 23% with Emgality, and 45% with Ajovy.
- A 2023 network meta-analysis concluded the following:
  - Compared to Emgality, treatment with Ajovy has a higher odds ratio for serious adverse effects and treatment-emergent adverse effects. No significant differences were noted in serious adverse events between injectable CGRP treatments and placebo.

- Ajovy and Emgality showed greater odds of injection site erythema, induration and pruritus, while Aimovig and Ajovy had higher odds of injection site pain. Ajovy also showed higher odds of diarrhea, and Aimovig had greater odds of constipation, compared to placebo.
- Overall, the meta-analysis concluded that monoclonal antibodies targeting the calcitonin gene-related peptide pathway are a safe and well-tolerated option for migraine prevention.

- There is limited long term efficacy and safety with chronic use. The five years' extension studies for Aimovig reported no significant cardiovascular concerns.

Individual Product Characteristics

- **erenumab (Aimovig)** is available in two dosages, 70 mg and 140 mg. It is unclear whether the two doses differ in efficacy or safety. Advantages include publication of a five-year efficacy and safety extension study, fewer reported adverse effects, and availability of both a prefilled syringe and autoinjector, however the prefilled syringe contains latex. Aimovig is stable at room temperature for up to 7 days.
- **fremanezumab (Ajovy**) is the only CGRP inhibitor approved for quarterly dosing in addition to monthly dosing, however administration of three pens at the same time is required. Ajovy is available in both a prefilled syringe and autoinjector. Disadvantages include the high rate of injection site reactions, and stability at room temperature for only one day.
- **galcanezumab (Emgality)** requires a loading dose, administered as two pens at the same time, however it has a faster onset of action compared to the other drugs. One other advantage is stability at room temperature for up to 7 days. It is the only injectable CGRP with an additional indication for acute cluster headache. Emgality has a higher rate of injection site irritation than Aimovig.

Overall Clinical Conclusion

- Overall, there was no new data to substantially change the clinical effectiveness conclusion from the February 2019 class review.
- There is a high degree of interchangeability between the CGRP antagonists. However, there remains uncertainty regarding the long-term efficacy and safety of this drug class.
- At least one injectable CGRP inhibitor is required on the formulary to meet the needs of the majority of Military Health System (MHS) beneficiaries with chronic or episodic migraine headaches.

Relative Cost Effectiveness Analysis and Conclusion—The P&T Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA),

budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that erenumab (Aimovig), fremanezumab (Ajovy), and galcanezumab (Emgality) were all cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary, NF, or completely excluded on the UF. BIA results showed that designating the injectable CGRP agents in accordance with the formulary recommendation below demonstrated significant cost avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (18 for, 2 opposed, 0 abstained, 0 absent) the following for the CGRP Antagonist Prophylaxis agents, as outlined below, based on clinical and cost-effectiveness:

   Chronic and Episodic Migraine

   - UF and step-preferred
     - galcanezumab injection 120 mg (Emgality) – *moves from UF to UF and step-preferred*
   - UF and non-step-preferred
     - fremanezumab injection (Ajovy) – *moves from UF to UF and non-step-preferred*
     - erenumab injection (Aimovig) – *moves from UF to UF and non-step-preferred*
   - Note that for Ajovy and Aimovig, a trial of Emgality 120 mg is required first in new users.
   - NF – none
   - Complete Exclusion – none

   Cluster Headache

   - UF
     - galcanezumab injection 100 mg (Emgality) – *moves from NF to UF (not part of the step therapy for chronic and episodic migraines)*
   - NF – none
   - Complete Exception – none

2. ***COMMITTEE ACTION: MANUAL PRIOR AUTHORIZATION CRITERIA***—Current PA criteria require a trial of standard oral preventive

therapies for migraine headache first (antiepileptic medications, beta blockers, or antidepressants), consistent with the American Headache Society Consensus Statement.

The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updates to the current manual PA criteria. The PA for Emgality 120 mg was removed, based on cost effectiveness. The PAs for Aimovig and Ajovy were updated to require a trial of Emgality 120 mg (the new step-preferred injectable CGRP) in new users, unless the patient has a contraindication, adverse event or therapeutic failure with Emgality 120 mg. Only new users will be affected by the step-therapy requirements. No changes were recommended for the existing PA criteria for the Emgality 100 mg formulation for cluster headache. (See Appendix C for the full criteria.)

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) maintaining the existing quantity limits for the three CGRP antagonists, with the exception that the QL for Emgality 120 mg was increased to allow for the initial loading dose. See Appendix D.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding Ajovy and Aimovig to the program due to pricing differences by point of service (POS). Emgality 120 mg and 100 mg were not added due to flat-pricing across POS. See Appendix F.

5. ***COMMITTEE ACTION: UF, PA, QL, EMMPI, AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all POS, with the exception that the current PA for Emgality 120 mg will be removed 2 weeks after signing of the minutes and the higher QL for Emgality 120 mg 2 weeks after signing of the minute; see Appendix G.

B. Neurological Agents Miscellaneous – Movement Disorders Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the Movement Disorder subclass, which includes the vesicular monoamine transporter type 2 (VMAT2) inhibitors. The drugs evaluated were tetrabenazine (Xenazine, generics), deutetrabenazine immediate release and extended release (Austedo IR and XR), and

valbenazine (Ingrezza). All four drugs are approved for treating Huntington's disease chorea. Deutetrabenazine and valbenazine are also approved for tardive dyskinesia, while tetrabenazine is used off-label for this indication. The class was last reviewed for formulary status in November 2018; since then, there are now overlapping indications for deutetrabenazine and valbenazine. Austedo XR was reviewed as a new drug at the August 2023 P&T Committee meeting. The clinical review focused on available published trials, clinical practice guidelines, meta-analyses, and systematic reviews.

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

Guidelines

- *Huntington's disease chorea*: Professional clinical practice guidelines from the 2019 International Guideline for Treatment of Huntington's Disease from the European Huntington's Disease Network recommend considering treatment when the disorder causes patient distress or discomfort. Tetrabenazine is mentioned as a first-line treatment option, with deutetrabenazine considered as an alternative to tetrabenazine. Deutetrabenazine ER (Austedo XR) and valbenazine (Ingrezza) were recently FDA-approved for Huntington's disease chorea in 2023 and are not mentioned in this publication.
- *Tardive dyskinesia*: The 2019 Canadian Journal of Psychiatry treatment recommendations for tardive dyskinesia state that all antipsychotic mediations are associated with risk. Recommendations include considering switching from a first-generation antipsychotic to a second-generation (atypical) antipsychotic. For the VMAT2 inhibitors, recommendations are specified for valbenazine and deutetrabenazine (Evidence I+, Grade A), and tetrabenazine Evidence I-, Grade B.

Efficacy

- There are currently no head-to-head trials comparing Xenazine, Austedo, or Ingrezza for tardive dyskinesia or Huntington's disease chorea.
- *Huntington's disease chorea:* An indirect efficacy analysis of individual placebo-controlled clinical trials of Xenazine, Austedo IR, and Ingrezza was reviewed. Each trial demonstrated statistically significant and similar magnitude of reductions in Unified Huntington's Disease Rating Scale (UHDRS) Total Chorea Scores when the individual drugs were compared to placebo. Of note, Austedo XR was approved via the FDA 505(b)(2) pathway using pharmacokinetic date from the Austedo IR FDA application, and there was no new clinical trial data available for review.
- *Tardive dyskinesia*: A 2020 Journal of Clinical Psychiatry network meta-analysis evaluating data for Xenazine, Austedo IR, and Ingrezza suggested the VMAT2 inhibitors may be effective for tardive dyskinesia treatment. An additional 2017

network meta-analysis concluded Ingrezza and Austedo IR were promising but inconclusive, based on improvement in Abnormal Involuntary Movement Scale (AIMS) scores. Additionally, the network meat-analysis suggested a possible benefit for Xenazine for treating tardive dyskinesia symptoms but overall was rated as insufficient.

Safety

- In terms of safety, all agents carry similar warnings, including a black box warning for increased risk of depression and suicidal ideation in patients with Huntington's disease. Multiple contraindications are listed for tetrabenazine (generic Xenazine) and Austedo, whereas Ingrezza only lists a contraindication for hypersensitivity. Overall, more sedation and extra-pyramidal symptoms are reported with tetrabenazine (generic Xenazine), while the rates of dry mouth and diarrhea are higher with Austedo IR and XR, and urticaria and rash are more common with Ingrezza.

Individual Product Characteristics

- **tetrabenazine (generic Xenazine):** Advantages include generic availability and long history of use. Although tetrabenazine does not carry a tardive dyskinesia indication, off-label use is widely accepted. Disadvantages include the lack of data regarding special populations, such as dosing adjustments for geriatric patients and those with renal failure, and the need for genotyping to identify possible drug interactions with CYPD26 metabolic variants. Multiple daily dosing is also required.
- **deutetrabenazine (Austedo IR and Austedo XR):** Both formulations are indicated for treating tardive dyskinesia, in addition to Huntington's disease chorea. Austedo IR uniquely requires administration with food and multiple daily dosing. Advantages of Austedo XR include once daily administration, however there is insufficient evidence at this time to determine what the average daily dosage requirement will be in terms of numbers of tablets required. Data regarding dosage adjustments in special populations is not available.
- **valbenazine (Ingrezza):** Advantages of Ingrezza include FDA-approval for both Huntington's disease chorea and tardive dyskinesia, once daily dosing, and no requirement for dosage adjustment in geriatric patients or patients with renal failure.

Clinical Coverage

- At least one VMAT2 inhibitor is required on the formulary to meet the needs of the majority of MHS beneficiaries with either Huntington's disease chorea or tardive dyskinesia.

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

- CMA results showed that within the Movement Disorder subclass, the generic formulation of tetrabenazine (Xenazine) is the most cost-effective agent.
- BIA was performed to evaluate the potential impact of designating the Movement Disorder subclass agents as UF, NF, or completely excluded from the formulary. BIA results showed that designating all agents as UF offered cost avoidance to the MHS.

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

    - UF
        - tetrabenazine (generic Xenazine)
        - deutetrabenazine IR (Austedo IR)
        - deutetrabenazine ER (Austedo XR)
        - valbenazine (Ingrezza)
    - NF - none
    - Complete Exclusion - none

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—Manual PA criteria have been in place for both Austedo and Ingrezza for several years, and for Austedo XR since the new drug review in August 2023. PA is not required for tetrabenazine. The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) minor updates to manual PA criteria for Austedo IR/XR and Ingrezza, in new users, primarily focusing on streamlining the safety monitoring requirements. For Huntington's disease chorea, the PA will still require a trial of generic tetrabenazine first, based on cost-effectiveness. There were no changes to the criteria for tardive dyskinesia. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent), maintaining a 30-day supply at all points for deutetrabenazine (Austedo IR/XR) and valbenazine (Ingrezza). See Appendix D.

4. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS—***The P&T Committee recommended (18 for, 0 opposed, 1 abstained, 1 absent) adding deutetrabenazine (Austedo IR, Austedo XR) and valbenazine

(Ingrezza) to EMMPI program, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing at mail order). The specific medications are outlined in Appendix F.

5. ***COMMITTEE ACTION: UF, PA and QL IMPLEMENTATION PERIOD—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 30 days after the signing of the minutes in all POS; see Appendix G.

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

The products were divided into three groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included the Humira biosimilars, Brenzavvy, LODOCO, Iyuzeh, Akeega, Suflave, Vanflyta, and Olpruva; Group 2 was comprised of Xdemvy, Ngenla, Opvee nasal, Sohonos, and Airsupra inhaler; and Group 3 included the coronavirus disease (COVID-19) drugs, Paxlovid and Lagevrio. Paxlovid was granted formal FDA approval in May 2023, while Lagevrio is available under an Emergency Use Authorization (EUA).[1]

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; Group 2: 19 for, 0 opposed, 0 abstained, 1 absent; and Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the November 2023 P&T Committee meeting, a brief summary of their clinical attributes, and their formulary recommendations; see Appendix F for their restriction to or exemption from the Mail Order Pharmacy.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; Group 2: 18 for, 0 opposed, 0 abstained, 2 absent; and Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) the following:

    - UF
        - nalmefene nasal spray (Opvee) – Alcohol Deterrents-Narcotic Antagonists
        - lotilaner 0.25% ophthalmic solution (Xdemvy) – Ophthalmic Anti-infectives

[1] Based on the FDA EUA status, this drug is technically not subject to 32 CFR 199.21(g)(5) and EUA drugs, in general, are not subject to automatic addition to the UF.

- niraparib/abiraterone acetate (Akeega) – Oncological Agents
- palvarotene (Sohonos) –Skeletal Muscle Relaxants and Combination
- polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride powder for oral solution with flavor-enhancing packets (Suflave) – Laxatives-Cathartics-Stool Softeners: Bowel Preparations
- quizartinib (Vanflyta) – Oncological Agent for Acute Myelogenous Leukemia (AML)
- sodium phenylbutyrate packets for oral suspension (Olpruva) – Gastrointestinal-(GI) 2 Agents
- nirmatrelvir/ritonavir (Paxlovid) – Antivirals for Coronavirus Disease (COVID-19)
- molnupiravir (Lagevrio) Emergency Use Authorization – Antivirals for COVID-19

- NF
  - adalimumab (Humira) biosimilars–Targeted Immunomodulatory Biologics (TIBs)
    - adalimumab-adbm injection (Cyltezo)
    - adalimumab-fkip injection (Hulio)
    - adalimumab-fkip injection (unbranded biologic)
    - adalimumab-aacf injection (Idacio)
    - adalimumab-bwwd injection (Hadlima)
    - adalimumab-aqvh injection (Yusimry)
    - adalimumab-aaty injection (Yuflyma)
    - adalimumab-adaz injection (Hyrimoz)
    - adalimumab-adaz injection (unbranded biologic)
  - albuterol and budesonide metered dose inhaler (Airsupra) – Short-Acting Beta Agonists (SABAs)
  - bexagliflozin (Brenzavvy) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
  - latanoprost 0.005% ophthalmic solution (Iyuzeh) – Glaucoma Agents: Prostaglandin Analogs
  - somatrogon-ghla injection (Ngenla) – Growth Stimulating Agents

- Complete Exclusion: See Appendix H for additional detail regarding excluded agents and formulary alternatives.
    - colchicine 0.5 mg tabs (LODOCO) – Cardiovascular Agents Miscellaneous
        - LODOCO was recommended for complete exclusion as it has little to no clinical benefit relative to other colchicine formulations when used for cardiovascular risk prevention, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include colchicine 0.6 mg tablets (generic Colcrys) and 0.6 mg capsules (generic Mitigare).

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) MN criteria for the adalimumab biosimilars, Airsupra, Brenzavvy, Iyuzeh, and Ngenla. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) the following PA criteria (see Appendix C for the full criteria):
    - Applying manual PA criteria to new users of Akeega, Iyuzeh, Sohonos, and Vanflyta.
    - Applying manual PA criteria to new and current users of Xdemvy.
    - Applying manual PA criteria to new users of the Humira biosimilars, similar to what is in place for the first Humira biosimilar, Amjevita. 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 Brenzavvy, similar to what is in place for the other non-step-preferred SGLT2 Inhibitors. New patients receiving Brenzavvy or one of the other non-step-preferred SGLT2 Inhibitors (Farxiga, Invokana, Steglatro, or Inpefa) will require a trial of Jardiance first.
    - Applying manual PA criteria to Ngenla, similar to what is in place for the other non-step-preferred growth stimulating agents. A trial of Norditropin, the step-preferred product is required first.
    - Applying interim manual PA criteria for colchicine 0.5 mg tabs (LODOCO) prior to implementation of complete exclusion status, in order to minimize the impact on beneficiaries. See Appendix C for full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) QLs for Airsupra, Humira biosimilars, Xdemvy, Akeega, Olpruva, Opvee nasal, Vanflyta and Sohonos. Additionally, the P&T Committee recommended (Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) QLs for Paxlovid and Lagevrio. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS***—The P&T Committee recommended (Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent); adding or exempting the drugs listed in Appendix F to/from the EMMPI program for the reasons outlined in the table. Brenzavvy will not be added to the EMMPI program. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement. The recommendation for Ngenla was tabled due to the upcoming full drug class review. The COVID-19 drugs, Paxlovid and Lagevrio, are not maintenance drugs and are not appropriate for EMMPI program addition.

6. ***COMMITTEE ACTION: NALMEFENE NASAL (OPVEE) TIER 1 COPAY***—P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) applying the Tier 1 (generic) copay for Opvee nasal spray per 32 CFR 199.21(e)(3)(iii). Other narcotic antagonists (i.e., naloxone) are also available at the Tier 1 copay. Availability of Opvee at the Tier 1 copay will provide a greater incentive for beneficiaries to use a cost effective narcotic reversal agent in the private sector points of service.

7. ***COMMITTEE ACTION: UF, MN, PA, QL EMMPI PROGRAM AND TIER 1 COPAY IMPLEMENTATION PERIOD***—The P&T Committee recommended (Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and for Group 2 and Group 3: 19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the following:

    - **New Drugs Recommended for UF or NF Status:** an effective date of the first Wednesday two weeks after signing of the minutes in all POS; see Appendix G.
    - **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the complete exclusion recommendation at 30 days and 60 days prior to implementation; see Appendix G.
    - **New COVID-19 drugs Paxlovid and Lagevrio:** an effective date of no later than two weeks after signing of the minutes.

Addendum to the UF recommendation – COVID Therapeutics

- ***Tier 1 Copay for Paxlovid*:** After the DoD P&T Committee meeting, updated information was received regarding Paxlovid pricing for DoD. The new information was presented to the DoD P&T Committee members via electronic means. An electronic vote was obtained to recommend a Tier 1 copay for Paxlovid.

COMMITTEE ACTION: ADDENDUM TO UF RECOMMENDATION FOR TIER 1 COPAY: The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) applying the Tier 1 copay for Paxlovid, with implementation occurring no later than 2 weeks after signing of the minutes.

VI. RE-EVALUATION OF NF GENERICS/EMMPI PROGRAM REQUIREMENTS: PULMONARY-1 AGENTS and CONTRACEPTIVES

Background—The DHA Pharmacy Operations Division (POD) Formulary Management Branch (FMB) monitors changes in clinical information, current costs, and utilization trends to determine whether the formulary status of NF drugs now available in generic formulations requires reassessment. Refer to the May 2007, November 2012, and November 2022 P&T Committee minutes for additional information regarding established procedures for returning generic NF agents to formulary status.

A. Pulmonary-1 Agents: Short-Acting Beta Agonists (SABAs) and Combinations (Inhaled Corticosteroids/Long-Acting Beta Agonists-ICS/LABAs) Subclasses

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 30-day equivalent prescriptions for two NF Pulmonary-1 Agents.

1) **Pulmonary-1 Agents: Combinations Subclass: budesonide/formoterol hydrofluoroalkane inhaler (Symbicort HFA)—**At the February 2014 P&T Committee meeting, Symbicort was designated as NF, non-step-preferred, with PA requiring a trial of fluticasone/salmeterol (Advair) first. Subsequently the Symbicort manual PA criteria were updated in November 2019 to allow for acute use as a rescue therapy, based on clinical practice guidelines from the Global Initiative for Asthma (GINA) supporting ICS-formoterol over SABAs. The criteria were updated again in February 2021 to allow for intermittent and daily therapy, known as maintenance and reliever therapy or "MART", based on the U.S. National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC) focused update to the Asthma Management Guidelines. Feedback from MTF providers supports moving Symbicort to UF status to expand beneficiary access to guideline-recommended MART treatment.

Generic formulations of Symbicort are now available, including the product labeled as Breyna and an authorized generic from Prasco. The cost of generic budesonide/formoterol HFA was compared to ICS/LABA formulary alternatives, including Advair Diskus, Advair HFA and generic fluticasone/salmeterol diskus. The P&T Committee concluded that the weighted average cost per 30-day equivalent prescriptions for generic budesonide/formoterol HFA inhalers is within the range of other formulary options.

2) **Pulmonary-1 Agents: SABAs: albuterol HFA 90 mcg (6.7 gram) inhaler (Proventil HFA)**—The ProAir formulation (18 gram) of albuterol HFA inhaler was designated UF at the November 2013 P&T meeting, with other albuterol HFA inhalers designated as NF, including Proventil (6.7 gram) and Ventolin (8.5 gram). Step therapy does not apply to the class, since SABAs are used acutely for asthma and COPD symptoms.

   Brand ProAir HFA has been discontinued from the market. There is now significant generic penetration into the SABA market basket, with availability of generic formulations for ProAir HFA, Proventil HFA and Ventolin HFA. The costs for the albuterol HFA inhalers and respective generics were evaluated. The P&T Committee concluded that the cost of generic Proventil HFA has decreased substantially and is now similar to generic ProAir HFA. Moving Proventil to UF status will allow another rescue option for patients.

   COMMITTEE ACTION: PULMONARY-1 AGENTS FORMULARY STATUS, AND IMPLEMENTATION—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes. (See Appendix F for implementation dates).

   - *Pulmonary-1 Agents: Combinations: budesonide/formoterol HFA*
     - Returning budesonide/formoterol HFA (generic Symbicort HFA) to UF status
     - Removing the budesonide/formoterol HFA PA criteria
   - *Pulmonary-1 Agents: SABAs*: albuterol HFA 90 mcg (6.7 gram), (Proventil HFA)
     - Returning generic Proventil HFA to UF status

B. Contraceptives

The P&T Committee reviewed current utilization, formulary status, generic availability, and relative cost-effectiveness, including the weighted average cost per 28-day cycle, for the NF contraceptive products.

After comparison to similar agents on the UF, the P&T Committee agreed that seven products, including two chewable tablet formulations and two extended cycle products,

should return to UF status. The P&T Committee noted that the two extended cycle products, which are packaged as 84 tablets containing active ingredients followed by 7 placebo tablets, are considered 3-month supply products. An 84-day supply of active drug would require the payment of 3 copays at retail. However, under existing "lesser-of" logic in place for retail network pharmacies for generic medications, patients pay the lesser of standard copays or the cost of the medication, sometimes resulting in total copayments for a 90-day supply that are less than the 30-day supply amount. Generic versions of these products have now dropped in cost below standard generic/Tier 1 copays. Patients would pay the standard generic/Tier 1 copay for a 3-month supply at mail order.

COMMITTEE ACTION: CONTRACEPTIVES FORMULARY STATUS, IMPLEMENTATION—The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) returning the following generically available contraceptives products to UF status, effective the first Wednesday 2 weeks after the signing of the minutes. (See Appendix F for implementation dates).

- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (chew tab) (e.g., Charlotte 24 Fe, Finzala, Mibelas 24 Fe) – Generic Code Number (GCN) 34725
- norethindrone 1 mg/ethinyl estradiol 20 mcg/iron (e.g., Aurovela 24 Fe, Blisovi 24 Fe, Hailey 24 Fe, Junel Fe 24, Larin 24 Fe, Microgestin 24 Fe, Tarina 24 Fe) – GCN 26629
- norethindrone 0.8mg/ethinyl estradiol 25 mcg (chew tab) (e.g., Kaitlib Fe, Layolis Fe) – GCN 29719
- norethindrone 0.4mg/ethinyl estradiol 35 mcg (e.g., Balziva, Briellyn, Philith, Vyfemla) – GCN 11470
- norethindrone 0.4mg/ethinyl estradiol 35 mcg/iron (chew tab) (e.g., Wymzya Fe) – GCN 97167
- levonorgestrel 0.15 mg/ethinyl estradiol 30 mcg 3-month dose pack (e.g., Amethia, Ashlyna, Camrese, Daysee, Jaimiess, Simpesse) – GCN 27096
- levonorgestrel 0.1 mg/ethinyl estradiol 20 mcg 3-month dose pack (e.g., Camrese Lo, Lojaimiess) – GCN 18167

VII. UTILIZATION MANAGEMENT: PULMONARY-1 AGENTS

A. Pulmonary-1 Agents: Combinations with Inhaled Corticosteroids/Long-Acting Beta Agonists (ICS/LABAs)

Background: Brand fluticasone/salmeterol (Advair Diskus and Advair HFA) are on the BCF and are the step-preferred ICS/LABA combination inhalers, dating back to the February 2014 drug class review. A generic formulation of fluticasone/salmeterol diskus

(Wixela) was launched in January 2019. A trial of fluticasone/salmeterol is required before the NF non-step-preferred products, [budesonide/formoterol (Symbicort), mometasone/formoterol (Dulera), fluticasone/vilanterol (Breo Ellipta) and fluticasone /salmeterol respiclick (AirDuo Respiclick)] in patients 12 years of age and older. The generic (Tier 1 copay) applies to Advair Diskus, while Advair HFA has a Tier 2 copay. (The May 2023 recommendations for a generic/Tier 1 copay for Advair HFA and brand over generic HFA PA requirement were not implemented, due to market changes – see clarification section on page 2). Authorized generic formulations of Advair HFA, Advair Diskus, Breo Ellipta and Symbicort are available; additionally, Advair Diskus and Symbicort also have multiple "traditional" generics.

Guidelines now recommend use of ICS-formoterol as both maintenance and reliever therapy ("MART") for asthma symptom control; MART therapy does not apply to ICS combinations containing salmeterol. *(See previous section on NF Generics information for Symbicort see pp 14-15*).

Current step-therapy PA criteria and MN criteria were reviewed for the ICS/LABA combinations, due to the updated clinical practice guidelines, impending changes in availability for brand Advair HFA and Advair Diskus on December 31, 2023 (authorized generics by Prasco will remain available), and upcoming termination of current pricing agreements in January 2024.

The P&T Committee evaluated utilization trends and pricing for the ICS/LABA combinations. With the termination of current pricing agreements, Advair Diskus brand and Advair HFA brand will be less cost-effective, relative to other formulations.

COMMITTEE ACTION: PULMONARY-1 AGENTS PA AND MN CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes. (See Appendix F for implementation dates). There are no changes in the UF status for the ICS/LABA combinations, with the exception of Symbicort, which will move from NF to UF as noted in the NF Generic section on pp 14-15.

- *Advair Diskus brand:*
  - Remove the Tier 1 copay and return to the Tier 2 copay.
  - Remove BCF designation; will remain UF.
  - Note that PA will not be required for generic fluticasone/salmeterol diskus (e.g., Wixela and other generics).
- *Advair HFA brand and fluticasone/salmeterol HFA generics*
  - Remove BCF designation, will remain UF.
  - New PA criteria requiring a trial of the more cost-effective generic fluticasone/salmeterol diskus (e.g., Wixela and other generics) in new

users older than 12 years of age. Providers will also acknowledge that PA is not required for Symbicort. See Appendix C.

- *Dulera, Breo Ellipta, AirDuo Respiclick*
  - Update the PA criteria for Dulera, Breo Ellipta and AirDuo Respiclick requiring a trial of the more cost-effective generic fluticasone/salmeterol diskus (e.g., Wixela and other generics, rather than brand Advair Diskus or brand Advair HFA) in new users older than 12 years of age. The current automated step for the Advair Diskus/HFA lookback will be removed. Providers will also acknowledge that PA is not required for Symbicort. See Appendix C.
  - Update MN criteria to change the formulary alternatives to fluticasone/salmeterol diskus (Wixela) and budesonide/formoterol. See Appendix B.
  - Will remain NF.
- *budesonide/formoterol (Symbicort and generics)* -will move from NF to UF, and the PA will be removed

B. Pulmonary-1 Agents: Inhaled Corticosteroids (ICS)

Background: Both of the fluticasone formulations, Flovent Diskus and Flovent HFA, are designated BCF and are the step-preferred ICS agents, dating back to the May 2014 class review. An authorized generic fluticasone HFA formulation entered the market in August 2022, and a brand over generic requirement for a trial of brand Flovent HFA or Flovent Diskus was required before dispensing of the generic fluticasone HFA. The generic (Tier 1) copay applies to both Flovent HFA and Flovent Diskus.

Current PA criteria, utilization trends, and costs were evaluated for the ICS inhalers, due to upcoming market withdrawal of branded Flovent HFA and Flovent Diskus on December 31, 2023, with subsequent termination of current pricing agreements in January 2024. As a result, brand Flovent Diskus, brand Flovent HFA and authorized generic fluticasone HFA will not be cost effective. At the time of the meeting there were no AB-rated or generics or authorized generics for Flovent diskus.

COMMITTEE ACTION: PULMONARY-1 AGENTS PA AND MN CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following, effective the first Wednesday 30 days after the signing of the minutes. (See Appendix F for implementation dates).

- *Flovent HFA*
  - Remove Tier 1 copay and return to the Tier 2 copay
  - Remove BCF designation; will remain UF

- Remove brand over generic preference for Flovent HFA (remove the current PA for generic fluticasone HFA requiring a trial of Flovent HFA first).
- No PA is required for Flovent HFA

- *Flovent Diskus*
  - Remove Tier 1 copay and return to Tier 2 copay
  - Remove BCF designation; will remain UF
- Note that there are no changes to the PA or MN criteria for the NF, non-step-preferred ICS, as the subclass will be reviewed at an upcoming meeting.

VIII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended 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) Targeted Immunomodulatory Biologics (TIBs): **Tumor Necrosis Factor (TNF) Inhibitors Agents—adalimumab-atto (Amjevita)**—Amjevita is now indicated for the treatment of uveitis in adults, including non-infectious intermediate uveitis, posterior uveitis, and panuveitis in adults. The manual PA criteria were updated to allow for this indication, with the criteria matching what is currently in place for Humira.

b) Metabolic Agents-Miscellaneous

- **odevixibat (Bylvay)—**Bylvay has a new indication for cholestatic pruritis in patients 12 months of age and older with Alagille syndrome. The manual PA criteria were updated to allow for this new indication without an age limitation.
- **maralixibat (Livmarli)—**The manual PA criteria were updated to reflect the new expanded age indication in children as young as 3 months old with cholestatic pruritus from Alagille syndrome.

c) Oncological Agents—dabrafenib (Tafinlar) and trametinib (Mekinist)— The manual PA criteria were updated to allow for use in 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.

d) **Oncological Agents: Breast Cancer—talazoparib (Talzenna)—**The manual PA criteria were updated to allow for Talzenna use in combination with Xtandi for the treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in adults. In addition, the PA was updated to include conception and breastfeeding warnings similar to what is in place for other oncology agents.

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 Amjevita, Bylvay, Livmarli, Mekinist, Tafinlar, and Talzenna 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.

2. **Updated PA Criteria and/or Medical Necessity Criteria for Reasons other than New Indications**

a) **Antipsychotics: Atypical— brexpiprazole (Rexulti)**—Earlier this year, Rexulti received a new indication for treatment of agitation associated with dementia due to Alzheimer's disease. It was previously approved for schizophrenia and as adjunctive therapy to antidepressants in major depressive disorder. Updated manual PA criteria were recommended for the new agitation indication based on provider feedback. The new PA criteria will require specialist prescribing, ruling out other causes of agitation, and trial and failure of non-pharmacologic methods first. The manual PA criteria for the other indications will remain unchanged.

b) **Phosphodiesterase-5 (PDE-5) Inhibitors—tadalafil**—The PDE-5 inhibitors for erectile dysfunction were last reviewed in November 2019. Since the review, generic sildenafil and generic tadalafil prices have dropped precipitously. MTF providers requested a re-review of the current tadalafil PA criteria. TRICARE policy precludes eliminating the PDE-5 inhibitor PA, as treatment of organic impotency is a covered benefit subject to all applicable provisions of 32 CFR 199.4, but impotence solely due to psychological or psychiatric reasons is not covered.

The current tadalafil manual PA requires a trial of sildenafil first, unless the patient has failed therapy, experienced an adverse event or has a contraindication to sildenafil. Tadalafil also is approved for benign prostatic hyperplasia (BPH) which requires use of an alpha blocker (alfuzosin or tamsulosin) first. Upon review of clinical and cost data, the following three edits were recommended: adding an age and gender edit, to allow men 40

years and older to bypass the PA; removing the sildenafil step preference; and removing the BPH step requiring a trial of tamsulosin or alfuzosin.

c) **Skeletal Muscle Relaxants and Combinations—baclofen oral solution (Ozobax), baclofen oral suspension (Fleqsuvy), and baclofen oral granules (Lyvispah)—**Ozobax, Fleqsuvy, and Lyvispah are all alternate oral baclofen dosage formulations and are designated as NF. Current PA criteria restricts use to the sole FDA-approved indication for treatment of spasticity. An MTF oncologist requested allowing use for oncology patients experiencing hiccups as a side effect to their chemotherapy regimens. The PA was updated accordingly.

d) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Constipation-predominant Irritable Bowel Syndrome (CIC/IBS-C)—linaclotide (Linzess) and lubriprostone (Amitiza)—**The CIC/IBS-C class was last reviewed in November 2018. At that time, Linzess and Amitiza were designated as UF, and the PAs for both drugs required a trial of standard laxatives first. Annual PA resubmission was also required. At the May 2021 P&T meeting, PA criteria were updated for Amitiza requiring new users to try Linzess first. The PAs for both Linzess and Amitiza were re-reviewed due to changes in commercial practice and analysis of PA submission rates by MHS providers. Based on a review of available clinical and cost data, the Linzess and Amitiza PAs will now expire after the first year and then afterwards will be approved indefinitely if renewal criteria are met. In addition, the requirement for a trial of Linzess first before Amitiza was removed.

e) **Weight Loss Agents—topiramate extended-release/phentermine (Qsymia) MN criteria—**In February 2023, the manual PA criteria for Qsymia were updated to include the new indication allowing for use in children 12 to 17 years of age for weight management. At this meeting, edits were recommended to the MN criteria to allow for children between the ages of 12 and 15 to bypass the requirement to try phentermine first.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, MEDICAL NECESSITY CRITERIA, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) criteria updates to the manual PA criteria for Rexulti, tadalafil, Ozobax, Fleqsuvy, Lyvispah, Linzess, and Amitiza, and MN criteria for Qsymia. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix B and Appendix C for the full criteria.

B. Line Extensions

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

a) **Oral Oncologic Agents: Poly Adenosine Diphosphate-Ribose Polymerase (PARP) Inhibitors**—designating **niraparib (Zejula) tablets** with the same formulary status (UF), PA, QL and Specialty status as the parent Zejula capsules.

b) **Targeted Immunomodulatory Biologics: Non-Tumor Necrosis Factor Inhibitors**—designating **secukinumab (Cosentyx UnoReady) autoinjector pen** with the same formulary status (UF), PA, QL, Specialty, and EMMPI status as the parent Cosentyx 300 mg/2 mL prefilled syringe.

c) **Pulmonary-1 Agents: Combinations**—designating **fluticasone/vilanterol (Breo Ellipta) 50/25 mcg inhaler** with the same formulary status (NF), PA, QL, and EMMPI status as the parent Breo Ellipta 100/25 mcg and 200/25 mcg inhalers. See Appendix C for the updated Breo Ellipta PA criteria.

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 program, and EMMPI program status of the line extension products, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes, with the exception that the Breo Ellipta new formulation will be updated at 30 days with the other pulmonary UM drugs.

IX. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY: PULMONARY-2 AGENTS: LONG-ACTING MUSCARINIC ANTAGONISTS (LAMAs): TIOTROPIUM (SPIRIVA) HANDIHALER

Tiotropium dry powder inhaler (Spiriva) HandiHaler was reviewed for formulary status in February 2013 and designated as UF (and also added to the Basic Core Formulary [BCF]). AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, dispensing of the branded Spiriva HandiHaler will continue at all three POS and the generic will only be available with PA (i.e., the reverse of the current brand to generic policy). The Tier 1 copay for brand Spiriva HandiHaler is recommended.

COMMITTEE ACTION: TIOTROPIUM DRY POWDER INHALER (HANDIHALER) 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) requiring brand Spiriva HandiHaler over the generic in all new users at all POS, 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 Spiriva HandiHaler. The effective date will be no later than 30 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. Additionally, Spiriva HandiHaler will be added to the rapid response ("safety net") program, which is included in the new TRICARE Pharmacy 5th Generation (TPharm5) contract. See Appendix C for full criteria.

Note that this recommendation does not affect the current status of tiotropium soft mist inhaler (Spiriva Respimat) which was added to the BCF in November 2016. The Tier 1 copay will continue to apply to Spiriva Respimat. At the August 2022 meeting manual PA criteria was recommended for Spiriva HandiHaler, requiring use of Spiriva Respimat first, due to compelling advantages of the delivery mechanism. The brand over generic PA for the generic tiotropium dry powder inhaler would apply after the patient has met Spiriva Respimat step requirement.

X. OVER-THE-COUNTER (OTC) DRUG BENEFIT—PROGESTIN-ONLY CONTRACEPTIVES: NORGESTREL TABLETS (OPILL)

Background: In accordance with 10 U.S.C. 1074g(a)(2)(F), implemented by 32 CFR 199.21(h)(5), an OTC drug may be included on the UF upon the recommendation of the P&T Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. OTC drugs placed on the UF, in general, will be treated the same as generic drugs on the UF for purposes of availability in the MTF pharmacies, retail pharmacies, and the Mail Order pharmacy program and other requirements. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the requirement for the prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special retail pharmacy network copayment may be established under 32 CFR 199.21(i)(2)(xii) for OTC drugs specifically used in certain emergency care treatment situations.

Progestin-Only Contraceptive—OTC Opill:

The P&T Committee evaluated the clinical and cost-effectiveness of the first OTC oral contraceptive, norgestrel 0.075 mg (Opill), for UF addition. Norgestrel 0.075 mg (under the brand name Ovrette) was previously a legend drug but was pulled from the market in 2005 for business reasons, not due to efficacy or safety concerns. Opill was FDA-approved in July 2023 for OTC use, with commercial launch planned for early 2024.

Opill is a progestin-only contraceptive pill (POP). Other POPs include norethindrone 0.35 mg which is UF and drospirenone 4 mg (Slynd) which is NF. POPs require strict adherence and administration at the same time each day for maximal efficacy. Opill has similar efficacy to other prescription oral contraceptives and greater efficacy than other OTC contraceptives (e.g., condoms and spermicides.) POPs have fewer contraindications than combined oral contraceptives which contain estrogen. POPs can be safely used in a wider

population including women who have just given birth, are breastfeeding, or have a history of, or risk factors for venous thromboembolism.

Retail pricing for Opill was not available at the time of the P&T Committee review as the product was not yet commercially launched. A cost-analysis of other contraceptive agents including other POPs was presented. Price bands were established for Opill to define cost effectiveness and to determine formulary placement when pricing is released.

COMMITTEE ACTION: UF RECOMMENDATION, COPAY, PRESCRIPTION REQUIREMENT, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 2 abstained, 0 absent) the following:

- Adding OTC norgestrel 0.075 mg tablets (Opill) to the UF, contingent on retail pricing cost effectiveness. If Opill pricing is not cost effective, then the formulary recommendation will be brought back to the P&T Committee for further consideration at a later date.
- A copay is required pursuant to 10 USC 1074g(a)(6)(A) and 32 CFR 199.21(h)(5)(ii). The Tier 1 copay will apply.
- A prescription is required pursuant to 32 CFR 199.21(h)(5)(ii).
- Implementation plan of two weeks after signing of the minutes or, if OTC Opill has not launched when the minutes are signed, implementation will occur two weeks after market launch of OTC Opill at all points of service

MHS provider feedback and opinions voiced by P&T Committee members were in support of waiving the copay and prescription requirement for Opill. In contrast to naloxone and the emergency contraceptive Plan B, Opill is not considered an emergency treatment, and the copay and prescription requirement cannot be waived. Notably, over half of U.S. states allow pharmacist prescribing of contraceptives, which is a potential option for MHS beneficiaries to obtain Opill.

The P&T Committee recognizes the continued challenges with variations in standards of practice and prescribing rules that are solely under the control of the individual U.S. states. MTF healthcare professionals should work with their local credentialing/privileging authority for any questions they have.

XI. EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST AND NF (TIER 3) MEDICATIONS AVAILABLE UNDER THE TRICARE MAIL ORDER PHARMACY PROGRAM

NF medications are generally restricted to the Mail Order program in accordance with 10 USC 1074g(a)(5) and 32 CFR 199.21(h)(3)(i) and (ii). Additionally, the Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g (9), added by Section 702(c)(2) of the NDAA 2015, which requires beneficiaries generally fill non-generic prescription maintenance medications at MTFs or the ESI-managed TRICARE mail order program.

The P&T Committee reviewed both individual medications and classes or subclasses of medications for potential addition to the EMMPI program and agreed that branded maintenance medications in the following classes or subclasses, as well as the following individual agents, are generally suitable for inclusion on the EMMPI program. The individual agents as well as specific agents in each class or subclass considered most likely to be suitable for the program are listed in Appendix F, Table 2.

- By class/subclass:
  - Oncological Agents: Acute Myelogenous Leukemia
  - Oncological Agents: Breast Cancer
  - Oncological Agents: Chronic Myelogenous Leukemia
  - Oncological Agents: CYP-17 Inhibitors
  - Oncological Agents: EGFR-positive Non-Small Cell Lung Cancer
  - Oncological Agents: Lung Cancer
  - Oncological Agents: Multiple Myeloma
  - Oncological Agents: Myelofibrosis
  - Oncological Agents: PARP Inhibitors
  - Neurological Miscellaneous: Movement Disorders
- By individual agent:
  - dabrafenib mesylate (Tafinlar)
  - trametinib dimethyl sulfoxide (Mekinist)
  - pirtobrutinib (Jaypirca)
  - topotecan HCl (Hycamtin)
  - sonidegib phosphate (Odomzo)
  - vorinostat (Zolinza)
  - alpelisib (Vijoice)
  - carglumic acid (Carbaglu)
  - eltrombopag olamine (Promacta)
  - tafamidis meglumine (Vyndaqel, Vyndamax), plus any future branded tafamidis agent
  - emicizumab-kxwh (Hemlibra)
  - lanadelumab-flyo (Takhzyro)
  - pegvisomant (Somavert)
  - follitropin alfa, recombinant (Gonal-F, Gonal-F RFF, Gonal-F RFF Redi-ject)
  - follitropin beta, recombinant (Follistim AQ)
  - menotropins (Menopur)

- vosoritide (Voxzogo)
- belimumab (Benlysta)

COMMITTEE ACTION: EMMPI PROGRAM STATUS—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) addition of the designated agents as well as appropriate agents in the designated classes or subclasses to the EMMPI program or clarification of their status with regard to the NF to mail requirement, with both addition to the program and implementation date contingent on cost-effectiveness and operational considerations (including feasibility of dispensing at mail order). The specific medications are outlined in Appendix F (Table 2). Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

XII. CONSIDERATIONS OF BETTER CARE, HEALTHIER PEOPLE AND SMARTER SPENDING AND MISCELLANEOUS EMMPI PROGRAM UPDATES:

Background: In accordance with 10 U.S.C. 1074g(a)(10), as implemented in 32 CFR 199.21(e)(3)(i), the P&T Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve 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.

Contraceptives:

- Segesterone acetate/ethinyl estradiol vaginal ring (Annovera) was reviewed as an innovator in November 2019. It is the second contraceptive vaginal ring in the U.S. and can be used for up to one year. Annovera is currently available as UF with a Tier 2 copay, is cost effective and is not on the EMMPI program. It is cost-effective compared to other alternate dose formulations.
- Medroxyprogesterone acetate (Depo-subq Provera) is a SC contraceptive injection administered every 3 months. Depo-subq Provera is currently available as UF with a Tier 2 copay and is not on the EMMPI program. Depo-subq Provera is cost-effective and is similar in price to Depo-Provera which is available at a Tier 1 copay.

Menopausal Hormone Therapy:

- Estradiol acetate vaginal ring (Femring) and estradiol vaginal system (Estring) are both vaginal rings used to treat menopausal symptoms and were last reviewed at the May 2021 meeting. Femring is a systemically acting agent whereas Estring is locally acting. Both agents can be used for up to three months and are available as UF with a Tier 2 copay. At the time of the class review, Femring remained on the EMMPI program and Estring was removed from the EMMPI program due to flat pricing across POS. A look at current cost data shows that Estring is no longer flat-priced. It

is worth noting that the Tier 2 copay at Mail Order is less than the Tier 1 copay at Retail network pharmacies for a three-month supply of medication.

- Conjugated equine estrogens cream (Premarin) was also last reviewed as part of the May 2021 class review. Dosing of Premarin cream is highly variable ranging from 0.5 to 1 g applied one to three times a week. Premarin cream is available as UF at a Tier 2 copay and is not on the EMMPI program. Similar to Estring, it was removed from the EMMPI program due to flat pricing across POS at the time of the class review, but this is no longer the case.

  COMMITTEE ACTION: TIER 1 COPAY, EMMPI PROGRAM REQUIREMENTS, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) the following updates to the Tier 1 and EMMPI status for Annovera, Depo-subq Provera, Femring, Estring, and Premarin Cream. Implementation will be effective the first Wednesday 30 days after the signing of the minutes.

  - Applying the Tier 1 copay at Mail/Retail for Annovera and Depo-subq Provera
  - Maintaining Femring on the EMMPI program
  - Adding Estring to the EMMPI program
  - Adding Premarin cream to the EMMPI program

XIII. MHS GENESIS OTC LIST

Background—The DoD P&T Committee reviewed an MTF request to add an oral urea product for hyponatremia to the MHS GENESIS OTC. The P&T Committee noted the clinical evidence supports use for hyponatremia. The 2014 European Society of Endocrinology clinical practice guideline on diagnosis and treatment of hyponatremia recommends either urea or low-dose diuretics and oral sodium chloride as second-line treatment (after fluid restriction) for moderate or profound hyponatremia. The legend vasopressin antagonist tolvaptan (Samsca) is the most relevant clinical comparator and is not cost effective compared to urea. The specific product purchased by MTFs since Fiscal Year 2018 and available from the national prime vendor is Ure-Na (15 g powder pack), GCN 43481, National Drug Code number (NDC) 62530000011.

COMMITTEE ACTION: STATUS ON THE MHS GENESIS OTC LIST/IMPLEMENTATION—The P&T Committee recommended (15 for, 0 opposed, 1 abstained, 4 absent) adding oral urea 15 g powder pack (GCN 43481) to the MHS GENESIS OTC list. Implementation will occur on signing of the minutes,

as per previous guidance outlined in the May 2020 P&T Committee meeting minutes.

XIV. CLARIFYING LANGUAGE APPLICABLE TO ALL PAs REGARDING CONTRAINDICATIONS

Background: Questions have arisen about appeal rights in cases where a PA does not specifically address what to do when a given beneficiary has a contraindication to a specific medication that is required to be tried before the PA may be approved.

Recommendation: Update the P&T minutes to include the following clarifying language that is recommended to be applicable to all PAs: If the use of a specific pharmaceutical agent(s), required to satisfy the PA, is contraindicated, please attach a narrative explanation and supporting medical documentation explaining the contraindication. When the contraindication is validated clinically, then the specific PA criteria will be considered met.

COMMITTEE ACTION: SECONDARY APPEALS LANGUAGE FOR CONTRAINDICATIONS—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 4 absent) the wording stated above.

XV. P&T COMMITTEE ADMINISTRATIVE AUTHORITY

Background—The Administrative Authorities document outlines which P&T Committee functions can be performed administratively prior to the quarterly meeting, and subsequently presented to the P&T Committee for formal recommendation; those functions which require both Uniform Formulary Beneficiary Advisory Panel (UF BAP) and Director, DHA review, and those which solely require Director, DHA review and do not fall under the purview of the UF BAP panel. The most recent update to the Administrative Authorities document occurred at the May 2023 P&T Committee meeting. The document was previously updated to allow PA criteria changes due to shortages and national emergencies (e.g., pandemic).

Recommendation: The P&T Committee recommended updating the Administrative Authorities document to include revising MN criteria to respond to shortages. The goal is to reduce disruptions in care for MHS beneficiaries. Upon resolution of shortage situations, the MN changes implemented in these situations will be removed.

COMMITTEE ACTION: ADMINISTRATIVE AUTHORITY—The P&T Committee recommended (16 for, 0 opposed, 0 abstained, 4 absent) updates to the Administrative Authorities to allow revisions of MN criteria during drug shortage situations, as outlined above. See Appendix I.

XVI. ITEMS FOR INFORMATION

A. Antirheumatics: Methotrexate vials shortage and MN criteria for alternate methotrexate dosage formulations—Due to an ongoing national shortage of methotrexate vials for injection, the PA was temporarily removed for the prefilled syringe and autoinjector methotrexate formulations of Otrexup, Rasuvo, and Reditrex, which are NF. The MN criteria was also updated to allow a clinical exception if the methotrexate vials are not available due to shortages. MN criteria to allow oral methotrexate tablets was also updated. Otrexup, Rasuvo and Reditrex will all remain on the EMMPI program. See Appendix B.

B. Amikacin liposome inhalation suspension (Arikayce) for refractory non-TB pulmonary MAC infections

Arikayce was designated as NF at the November 2018 P&T Committee, with PA and MN criteria applying. IV amikacin administered via nebulizer is required first before Arikayce. However, due to issues with obtaining the nebulizer device through the TRICARE Medical benefit, the requirement for IV amikacin will be removed from the PA and MN criteria. See Appendices B and C.

C. Sodium-Glucose Co-Transporter 2 (SGLT-2) Inhibitors PA criteria

Empagliflozin (Jardiance) is the UF step-preferred SGLT-2 inhibitor; dapagliflozin (Farxiga) is NF and non-step-preferred. Farxiga received a new indication for heart failure with preserved ejection fraction (HFpEF), however this indication will not be added to the current PA criteria. Empagliflozin is approved for heart failure with any ejection fraction, based on the EMPEROR-Preserved trial. General consensus from Cardiology and Renal guideline groups are that the SGLT-2 inhibitors exhibit a class effect.

XVII. ADJOURNMENT

The meeting adjourned at 1700 hours on November 2nd. The next meeting is scheduled for February 2024.

Appendix A—Attendance: November 2023 DoD P&T Committee Meeting
Appendix B—Table of Medical Necessity Criteria
Appendix C—Table of Prior Authorization Criteria
Appendix D—Table of Quantity Limits
Appendix E—Table of Formulary Recommendations for Newly Approved Drugs per 32 CFR 199.21(g)(5)
Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the November 2023 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Completely Excluded Agents and Therapeutic Alternatives
Appendix I—Table of Administrative Authorities

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

[redacted]

Brian C. Lein, MD
Assistant Director,
Healthcare Administration
for Telita Crosland LTG, MC, USA
Director

29Jan24
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen for COL Paul Carby, MSC	DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD , CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
LTC Charles Lin, MC	Army, Internal Medicine Physician
Ruben Salinas, MD, COL (Ret.) MC, USA	Army, Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Consultant
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CAPT Peter Cole, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Col Larissa Weir, MC	Air Force, OB/GYN Physician
MAJ Courtney Clutter, MC	Air Force, Internal Medicine Physician
Capt Andrew Gaillardetz, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	Physician at Large, DHA
COL Jason Burris, MC	Oncology Physician
Laura Au, RPh, BCOP	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 Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder	DHA, Attorney Advisor, Contract Law
Denis Dyke	DHA, Attorney Advisor, Contract Law
Eugene Moore, PharmD	TPharm4 Clinical COR
CAPT Bill Kelly	Defense Logistics Agency
Guests	
CAPT Tiffany Cline	DHA Direct Care Branch
Lt Col Leighcraft Shakes	DHA Direct Care Branch
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Julianne Canaley	DHA Contracting
Ms. Pat Legra	DHA Contracting
Ms. Sheila Mirrielees	DHA Contracting
Mr. Keith Marasigan	DHA Contracting
Ms. Viktoria Reed	DHA Contracting
Julia Trang, PharmD	DHA Contracting
Ms. Patricia Tyson	DHA Contracting
Mr. Dwight Bonham	DHA Contracting
CAPT Marisol Martinez	Centers for Disease Control and Prevention National Institute for Occupational Safety and Health World Trade Center Health Program (CDC WTCHP)
Hazel Richardson, PharmD	CDC WTCHP
CDR Kendra Jenkins	Bureau of Prisons
CAPT Ryan Schupbach	Indian Health Service
CAPT Weston Thompson	Indian Health Service
Others Present	
CDR Scott Raisor, USPHS	Chief, P&T Section, DHA Formulary Management Branch
Angela Allerman, PharmD, BCPS	DHA Formulary Management Branch
Shana Trice, PharmD, BCPS	DHA Formulary Management Branch

Appendix A—Attendance

CDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
CDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Heather Johnson, PharmD, MS, BCCCP, BCCP	DHA Formulary Management Branch
David Folmar, MS, MBA, RPh	DHA Formulary Management Branch Contractor
Kirk Stocker, BS Pharm, MBA, MHSA	DHA Formulary Management Branch Contractor
Michael Lee, R.Ph., MBM, MPharm-Econ	DHA Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA Formulary Management Branch Contractor
Dean Valibhai, PharmD	DHA Purchased Care Branch
Eric Parsons, R.Ph.	DHA Purchased Care Branch
CDR Teisha Robertson, USPHS	DHA Purchased Care Branch
Julie Mercer, PharmD	University of Texas at Austin pharmacy resident

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
N/A	(No drugs designated as NF from the VMAT2 or injectable CGRP class reviews)
New Drugs MN Criteria	
Humira biosimilars • adalimumab-adbm injection (Cyltezo) • adalimumab-fkip injection (Hulio) and unbranded biologic • adalimumab-aacf injection (Idacio) • adalimumab-bwwd injection (Hadlima) • adalimumab-aqvh injection (Yusimry) • adalimumab-aaty injection (Yuflyma) • adalimumab-adaz injection (Hyrimoz) and unbranded biologic **TIBs: Tumor Necrosis Factor Inhibitors**	• Patient has experienced significant adverse effects from all formulary agents **Formulary alternatives:** adalimumab (Humira)
• albuterol and budesonide inhaler (Airsupra) **Pulmonary-1 Agents: Short-Acting Beta Agonists (SABAs)**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure **Formulary alternatives**: albuterol HFA, budesonide/formoterol HFA
• bexagliflozin (Brenzavvy) **Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	• Patient has experienced significant adverse effects from all formulary agents **Formulary alternatives:** empagliflozin-containing agents (Jardiance/Glyxambi/Synjardy/Synjardy XR/Trijardy XR)

Appendix B—Table of Medical Necessity Criteria

• latanoprost (Iyuzeh) **Glaucoma Agents**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • All formulary agents resulted in therapeutic failure **Formulary alternatives:** latanoprost 0.005% ophthalmic solution (generic Xalatan), bimatoprost (generic 0.03% Lumigan)
• somatrogon-ghla (Ngenla) **Growth Stimulating Agents**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents **Formulary alternatives:** somatropin (Norditropin), somatropin (Omnitrope), somatropin (Zomacton)
Utilization Management Pulmonary Is: ICS/LABA Combinations MN Criteria	
• mometasone/formoterol (Dulera) • fluticasone/vilanterol (Breo Ellipta) • ~~**budesonide/formoterol (Symbicort)**~~ **Pulmonary -1 Agents: Combinations Inhaled Corticosteroid/Long-Acting Beta Agonists (ICS/LABAs)**	**Updates from the November 2023 meeting are in bold and strikethrough** • Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents that is not expected to occur with the nonformulary medication • Formulary agents resulted in therapeutic failure • Patient previously responded to nonformulary agent and changing to a formulary agent would incur unacceptable risk • No alternative formulary agent: • For ~~Symbicort or~~ Dulera – the patient has asthma and requires rescue therapy or intermittent and daily ICS-LABA with an ICS-formoterol combination and **generic budesonide/formoterol is not acceptable** Formulary alternatives: ~~Advair Diskus, Advair HFA~~, **fluticasone/salmeterol diskus (Wixela other generics), budesonide/formoterol (generic Symbicort)**

• fluticasone/salmeterol respiclick (AirDuo Respiclick)
 	
Pulmonary -1 Agents: Combinations (ICS/LABAs)
	Updates from the November 2023 meeting are in bold and strikethrough
	
	• No alternative formulary agent:
	  • The patient requires salmeterol as the LABA component and requires the lower dose found in AirDuo compared to ~~A~~dvair OR
	  • The patient requires fluticasone/salmeterol and cannot manipulate the **generic fluticasone/salmeterol diskus (Wixela**) ~~or hydrofluoroalkane metered-dose inhaler (HFA MDI)~~ device
	
	Formulary alternatives: ~~Advair Diskus, Advair HFA~~, **fluticasone/salmeterol Diskus (Wixela other generics)**

Appendix B—Table of Medical Necessity Criteria

Utilization Management MN Criteria	
• methotrexate prefilled syringe (Reditrex) • methotrexate autoinjector (Otrexup) • methotrexate autoinjector (Rasuvo) **Antirheumatics**	**Updates from the November meeting are in bold** For generic methotrexate tablets: • **The patient requires injectable methotrexate due to therapeutic failure with oral methotrexate** • **The patient requires injectable methotrexate because the patient is unable to tolerate oral tablets despite efforts to mitigate like split dosing or increased doses of folic/folinic acid** For generic methotrexate tablets: • No alternative formulary agent: ▪ **Patient cannot obtain generic methotrexate vials due national supply shortage** ▪ Patient requires a prefilled syringe due to decreased finger dexterity, limited vision or impaired cognition **Formulary alternatives:** methotrexate tablets, methotrexate vials
• topiramate extended release/phentermine (Qsymia) **Weight Loss Agents**	**Updates from the November meeting are in bold** • Use of phentermine has resulted in therapeutic failure • **No alternative formulary agent: The patient is between 12 and 15 years of age** **Formulary alternatives:** phentermine
• amikacin liposome inhalation suspension (Arikayce) **Antibiotics: Aminoglycosides**	**Updates from the November 2023 meeting are in bold** • Formulary agents have resulted in therapeutic failure • Use of formulary agents is contraindicated • **No formulary alternative: patient is not able to obtain IV amikacin** **Formulary Alternatives:** IV amikacin

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• erenumab-aooe (Aimovig) • fremanezumab-vfrm (Ajovy) **Migraine Agents: CGRP Preventative**	**Changes from the November 2023 meeting are in BOLD and strikethrough.** Manual PA criteria applies to all new users of Aimovig and Ajovy Manual PA Criteria: Aimovig or Ajovy is approved if all criteria are met: • **Provider acknowledges that Emgality 120 mg is the DoD's preferred injectable CGRP inhibitor and is available without a PA.** • **Patient has tried and failed Emgality 120 mg OR** • **Patient has experienced an adverse reaction to Emgality 120 mg that is not expected to occur with Aimovig or Ajovy OR** • **Patient has a contraindication to Emgality 120 mg** • Patient is 18 years of age or older • Patient is not pregnant • The drug is prescribed by or in consultation with a neurologist • The patient also meets one of the following: ▪ Patient has episodic migraines at a rate of 4 to 7 migraine days per month for 3 months and has at least moderate disability shown by Migraine Disability Assessment (MIDAS) Test score > 11 or Headache Impact Test-6 (HIT-6) score > 50 OR ▪ Patient has episodic migraine at a rate a migraine diagnosis with of at least 8 migraine days per month for 3 months OR ▪ Patient has a diagnosis of chronic migraine • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE drug from TWO of the following migraine prophylactic drug classes: ▪ Prophylactic antiepileptic medications: valproate, divalproic acid, topiramate ▪ Prophylactic beta-blocker medications: metoprolol, propranolol, atenolol, nadolol, timolol ▪ Prophylactic antidepressants: amitriptyline, duloxetine, nortriptyline, venlafaxine • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Ajovy, Emgality) is not allowed 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 one of the following apply: • The patient has had a reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline (as shown by patient diary documentation or healthcare provider attestation) OR • The patient has shown a clinically meaningful improvement in ANY of the following validated migraine-specific patient-reported outcome measures: ▪ Migraine Disability Assessment (MIDAS) – Reduction of ≥ 5 points when baseline score is 11–20 – Reduction of ≥ 30% when baseline score is > 20 ▪ Headache Impact Test (HIT-6) – Reduction of ≥ 5 points ▪ Migraine Physical Functional Impact Diary (MPFID) – Reduction of ≥ 5 points

Appendix C—Table of Prior Authorization (PA) Criteria

• galcanezumab-gnlm 100 mg injection (Emgality) **Migraine Agents: CGRP Cluster Headache**	**Changes from the November 2023 meeting are in BOLD and strikethrough.** Note that this PA applies to the Emgality 100 mg cluster headache formulation. **The Emgality 120 mg migraine prophylaxis formulation is available without a PA**. ~~**The Emgality 120 mg migraine prophylaxis indication PA criteria is on a separate form.**~~ Manual PA criteria apply to all new users of Emgality for episodic cluster headaches. Manual PA Criteria: Emgality 100 mg at a dosage of 300 mg/month is approved if all criteria are met: • Patient is 18 years of age or older • Patient is not pregnant • The drug must be prescribed by or in consultation with a neurologist • Patient has a diagnosis of episodic cluster headaches • Patient has a contraindication to, intolerability to, or has failed an adequate trial of verapamil, topiramate, or lithium • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Emgality 120 mg, Ajovy) is not allowed Non-FDA-approved uses, including for migraine prophylaxis, chronic cluster headache, medication overuse headache, etc., 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 there is a clinically appropriate reduction in weekly attacks (≥ 50% reduction in weekly cluster headache attack frequency) during an episode as reported by the patient.
• deutetrabenazine immediate release (Austedo) • deutetrabenazine extended-release (Austedo XR) • valbenazine (Ingrezza) **Neurological Agents Miscellaneous: Movement Disorders**	**Changes from the November 2023 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Austedo IR, Austedo XR **and Ingrezza** Manual PA Criteria: Coverage is approved for initial therapy for one year if all criteria are met: • ~~**Patient does not have congenital or acquired long QT syndrome or arrhythmias associated with QT prolongation**~~ • ~~**Patient does not have severe hepatic impairment**~~ • ~~**Patient is not taking any of the following: MAOI within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine [Austedo, Austedo XR], valbenazine [Ingrezza])**~~ • **Patient is 18 years of age or older** • **Provider acknowledges the FDA safety alerts, boxed warnings, precautions, and drug interactions** Huntington's Disease Chorea • Prescribed by or in consultation with a neurologist • Patient has a diagnosis of chorea associated with Huntington's Disease • Patient does not have suicidal ideation • Patient does not have depression or is being adequately treated for depression

	• Patient has had an adequate trial of tetrabenazine for 12 weeks and has experienced treatment failure or experienced an adverse event that is not expected to occur with Austedo IR, **Austedo XR or Ingrezza** Tardive Dyskinesia • ~~**The patient is 18 years of age or older**~~ • Prescribed by or in consultation with a neurologist or psychiatrist • Patient does not have suicidal ideation • Patient does not have depression or is being adequately treated for depression • Patient has moderate to severe tardive dyskinesia causing functional impairment along with schizophrenia, schizoaffective disorder, or a mood disorder • Provider has considered a dose reduction, tapering, or discontinuation of the dopamine receptor blocking agent suspected of causing the symptoms Non-FDA-approved uses are NOT approved (e.g., Tourette's, dystonia) PA expires in one year Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met: • Huntington's Disease Chorea: ▪ Patient has demonstrated improvement in symptoms based on clinician assessment. ▪ Patient is being monitored for depression and suicidal ideation. • Tardive Dyskinesia: ▪ Patient has demonstrated improvement in symptoms based on an improvement of at least 2 on the Abnormal Involuntary Movement Scale (AIMS). ▪ Patient is being monitored for depression and suicidal ideation.
Newly Approved Drug PAs	

Appendix C—Table of Prior Authorization (PA) Criteria

• adalimumab-adbm injection (Cyltezo) • adalimumab-fkip injection (Hulio) • adalimumab-fkip injection unbranded biologic • adalimumab-aacf injection (Idacio) • adalimumab-bwwd injection (Hadlima) • adalimumab-aqvh injection (Yusimry) • adalimumab-aaty injection (Yuflyma) • adalimumab-adaz injection (Hyrimoz) • adalimumab-adaz injection unbranded biologic • **adalimumab-atto (Amjevita) (included from the UM section)** Targeted Immunomodulatory Biologics (TIBs)	**Updates from November 2023 are in bold** Manual PA criteria apply to all new and current users of the Humira biosimilar Manual PA criteria: 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 • 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, **non-infectious uveitis, intermediate uveitis, posterior uveitis and panuveitis**, 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, with the exception **that if an indication is approved for Humira, it is approved for a biosimilar** PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• bexagliflozin (Brenzavvy) **Diabetes Non-Insulin: Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor**	Manual PA criteria apply to all new users of Brenzavvy. <u>Manual PA Criteria:</u> Brenzavvy will be approved if all criteria are met: • The patient is 18 years of age or older • Provider is aware and acknowledges that empagliflozin (Jardiance) and empagliflozin/metformin (Synjardy, Synjardy XR) DoD's preferred SGLT2 inhibitors, and that PA is not required for these drugs • Brenzavvy is prescribed to improve glycemic control in patients with Type 2 Diabetes Mellitus • Patient has experienced an inadequate response to metformin OR • Patient has experienced a significant adverse effect to metformin OR • Patient has a contraindication to metformin OR • Patient has experienced significant adverse reactions to empagliflozin (Jardiance) or empagliflozin/metformin (Synjardy, Synjardy XR) OR • Patient has a contraindication to empagliflozin (Jardiance) or empagliflozin/metformin (Synjardy, Synjardy XR) Non-FDA-approved uses are not approved, including type 1 Diabetes Mellitus PA does not expire
• latanoprost 0.005% ophthalmic solution (Iyuzeh) **Glaucoma Agents**	Manual PA criteria apply to all new users of latanoprost ophthalmic solution (Iyuzeh) <u>Manual PA criteria: Coverage is approved if all criteria are met:</u> • Iyuzeh is prescribed by an ophthalmologist or an optometrist • Patient has a diagnosis of ocular hypertension or open-angle glaucoma • Patient has had a trial of appropriate duration with two different formulary options, from any of the following glaucoma drug classes, in combination or separately: ▪ prostaglandin analogs (e.g., Lumigan, Travatan, Xalatan) ▪ beta blockers (e.g., Timoptic) ▪ alpha2-adrenergic agonists (e.g., Alphagan P) ▪ topical carbonic anhydrase inhibitors (e.g., Azopt, Trusopt, Cosopt) • Patient has failed to reach intraocular target goals using medications from standard therapy classes (standard therapy classes include prostaglandin analogs, beta blockers, alpha2-adrenergic agonists, topical carbonic anhydrase inhibitors) • Patient is currently taking latanoprost and requires a preservative-free formulation due to experiencing adverse events OR • Patient is on three or more different ocular medications that contain preservatives and accumulation of preservatives is a concern Non-FDA-approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• niraparib and abiraterone acetate tabs (Akeega) **Oncologic Agent Miscellaneous**	Manual PA criteria apply to all new users of niraparib and abiraterone acetate (Akeega) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Akeega is prescribed by or in consultation with hematologist/oncologist or urologist • Patient has deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) • Patient is using Akeega concurrently with a gonadotropin – releasing hormone (GnRH) analog (e.g., leuprolide, Eligard, Triptorelin, Goserelin) or has had a bilateral orchiectomy • Akeega will be used in combination with prednisone OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis:_____. AND • Males with female partners will use effective contraception during treatment and for 4 months after the last dose • Provider is aware of the warnings, screening and monitoring precautions for Akeega. Other non-FDA-approved uses are NOT approved except as noted above PA does not expire
• lotilaner 0.25% ophthalmic solution (Xdemvy)	Manual PA criteria apply to all new and current users of Xdemvy Manual PA Criteria: Xdemvy will be approved if all criteria are met: • The patient is 18 years of age or older • The drugs is prescribed by an ophthalmologist or optometrist • Patient has a diagnosis of Demodex blepharitis confirmed by the presence of Demodex mites on microscopic examination • Patient has Demodex infestation with at least 10 eyelashes with collarettes • Patient tried and failed an adequate treatment course with topical tea tree oil • Patient will continue to practice good eyelid hygiene including eye lid wipes (e.g., Ocusoft) Non-FDA-approved uses are NOT approved, including for dry eye disease or meibomian gland dysfunction PA expires in 6 months; a new PA must be submitted

Appendix C—Table of Prior Authorization (PA) Criteria

• palovarotene caps (Sohonos) **Skeletal Muscle Relaxants and Combination**	Manual PA criteria apply to all new users of palovarotene (Sohonos). <u>Manual PA criteria: Coverage is approved if all criteria are met:</u> • Female patients are 8 years of age and older • Male patients are 10 years of age and older • The drug is prescribed by a provider who specializes in the treatment of Fibrodysplasia Ossificans Progressiva • Patient has a diagnosis of Fibrodysplasia Ossificans Progressiva confirmed with a genetic test • Female patients of childbearing age are not pregnant as confirmed by (-) HCG prior to the first dose and then periodically during treatment • Female patients of childbearing potential have been counseled to use effective contraception 1 month prior to treatment, during treatment and for 1 month after the cessation of therapy • Pediatric patients with open epiphyseal plates will undergo assessments of skeletal maturity and linear growth prior to the first dose and every 6 to 12 months thereafter until reaching skeletal maturity or final adult height • Provider is aware of the warnings, screening and monitoring precautions for Sohonos. Non-FDA-approved uses are not approved PA expires in 1 year. <u>Renewal Criteria:</u> Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if all criteria are met: • The patient has had a positive response to therapy • The risks of continued therapy do not outweigh the benefits
• quizartinib tab (Vanflyta) **Oncological Agents: Acute Myelogenous Leukemia**	Manual PA criteria apply to all new users of Vanflyta <u>Manual PA Criteria:</u> Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with a hematologist/oncologist • Patient has newly diagnosed acute myeloid leukemia (AML) that is tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive as detected by an FDA-approved test • The provider is aware of all warnings, monitoring and screening precautions for Vanflyta • Provider is certified to prescribe Vanflyta per REMS requirements OR • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, the provider must list the diagnosis:_____ Other non-FDA-approved uses are not approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• somatrogon-ghla injection (Ngenla) **Growth Stimulating Agents**	Manual PA criteria apply to all new users of Ngenla Manual PA criteria: Ngenla is approved if all criteria are met: • Provider acknowledges that Norditropin is the Department of Defense's preferred somatropin agent. • Patient is a pediatric patient between the ages of 3 to 17 years of age • Ngenla is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients • Ngenla is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment • Patient has a contraindication to Norditropin OR • Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Ngenla *Note, all possible preservative formulations are available between Norditropin, Omnitrope and Zomacton. *Note that patient preference for a particular device is insufficient grounds for approval of an NF agent. AND • Patient requires a less than daily dosing regimen due to needle intolerance or aversion Non-FDA-approved uses are not approved, including Idiopathic Short Stature, normal aging process, obesity, and depression Coverage not approved for concomitant use of multiple somatropin agents PA expires in 1 year; provider must fill out a new PA
Newly Approved Drug Interim PAs for Completely Excluded Drugs	
• colchicine 0.5 mg tabs (LODOCO) **Cardiovascular Agents Miscellaneous**	Interim Manual PA criteria apply to all users of colchicine 0.5 mg tabs (LODOCO) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that LODOCO will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of these meeting minutes by the Director, DHA • Provider acknowledges that other formulations of colchicine are available to TRICARE beneficiaries and do not require prior authorization including colchicine 0.6 mg tablets (generic Colcrys) and colchicine 0.6 mg capsules (generic Mitigare) • Patient is 18 years of age or older • Prescription is written by or in consultation with a cardiologist • Patient has had a previous myocardial infarction or a history of an acute coronary syndrome, angina, history of stroke or transient ischemic attack, coronary artery disease, peripheral arterial disease or has undergone a coronary or other arterial revascularization procedure in the past. • Patient is on guideline-directed standard therapies for the secondary prevention of cardiovascular events • Patient has a creatinine clearance ≥ 50 mL/min • Patient does not have severe liver disease or pre-existing blood dyscrasias Non-FDA-approved uses are NOT approved, including for gout, pericarditis, primary biliary cirrhosis or periodic fever syndrome (must use the generic 0.6 mg formulations instead) PA does not expire (until complete exclusion status implementation)

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management Pulmonary-1 Agents and Pulmonary-2 Agents	
• fluticasone/salmeterol HFA (Advair HFA) and authorized generic fluticasone/salmeterol diskus **Pulmonary -1 Agents: Combinations Inhaled Corticosteroid/Long-Acting Beta Agonists (ICS/LABAs)**	Manual PA criteria apply to all new users of fluticasone/salmeterol HFA(Advair HFA) and authorized generic fluticasone/salmeterol HFA in patients 12 years of age and older PA is not required in patients younger than 12 years of age Manual PA Criteria: Advair HFA is approved if: • Provider acknowledges that generic fluticasone/salmeterol diskus (e.g., Wixela and other generics) and generic budesonide/formoterol (Symbicort) are available without requiring prior authorization and the provider should consider writing for generic fluticasone/salmeterol diskus or generic budesonide/formoterol instead. • Provider acknowledges that if the patient requires an hydrofluoroalkane (HFA) inhaler that generic budesonide/formoterol (Symbicort) is an HFA inhaler and the provider should consider writing for generic budesonide/formoterol instead • Patient has experienced significant adverse effects from generic fluticasone/salmeterol diskus that is not expected to occur with brand Advair HFA • Patient has had an inadequate response to generic fluticasone/salmeterol diskus • Patient previously responded to Advair HFA and changing to fluticasone/salmeterol diskus would incur unacceptable risk Non-FDA-approved uses are NOT approved PA does not expire
• mometasone/formoterol (Dulera) • fluticasone/vilanterol (Breo Ellipta) ~~• budesonide/formoterol (Symbicort)~~ **Pulmonary -1 Agents: Combinations (ICS/LABAs)**	**Changes from the November 2023 meeting are in bold and strikethrough. The previous automated step therapy has been removed** Manual PA criteria apply to all new users of Dulera or Breo Ellipta 12 years of age and older PA is not required in patients younger than 12 years of age Manual PA Criteria: Dulera or Breo Ellipta is approved if: • **Provider acknowledges that generic fluticasone/salmeterol diskus (e.g., Wixela) and budesonide/formoterol (Symbicort) are available without requiring prior authorization and the provider should consider writing for generic fluticasone/salmeterol or generic budesonide/formoterol instead.** • Use of **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus (e.g., Wixela)** ~~formulary agents (Advair Diskus and Advair HFA) is~~ are contraindicated • Patient has experienced significant adverse effects from **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus (e.g., Wixela)** ~~Advair~~ that is not expected to occur with **Dulera or Breo Ellipta** ~~the nonformulary ICS/LABA medication~~ • ~~Formulary agents (Advair Diskus and Advair HFA)~~ Use of **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus (e.g., Wixela)** have resulted or are like to result in therapeutic failure • Patient previously responded to **Dulera or Breo Ellipta** ~~nonformulary agent~~ and changing to **generic budesonide/formoterol (Symbicort) and generic fluticasone/salmeterol diskus** ~~a formulary agent (Advair Diskus and Advair HFA)~~ would incur unacceptable risk

	• The patient has asthma and requires rescue therapy or intermittent and daily ICS-LABA therapy with an ICS-formoterol combination **and generic budesonide/formoterol is not an option. Note that this does not apply to Breo Ellipta** Non-FDA-approved uses are NOT approved PA does not expire
• fluticasone/salmeterol respiclick (AirDuo Respiclick) **Pulmonary -1 Agents: Combinations (ICS/LABAs)**	**Changes from the November 2023 meeting are in bold and strikethrough. The previous automated step therapy has been removed** Manual PA criteria apply to all new users of AirDuo Respiclick 12 years of age and older PA is not required in patients younger than 12 years of age Manual PA Criteria: AirDuo Respiclick is approved if: • **Provider acknowledges that generic fluticasone/salmeterol diskus (e.g., Wixela) and budesonide/formoterol (Symbicort) are available without requiring prior authorization and the provider should consider writing for generic fluticasone/salmeterol diskus or generic budesonide/formoterol instead.** • ~~Is the patient 12 years of age or older?~~ • The patient has a diagnosis of asthma • The patient requires salmeterol as the long-acting beta agonist (LABA) and requires a lower salmeterol dose than found in AirDuo vs. **generic fluticasone/salmeterol diskus (e.g., Wixela)** ~~Advair Diskus or Advair HFA.~~ • The patient requires fluticasone/salmeterol and cannot manipulate the **generic fluticasone/salmeterol diskus (e.g., Wixela**) ~~Advair Diskus or Advair HFA metered dose inhaler~~ devices. Non-FDA-approved uses are NOT approved, **including for chronic obstructive pulmonary disease (COPD)** PA does not expire
• generic tiotropium dry powder HandiHaler **Pulmonary II Agents: Long-Acting Muscarinic Antagonists (LAMAs)**	Manual PA criteria apply to all new users of generic tiotropium dry powder HandiHaler. Manual PA criteria: generic tiotropium dry powder HandiHaler is approved if all the following criteria are met: • The provider acknowledges that Spiriva Respimat is the Department of Defense's preferred long-acting muscarinic antagonist (LAMA) and does not require prior authorization and is available at the lowest (generic) copay. • The provider must document a patient-specific reason as to why the patient requires Spiriva HandiHaler and cannot use the Spiriva Respimat device. (blank write-in) ▪ Acceptable responses include that the patient cannot activate and prime the Respimat device. • In order to receive the generic tiotropium dry powder HandiHaler the provider must document why the patient requires the generic and not the brand Spiriva HandiHaler (blank write-in). ▪ Acceptable responses include that the patient has had an adverse reaction to an excipient in brand Spiriva HandiHaler that would not be likely to occur with the generic tiotropium HandiHaler.

	Non-FDA-approved uses are NOT approved PA does not expire
Utilization Management Updated PAs	
• adalimumab-atto (Amjevita) **TIBs: Tumor Necrosis Factor Inhibitors Agents**	See PA section above for the new drugs
• odevixibat (Bylvay) **Metabolic Agents-Miscellaneous**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of (Bylvay). Manual PA criteria: Coverage is approved if all criteria are met: • Patient **~~is ≥ 3 months and ≥ 5 kg and~~ has** diagnosed progressive familial intrahepatic cholestasis (PFIC) with sever refractory pruritis OR • **Patient has diagnosed Alagille Syndrome with severe refractory pruritus (ALGS) AND** • The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist • Has been evaluated for possible orthotopic liver transplant (OLT) • Has previously tried and failed all of the following: ▪ Ursodiol ▪ Cholestyramine ▪ Rifampin ▪ Naltrexone ▪ At least 1 antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as **~~Alagille syndrome,~~** non-alcoholic steatohepatitis (NASH), non-alcoholic 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 6 months if the following apply: Renewal Criteria TRICARE PA approval required ▪ Patient must demonstrate significant improvement in pruritis symptoms
• maralixibat (Livmarli) **Metabolic Agents-Miscellaneous**	**Updates from the November 2023 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 **~~1 year~~ 3 months** of age or older • The patient has diagnosed Alagille syndrome with severe refractory pruritus • 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), non-alcoholic 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: ▪ TRICARE PA approval required ▪ Patient must demonstrate significant improvement in pruritus symptoms.
• trametinib (Mekinist) **Oncological Agents**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Tafinlar. Manual PA criteria**:** Coverage will be approved if: • Treatment (alone or in combination with dabrafenib [Tafinlar]) of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation; OR • In combination with dabrafenib (Tafinlar), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation • For the treatment of adult and pediatric patients **~~6 years~~ 1 year** of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options • In combination with dabrafenib (Tafinlar), For the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy • Coverage not approved as a single agent in patients who have received prior BRAF inhibitor therapy • Combination with dabrafenib (Tafinlar) for locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options • 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. If so, please list the diagnosis: _____. Non-FDA-approved uses are not approved PA does not expire
• dabrafenib (Tafinlar) **Oncological Agents**	**Updates from the November 2023 meeting are in bold.** Manual PA criteria applies to all new users of Tafinlar. Manual PA criteria**:** Coverage will be approved if: • Utilized as a single agent for treatment of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutation • Combination use with trametinib (Mekinist) in the treatment of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations OR • In combination with trametinib (Mekinist), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation

Appendix C—Table of Prior Authorization (PA) Criteria

	• Combination with trametinib (Mekinist) for locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options • **For the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options** • In combination with trametinib (Mekinist), for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Non-FDA-approved uses are not approved PA does not expire
• talazoparib (Talzenna) **Oncological Agents: Breast Cancer**	**Updates from the November 2023 meeting are in bold.** Manual PA criteria apply to all new users of Talzenna. <u>Manual PA Criteria</u>: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Drug is prescribed by or consultation with a hematologist or oncologist • Patient has a diagnosis of: ▪ Deleterious or suspected deleterious germline BRCA mutated (gBRCAm) and human epidermal growth factor receptor 2-negative (HER2-) breast cancer ▪ **HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC) and Talzenna will be used in combination with enzalutamide** • 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: _____. • **Male patients with female partners of childbearing potential agree to use effective contraception during treatment and for 4 months after the cessation of treatment** • **Female patients of childbearing potential agree to use effective contraception during treatment and for 7 months after the cessation of treatment** • **Female patients will not breastfeed during treatment and for 1 month after the cessation of treatment** Non-FDA-approved uses are NOT approved PA does not expire
• brexpiprazole (Rexulti) **Antipsychotics: Atypical**	**Updates from the November 2023 meeting are in bold.** Note that there were no changes to the current Rexulti criteria for the other indications (depression and schizophrenia) Manual PA criteria apply to all new users of Rexulti for Alzheimer's Disease.

	Provider acknowledges that generic aripiprazole does not need a PA and is available at a lower copay **<u>Manual PA criteria</u>: Coverage is approved if all criteria are met:** • **Patient is 18 years of age or older** • **Patient is being treated for agitation associated with dementia due to Alzheimer's Disease (AD)** • **Rexulti is prescribed by a neurologist, psychiatrist, or specialist in geriatric medicine** • **Other causes of agitation have been ruled out or treated** • **Non-pharmacologic management of agitation has failed** • **Provider is aware of the warnings, screening and monitoring precautions for Rexulti.** Non-FDA-approved uses are NOT approved PA does not expire
• tadalafil **Phosphodiesterase-5 (PDE-5) Inhibitors**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of generic tadalafil. Note that brand Cialis is not covered by TRICARE. **Age and gender edit: Coverage approved for treatment of ED if the patient is a male aged 40 years or older** <u>Manual PA Criteria</u>: Coverage is approved if the following criteria are met: • Patient is older than 18 years of age AND ▪ ~~**Patient has tried generic sildenafil and has had an inadequate response or was unable to tolerate treatment due to adverse effects. OR**~~ ▪ ~~**Treatment with generic sildenafil is contraindicated. OR**~~ ▪ Patient is less than 40 of age and is being treated for ED of organic or mixed organic/psychogenic origin. ~~**The patient must try generic sildenafil first and is unable to use generic sildenafil due to reasons stated above (inadequate response or adverse events.)**~~ OR ▪ Patient is less than 40 years of age and is being treated for drug-induced ED where the causative drug cannot be altered or discontinued. ~~**The patient must try generic sildenafil first and is unable to use generic sildenafil due to reasons stated above (inadequate response or adverse events.)**~~ OR ▪ Use of generic tadalafil 2.5 mg or 5 mg for patients with benign prostatic hyperplasia (BPH) or BPH with erectile dysfunction (ED) ~~**meeting prior authorization criteria requiring use of an alpha blocker [(tamsulosin (Flomax) or alfuzosin (Uroxatral)] unless there is a contraindication, inadequate response, or intolerable adverse effects with the alpha blocker.**~~ • Coverage is approved for the following non-ED uses requiring daily therapy: ▪ Patient requires generic tadalafil for preservation/restoration of erectile function after prostatectomy. PA expires 1 year post surgery. ▪ Use of generic tadalafil for Raynaud's Phenomenon Other non-FDA-approved uses are not approved, including use for females for the treatment of sexual dysfunction PA does not expire except as noted above following prostatectomy

Appendix C—Table of Prior Authorization (PA) Criteria

• baclofen oral solution (Ozobax) • baclofen oral suspension (Fleqsuvy) • baclofen oral granules (Lyvispah) **Skeletal Muscle Relaxants and Combinations**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of baclofen oral solution (Ozobax), baclofen oral suspension (Fleqsuvy), and baclofen oral granules (Lyvispah). Manual PA criteria: Coverage is approved if all criteria are met: • Baclofen will be used for spasticity OR • Patient requires baclofen and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience • **If the indication is for something other than spasticity, please write in requested indication and rationale for use:_____ (blank write-in).** ▪ **Acceptable responses include "hiccups" or "singultus".** ~~**Non-FDA-approved uses are not approved**~~ PA does not expire
• linaclotide (Linzess) **Gastrointestinal-2 Agents: CIC/IBS-C**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA is required for all new users of Linzess. Manual PA Criteria: Coverage is approved if all criteria are met: • Functional constipation (FC) in pediatric patients ▪ Patient is between the age of 6 to 17 years old ▪ Patient has documented symptoms for ≥3 months ▪ Patient has tried or has an intolerance or FDA-labeled contraindication to at least 2 of these agents: lactulose, sorbitol, senna, bisacodyl, glycerin suppositories, or polyethylene glycol 3350) • Constipation-predominant irritable bowel syndrome (IBS-C)/Chronic Idiopathic Constipation (CIC)/Opioid Induced Constipation (OIC) ▪ Patient is 18 years of age or older ▪ Patient has documented symptoms for ≥ 3 months ▪ Patient has diagnosis of IBS-C or CIC or OIC in adults with chronic, non-cancer pain ▪ Patient is currently taking an opioid if used for OIC ▪ Patient has documentation of failure of an increase in dietary fiber/dietary modification to relieve symptoms ▪ Patient has absence of GI obstruction ▪ Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as • osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories) • bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids • stool softener (e.g., docusate) • stimulant laxative (e.g., bisacodyl, sennosides) • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik) Non-FDA-approved uses other than OIC are NOT approved

Appendix C—Table of Prior Authorization (PA) Criteria

	PA expires after 1 year Renewal PA Criteria: Coverage will be approved **indefinitely ~~for 1 year~~** for continuation of therapy if: • Patient has had improvement in constipation symptoms AND • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik).

• lubriprostone (Amitiza) **Gastrointestinal-2 Agents: CIC/IBS-C**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Amitiza. Manual PA Criteria: Coverage is approved if all criteria are met: • The patient is 18 years of age or older OR is prescribed in consultation with a pediatric gastroenterologist for pediatric patients • Patient has documented symptoms for ≥ 3 months • Patient has diagnosis of constipation predominant irritable bowel syndrome (IBSC) or chronic idiopathic constipation (CIC) or opioid induced constipation (OIC) in adults with chronic, non-cancer pain ▪ Patient is currently taking an opioid if used for OIC ▪ Patient is female if used for IBS-C • Patient has documentation of failure of an increase in dietary fiber/dietary modification to relieve symptoms • Patient has absence of GI obstruction • Patient has tried at least 2 standard laxative classes or has an intolerance or FDA-labeled contraindication to at least 2 standard laxative classes, defined as • osmotic laxative (e.g., lactulose, sorbitol, magnesium [Mg] citrate, Mg hydroxide, glycerin rectal suppositories) • bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids • stool softener (e.g., docusate) • stimulant laxative (e.g., bisacodyl, sennosides) • ~~**Patient has tried and failed linaclotide (Linzess)**~~ • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik) Non-FDA-approved uses are NOT approved PA expires after 1 year Renewal PA Criteria: Note that initial TRICARE PA approval is required for renewal. PA will be approved **indefinitely** ~~**for 1 year**~~ for continuation of therapy if: • Patient has had improvement in constipation symptoms AND • Patient is not taking any of these agents concomitantly (Linzess, Amitiza, Trulance, Symproic, Relistor, or Movantik)

• amikacin sulfate liposomal inhalation suspension (Arikayce) **Antibiotics: Aminoglycosides**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Arikayce. Manual PA Criteria: Arikayce is approved if ALL of the following criteria are met: • The patient is 18 years of age or older • Prescription is written by or in consultation with an Infectious Disease Specialist and/or Pulmonologist. • Patient has a diagnosis of refractory *Mycobacterium avium complex* (MAC) lung disease as defined as a patient who does not achieve negative sputum cultures after a minimum of 6 consecutive months of conventional therapy. • Patient continues to have a susceptible infection to amikacin. • Patient is on a concomitant multidrug background (baseline) regimen therapy. • ~~**Provider must explain why the patient cannot use IV amikacin (fill in the blank)**~~ • Provider acknowledges and patient has been informed that Arikayce carries a boxed warning for risk of increased respiratory adverse reactions that can lead to hospitalization. • Provider acknowledges and patient has been informed that warnings and precautions of Arikayce include hypersensitivity pneumonitis, hemoptysis, bronchospasm, exacerbation of underlying pulmonary disease, ototoxicity, nephrotoxicity, neuromuscular blockade, and embryo-fetal toxicity. • Provider acknowledges (and patient has been informed) the patient will be monitored for adverse reactions that include but are not limited to: (from package insert occurring at an incidence of ≥ 10% and higher than control) dysphonia, cough, bronchospasm, hemoptysis, ototoxicity, upper airway irritation, musculoskeletal pain, fatigue/asthenia, exacerbation of underlying pulmonary disease, diarrhea, and nausea. Non-FDA-approved uses are NOT approved (including for *Pseudomonas Aeruginosa*) PA does not expire

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• erenumab (Aimovig) • fremanezumab (Ajovy) **CGRP Prophylaxis Subclass**	• Retail: 1 syringe or pen per fill (allow multiple copays for multiple refills) • MTF/Mail: 3 syringes per fill
• galcanezumab120 mg (Emgality) **CGRP Prophylaxis Subclass**	• Retail: 2 syringe or pen per fill (allow multiple copays for multiple refills) • MTF/Mail: 4 syringes or pens per fill
• galcanezumab100 mg (Emgality) **Migraine Agents: CGRP** **Cluster Headache**	• Retail: 1 package (3 syringes) per fill • MTF/Mail: 3 packages (9 syringes) per fill
• deutetrabenazine (Austedo IR, Austedo XR) • valbenazine (Ingrezza) **Neurological Agents** **Miscellaneous: Movement Disorders**	• MTF/Mail/Retail: 30-day supply
• adalimumab (Humira) biosimilars ▪ Cyltezo ▪ Hulio and unbranded biologic ▪ Idacio ▪ Hadlima ▪ Yusimry ▪ Yuflyma ▪ Hyrimoz and unbranded biologic **TIBs**	• MTF/Mail/Retail: 60-day supply
• albuterol and budesonide inhaler (Airsupra) **SABAs**	• Retail: 3 inhalers per fill • MTF/Mail: 9 inhalers per fill
• niraparib and abiraterone acetate (Akeega) **Oncological Agents: Prostate Cancer**	• MTF/Mail/Retail: 60-day supply
• lotilaner 0.25% ophthalmic solution (Xdemvy) **Ophthalmic Agents**	• MTF/Mail/Retail: 1 bottle/ 6 weeks supply

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• nalmefene nasal spray (Opvee) **Alcohol Deterrents-Narcotic Antagonists: Narcotic Antagonists**	• MTF/Mail/Retail: 60-day supply
• palvarotene (Sohonos) **Skeletal Muscle Relaxants and Combination**	• MTF/Mail/Retail: 30-day supply
• quizartinib (Vanflyta) **Oncological Agents: Acute Myelogenous Leukemia**	• MTF/Mail/Retail: 60-day supply
• sodium phenylbutyrate packets for oral suspension (Olpruva) **Gastointestinal-2 Agents**	• MTF/Mail/Retail: 30-day supply
• ritonavir-boosted nirmatrelvir (Paxlovid) **Coronavirus dissease-19 (COVID-19) Antivirals**	• MTF/Retail: 30 tablets per 90 days Paxlovid is not available at mail due to acute use
• molnupiravir (Lagevrio)* **Coronavirus dissease-19 (COVID-19) Antivirals** Available pursuant to FDA-granted Emergency Use Authorization	• MTF/Retail: 40 tablets per 90 days Lagevrio is not available at mail due to acute use

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
adalimumab-abdm (Cyltezo) Targeted Immuno-modulatory Biologics (TIBs)	• adalimumab (Humira) • Other adalimumab biosimilars	• Prefilled pen: 40 mg/0.8 mL • Prefilled syringe: 10 mg/0.2 mL, 20 mg/0.4mL, 40 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%): • infections (e.g., upper respiratory, sinusitis) • injection site reactions • headache • rash	• Cyltezo is currently only available as a low concentration formulation • It is the only agent that is currently approved for interchangeability • This product is not latex free • There is a high concentration formulation in development • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL
adalimumab-bwwd (Hadlima) TIBs	• Same as Cyltezo	• PushTouch autoinjector: 40 mg/0.8 mL, 40 mg/0.4 mL • Prefilled syringe: 40 mg/0.8 mL, 40 mg/0.4 mL • Dosing: Varies based on indication	• Same as Cyltezo	• Same as Cyltezo	• Hadlima is marketed in a low concentration and a high concentration formulation • The low concentration formulation is not citrate-free • The high concentration formulation is seeking interchangeability status • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL
adalimumab-fkjp (Hulio) + unbranded biologic TIBs	• Same as Cyltezo	• Prefilled Pen: 40 mg/0.8 mL • Prefilled syringe: 20 mg/0.4 mL, 40 mg/0.8 mL • Dosing: Varies based on indication	• Same as Cyltezo	• Same as Cyltezo	• Hulio only comes in a low concentration formulation • Hulio has an unbranded version available as well • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
adalimumab-adaz (Hyrimoz) + unbranded biologic TIBs	• Same as Cyltezo	• Prefilled Pen: 40 mg/0.4 mL & 0.8 mL, 80 mg/0.8 mL • Prefilled syringe: 10 mg/0.1 mL & 0.2 mL 20 mg/0.2 mL & 0.4 mL, 40 mg/0.4 mL & 0.8 mL, 80 mg/0.8 mL • Dosing: Varies based on indication	• Same as Cyltezo	• Same as Cyltezo	• Hyrimoz is available as a low and high concentration formulation • Hyrimoz has an unbranded version available as well • The low concentration formulation is not citrate free • May be stored at room temperature for up to 21 days • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL
adalimumab-aacf (Idacio) TIBs	• Same as Cyltezo	• Prefilled pen and prefilled syringe: 40 mg/0.8 mL • Dosing: Varies based on indication	• Same as Cyltezo except is not indicated for uveitis	• Same as Cyltezo	• Idacio is only available as a low concentration formulation • May be stored at room temperature for up to 28 days • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL
adalimumab-aaty (Yuflyma) TIBs	• Same as Cyltezo	• Prefilled autoinjector and prefilled syringe: 40 mg/0.4 mL, 80 mg/0.8 mL • Dosing: Varies based on indication	• Same as Cyltezo except is not indicated for uveitis	• Same as Cyltezo	• Yuflyma is only available as a high concentration formulation • May be stored at room temperature for up to 31 days • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL
adalimumab-aqvh (Yusimry) TIBs	• Same as Cyltezo	• Prefilled pen: 40 mg/0.8 mL • Prefilled syringe: 40 mg/0.8 mL • Dosing: Varies based on indication	• Same as Cyltezo	• Same as Cyltezo	• Yusimry is only available as a low concentration formulation • There is a high concentration formulation in development • No new clinical data • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • PA • QL

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
albuterol and budesonide metered dose inhaler (Airsupra) Short-Acting Beta Agonists (SABAs)	• albuterol HFA (ProAir, Proventil, Ventolin) • budesonide	• Inhaler • 2 oral inhalations as needed for symptoms • max 6 doses (12 inhalations) in 24 hours	• As needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in asthma patient 18 years of age and older	• headache • oral candidiasis • cough • dysphonia	• Pressurized metered dose inhaler (pMDI) containing albuterol sulfate, a beta2-adrenergic agonist and budesonide, a corticosteroid • Administered as an as-needed rescue inhaler to treat or prevent asthma symptoms • In the MANDALA clinical trial, significantly ↓ risk of severe exacerbations compared to albuterol ○ 2° endpoint of mean annualized rate of severe asthma exacerbations was significantly reduced compared to albuterol • In the DENALI clinical trial, significantly improved lung function compared to the individual albuterol and budesonide components • Offers a combined treatment option that provides relief and reduces inflammation • The most appropriate place in therapy remains to be determined; is not yet included in any asthma professional treatment guidelines	• NF • MN • QL
bexagliflozin (Brenzavvy) Sodium-Glucose Co-Transporter-2 (SGLT-2) inhibitors	• canagliflozin (Invokana) • dapagliflozin (Farxiga) • empagliflozin (Jardiance) • ertugliflozin (Steglatro)	• 20 mg tabs • 1 tab daily	• Adjunct to diet/exercise to improve glycemic control in Type 2 Diabetes Mellitus	AEs reported >5% • female genital mycotic infections • UTI • increased urination	• 6th marketed SGLT-2 inhibitor • No cardiovascular (CV) outcomes data. Unlike empagliflozin, dapagliflozin and canagliflozin, is solely indicated for Hb1AC lowering (although likely a class effect for CV/CKD/HF benefits) • Warnings include lower limb amputation, volume depletion and Fournier's gangrene, similar to the other SGLT-2 inhibitors • The manufacturer has partnered with an online-pharmacy to market Brenzavvy at a significant discount compared to the other SGLT-2 inhibitors. However, the contracting condition sets from the August 2015 P&T meeting limits new SGLT-2 inhibitor market entrants to NF, non-step-preferred status • Provides no compelling clinical advantage over the other SGLT-2 inhibitors, due to its lack of data for positive CV outcomes	• NF non-step-preferred • PA • MN

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
colchicine 0.5 mg tablets (LODOCO) Cardiovascular Miscellaneous Agents	• colchicine 0.6 mg tablets (generic Colcrys) • colchicine 0.6 mg caps (Mitigare)	• 0.5 mg tablets • 1 tab daily	Reduce the risk of MI/stroke/ coronary revascularization and CV death in pts with est. ASCVD or multiple risk factors for CVD	• GI – diarrhea, vomiting, abdominal cramping • myalgia • males – transient infertility (rare)	• New low-dose colchicine formulation with a specific indication for reduced atherosclerotic cardiovascular disease (ASCVD) events • Mechanism is due to anti-inflammatory effects and decreased C-reactive protein levels • Historically 0.6 mg dose has been used in North America, with 0.5 mg used outside U.S. (Australia) • Approval based on 1 RCT (LoDoCo2) primarily conducted in Australia which showed significant reduction in composite endpoints in patients with established ASCVD • Cardiology guidelines recommend considering addition of colchicine for 2° prevention to reduce ASCVD events, but do not specify a dose (weak strength of recommendation based on 1 RCT of moderate quality of evidence) • Limitations include drug interactions (CYP3A4 inhibitors/p-glycoprotein inhibitors) and GI AEs • Contraindications include CrCl < 15 mL/min, hepatic impairment • Cost-effective generic formulations of Colcrys (0.6 mg tabs) and Mitigare (0.6 mg caps) are now available • Other CV uses (e.g., pericarditis) are off-label but supported by guidelines • Provides no compelling advantage over the 0.6 mg tablets	• Complete Exclusion • Interim PA until Complete Exclusion implementation
latanoprost 0.005% ophthalmic solution preservative-free (Iyuzeh) Glaucoma Agents: Prostaglandin Analogs	• latanoprost 0.005% (generic Xalatan) • latanoprost 0.005% ophth emulsion (Xelpros) • tafluprost (Zioptan)	• ophthalmic solution in single-dose containers. • Each pouch has 5 single-dose containers. • 1 drop in the affected eye every evening	• Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension	• conjunctival hyperemia • eye irritation • eye pruritus • abnormal sensation in eye • foreign body sensation in eyes • vision blurred • ↑ lacrimation	• 2nd preservative free ophthalmic prostaglandin • Generic latanoprost and bimatoprost contain benzalkonium chloride which is thought to cause corneal irritation • One Phase 3 study demonstrated non-inferiority to Xalatan in mean IOP reduction • Fewer patients in the Iyuzeh group experienced ocular AEs compared to Xalatan • Provides no compelling clinical advantage over existing agents	• NF • PA • MN

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
lotilaner 0.25% ophthalmic solution (Xdemvy) Ophthalmic Anti-Infectives	• Tea tree oil	• 0.25% ophthalmic solution in a 11 mL container • 1 drop in each eye BID x 6 weeks	• Treatment of Demodex blepharitis	• instillation site stinging and burning	• First FDA-approved antiparasitic treatment for Demodex blepharitis • Two phase 3 vehicle-controlled studies demonstrated 44% and 56% collarette cure (grade 0) • Clinically meaningful collarette cure (grade 0-1) was 81% and 89%, respectively • Patients experienced mild adverse effects which mainly consisted of instillation site pain • Although Xdemvy is the only FDA-approved therapeutic option for the treatment of Demodex blepharitis, there is no comparative data with other off-label treatments, and no data regarding re-treatment courses	• UF • PA • QL
nalmefene nasal spray (Opvee) Alcohol Deterrents-Narcotic Antagonists	• naloxone nasal spray (Narcan) • naloxone nasal spray (Kloxxado)	• Nasal spray: 2.7 mg of nalmefene in 0.1 mL 2 devices/carton) • Single spray intranasally. May repeat q2-5 minutes as needed	• Emergency treatment of known or suspected overdose induced by natural or synthetic opioids in patients aged 12 years and older	• nasal discomfort, headache, nausea, dizziness, hot flush, vomiting, anxiety, fatigue, nasal congestion, throat irritation, rhinalgia, anorexia, dysgeusia, erythema, hyperhidrosis	• Opioid antagonist indicated for emergency treatment of known or suspected overdose • Approval via 505(b)(2) pathway with no new clinical trial data available • Opvee has a long half-life of 11 hours and an onset of 3-5 minutes • Opvee provides an additional treatment option for reversal of opioid overdose	• UF • QL • T1 copay
niraparib/ abiraterone acetate (Akeega)	• olaparib (Lynparza) • talazoparib (Talzenna)	• 50 mg/500 mg, 100 mg/500 mg tablets • 200 mg niraparib/1,000 mg abiraterone acetate daily	• Indicated with prednisone for treatment of adults with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC)	• ↓ blood cell indices • musculoskeletal pain, fatigue • ↑ alk phosp, creatinine, AST/ALT, bilirubin • GI AEs hypertension, edema, dyspnea, abdominal pain, hemorrhage, UTI, cough, insomnia, arrhythmia, pyrexia	• Fixed-dose combination tablet. Individual components are available separately • Phase 3 study demonstrated a significant increase in median radiographic progression-free survival: 16.6 months with Akeega vs 10.9 months in the placebo + abiraterone group • No head-to-head trials available for the three PARP inhibitor combinations • Talzenna can be used in non-BRCAm and BRCAm mCRPC while Lynparza and Akeega can only be used in BRCAm mCRPC • Alternative to Lynparza or Talzenna in the first-line setting for patients with mCRPC with a BRCAm.	• UF • PA • QL

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
palovarotene (Sohonos) Skeletal Muscle Relaxants and Combinations	• N/A	• 1, 1.5, 2.5, 5, 10 mg capsules • ≥14 yr: maintenance: 5 mg QD flares 20 mg QD x 4 wk, then 10 mg QD x 8 wk • ≤ 13 yr: weight-based ranges	• Reduction in volume of new heterotopic ossification, 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP)	• dryness • arthralgia • pruritis, rash, erythema • alopecia • skin exfoliation • nausea • musculoskeletal pain • myalgia • dry eye • fatigue • hypersensitivity • peripheral edema	• First FDA-approved treatment for the orphan indication of FOP • In a phase 3, open-label study, the prespecified primary analysis for the primary endpoint failed to demonstrate efficacy • However, FDA re-review agreed with a post-hoc analysis which demonstrated substantial evidence of the effectiveness of Sohonos in the treatment of FOP, using a natural history study (NHS) as an external control • The FDA concluded effectiveness of Sohonos, with the mean annualized new HO volume of 9.4 cm3/year in subjects receiving Sohonos compared with 20.3 cm3/year in untreated subjects from the NHS, with a treatment difference of 10.9 cm3/year (95% CI: -21.2, -0.6). • Patients experienced known adverse effects with oral retinoids; additionally, the drug carries a block box warning for premature epiphyseal closure and embryo-fetal toxicity • Sohonos provides a pharmacologic option for this rare, progressive, and debilitating disorder	• UF • PA • QL
Polyethylene glycol 3350, NaS04, KCl, MgS04 and NaCl powder for oral solution with flavor enhancing packets (Suflave) Bowel Preparations	• GoLYTELY • NuLYTELY • Moviprep • Plenvu • Suprep	• Dose 1 on evening before colonoscopy • Dose 2 on morning of colonoscopy	• Cleaning of the colon in preparation for colonoscopy	• nausea • abdominal distension • vomiting • abdominal pain • headache	• Another osmotic bowel prep for colonoscopy • Two studies demonstrated non-inferiority to MoviPrep and SUPREP • This formulation has a lemon-lime flavor which is like a sports drink to enhance palatability • Designed to imitate the popular but unapproved PEG and sports drink preparation • Provides no compelling clinical advantage over existing agent	• UF

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
quizartinib (Vanflyta) Oncological Agents for Acute Myelogenous Leukemia	• midostaurin (Rydapt) • gilteritinib (Xospata)	• Tablet: 17.7 mg, 26.5 mg • Induction: 35.4mg daily on days 8-21 • Consolidation: 35.4mg daily on days 6-19 • Maintenance: 26.5mg daily on days 1-14, then 53mg daily on days 15-28	• Adults with new AML that is FLT3-ITD positive as detected by an FDA-approved test • Induction, consolidation and maintenance tx	• ↓ lymphocytes, Ca, albumin, K, Mg, PO4 • ↑ increased alkaline phosphatase, CPK • febrile neutropenia, diarrhea, mucositis, nausea, abdominal pain, sepsis, URI, neutropenia, vomiting, headache	• Approval was based on a single phase 3 study demonstrating improved overall survival with Vanflyta and standard therapy vs. placebo and standard therapy • Safety demonstrated febrile neutropenia and GI symptoms; notably • Vanflyta carries a black box warning for QT prolongation and arrhythmia, requiring REMS monitoring • Vanflyta provides an additional treatment option for this aggressive form of AML	• UF • PA • QL
sodium phenylbutyrate packets for oral suspension (Olpruva) Gastrointestinal (GI)-2 Agents	• Pheburane • Buphenyl • Ravicti	• 2 g, 3 g, 4 g, 5 g, 6 g, 6.67 g pellets in packets for reconstitution into oral suspension • 9.9 – 13 g/m^2/day with food	Adjunctive therapy to standard of care, which includes dietary management, for urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase, ornithine transcarb-amylase, or argininosuccinic acid synthetase	• menstrual dysfunction • decreased appetite • body odor • bad taste or taste aversion	• Another oral formulation of sodium phenylbutyrate supplied as packets for reconstitution • Approved in adult and pediatric patients weighing ≥20 kg and with a BSA > 1.2 m2 • No new clinical studies; approved via 505(b)(2) • Olpruva cannot be administered via NG tube or gastronomy tube, also has high Na content • Sodium phenylbutyrate is available generically as tablets/powder for oral use, has no age/BSA restrictions and can bd administered via NG/G tube • Olpruva, Pheburane and Ravicti were designed to enhance palatability of sodium phenylbutyrate's salty taste and odor • Provides no compelling clinical advantage over existing agents	• UF • QL
somatrogon-ghla injection (Ngenla) Growth Stimulating Agents	• somatropin (Norditropin, Genotropin, Omnitrope etc.) • lonapegsomatropin-tcgd) Skytrofa • somapacitan-beco (Sogroya)	• 24 mg/1.2 mL, 60 mg/1.2 mL single-use prefilled pen (needles not included) • 0.66 mg/kg given once weekly; individualized based on growth	• Treatment of children ≥ 3 years of age who have growth failure due to inadequate secretion of endogenous growth hormone	ADRs ≥5% • injection site reactions • oropharyngeal pain • pyrexia, cough • anemia, rash, hypothyroidism • abdominal pain • vomiting • arthralgia	• 3rd once weekly human growth hormone (GH) • Ngenla was non-inferior to Genotropin (pivotal trial) • AEs were similar to daily and other long-acting GH treatments with the exception of a relatively higher incidence of injection site pain • Ngenla does not provide a unique benefit to patients but offers an additional option for patients seeking a reduced burden of injection frequency	• NF non-step-preferred • PA • MN

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
nirmatrelvir and ritonavir (Paxlovid) Coronavirus dissease-19 (COVID-19) antivirals	• Lagevrio • remdesivir IV infusion (EUA)	• nirmatrelvir 150 mg tablet copackged with ritonavir 100 mg tablet • 300 mg nirmatrelvir (2 x 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) • All 3 tablets taken together orally twice daily for 5 days • dose reduction required in patients with moderate renal dysfunction (CrCl between 30 to 60 mL/min)	• Treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization and death	• dysgeusia • diarrhea • several potential serious drug-drug interactions	• Antiviral; nirmatrelvir is a SARS-CoV-2 main protease inhibitor while ritonavir is an HIV-1 protease inhibitor and CYP3A inhibitor • Ritonavir inhibits the CYP3A-mediated metabolism of nirmatrelvir, resulting in increased nirmatrelvir plasma concentrations • Previously available under an Emergency Use Authorization (EUA) since Dec 21, 2021; formally FDA-approved on May 25, 2023. • Paxlovid is not approved for children, more data is needed to determine the optimal dose. Availability for children 12 to 17 years of age remains under the EUA. • Paxlovid demonstrated overwhelming efficacy ($p<0.001$) in the pivotal EPIC-HR trial in reducing COVID-19 related hospitalization or death from any cause in unvaccinated adults with mild-to-moderate COVID-19 who were not hospitalized • Phase 2/3 study demonstrated an 88% risk reduction of hospitalization or death vs. placebo in adults • The National Institutes of Health (NIH) guidelines panel lists Paxlovid as the preferred treatment for COVID-19 in adults at high risk of progression • The major adverse reactions identified in the clinical trials were dysgeusia and diarrhea • The key safety concern is the risk of serious adverse reactions due to drug-drug interactions, including with strong CYP3A4 inhibitors • Paxlovid provides the only FDA approved oral treatment option for mild-to-moderate COVID-19 in patients who are at high risk	• UF • Tier 1 copay • QL

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

Generic (Trade) UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (AEs)	Clinical Summary	Recommendation
molnupiravir (Lagevrio) Coronavirus disease-19 (COVID-19) antivirals	• Paxlovid • remdesivir IV infusion EUA	• 200 mg capsules • 4x 200 mg (800 mg by mouth orally twice daily for 5 days	• Treatment for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate	• diarrhea • nausea • dizziness • may cause fetal harm; not recommended for use in pregnant patients	• Available pursuant to FDA-granted Emergency Use Authorization (EUA) • EUA is for the treatment of adults with mild-to-moderate (COVID19), who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate • Phase 2/3 study demonstrated an 3% adjusted risk difference in reduction of all-cause hospitalization or death vs. placebo in adults • The NIH guidelines panel currently recommends only using molnupiravir when Paxlovid and remdesivir are not available, feasible to use, or clinically appropriate • Lagevrio is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth. • Lagevrio provides an alternative treatment option when Paxlovid is not available, feasible or appropriate	• UF • QL

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

Table 1: Mail Order Status of Medications Designated Formulary or Nonformulary with implementation the first Wednesday 2 weeks after signing of the minutes)

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
November 2023	**Drug Class Reviews** **Migraine Agents: Injectable CGRPs** ***Designated UF*** • fremanezumab injection (Ajovy) • erenumab injection (Aimovig) **Neurologic Agents Miscellaneous: Movement Disorder Agents** *(see Table 2)* **Utilization Management** ***Designated UF*** *Retain on EMMPI* • estradiol acetate vaginal ring (Femring) *Add to EMMPI* • estradiol vaginal ring (Estring) • conjugated estrogens vaginal cream (Premarin cream) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated NF*** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list:* • latanoprost (Iyuzeh)	**Drug Class Reviews** **Migraine Agents: Injectable CGRPs** ***Designated UF*** *Not cost advantageous to government* • galcanezumab injection (Emgality) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** *Acute or limited duration of use* • lotilaner (Xdemvy) • nalmefene (Opvee) • polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride (Suflave) *For future evaluation* • palvarotene (Sohonos) • sodium phenylbutyrate (Olpruva) ***Designated NF*** *Acute or limited duration of use exception* • albuterol/budesonide (Airsupra) *Not cost-advantageous to government* • bexagliflozin (Brenzavvy) *Tabled due to upcoming class review* • somatrogon-ghla (Ngenla)

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

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

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
November 2023	**Drug Class Reviews** **Neurologic Agents Miscellaneous: Movement Disorder Agents** ***Designated UF*** • Neurological Miscellaneous: Movement Disorders: deutetrabenazine (Austedo, Austedo XR), valbenazine (Ingrezza) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • niraparib/abiraterone acetate (Akeega) • quizartinib (Vanflyta) ***Designated NF*** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list:* • adalimumab-aacf (Idacio) • adalimumab-aaty (Yuflyma) • adalimumab-adaz (Hyrimoz) • adalimumab-adaz (unbranded) • adalimumab-adbm (Cyltezo) • adalimumab-aqvh (Yusimry) • adalimumab-bwwd (Hadlima) • adalimumab-fkjp (Hulio) • adalimumab-fkjp (unbranded) **Drug Classes Designated by the P&T Committee as Generally Suitable for Inclusion** ***Designated UF*** *Specific agents listed within subclasses are those considered to be most likely to be feasible at mail order; does not include generics approved under an abbreviated new drug application:* ***By Class/subclass*** • Oncological Agents: Acute Myelogenous Leukemia: azacitidine (Onureg), enasidenib mesylate (Idhifa), glasdegib maleate (Daurismo), midostaurin (Rydapt) • Oncological Agents: Breast Cancer: alpelisib (Piqray) • Oncological Agents: Chronic Myelogenous Leukemia: asciminib (Scemblix), bosutinib (Bosulif); Note: dasatinib (Sprycel), nilotinib (Tasigna), and imatinib (Gleevec) are already on the EMMPI program	

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

DoD P&T Meeting	ADD to the Select Maintenance List (if Formulary, Add to EMMPI Program; if NF, NOT Exempted from Mail Order Requirement)	Do NOT Add to the Select Maintenance List (if Formulary, Do Not Add to EMMPI Program; if NF, Exempted from Mail Order Requirement)
	• Oncological Agents: CYP-17 Inhibitors: abiraterone acetate, submicronized (Yonsa) • Oncological Agents: EGFR-positive Non-Small Cell Lung Cancer (NSCLC): gefitinib (Iressa), Osimertinib mesylate (Tagrisso); Note: erlotinib (Tarceva) is already on the EMMPI program • Oncological Agents: Lung Cancer: capmatinib (Tabrecta), ceritinib (Zykadia), crizotinib (Xalkori), entrectinib (Rozlytrek), lorlatinib (Lorbrena), sotorasib (Lumakras); Note: alectinib (Alecensa) is already on the EMMPI program • Oncological Agents: Multiple Myeloma • Oncological Agents: Myelofibrosis: fedratinib dihydrochloride (Inrebic) • Oncological Agents: PARP Inhibitors: olaparib (Lynparza), talazoparib tosylate (Talzenna) • Neurological Miscellaneous: Movement Disorders: deutetrabenazine (Austedo, Austedo XR), valbenazine (Ingrezza); Note: subclass reviewed at this meeting ***As Individual Agents*** • dabrafenib mesylate (Tafinlar) • trametinib dimethyl sulfoxide (Mekinist) • pirtobrutinib (Jaypirca) • topotecan HCl (Hycamtin) • sonidegib phosphate (Odomzo) • vorinostat (Zolinza) • alpelisib (Vijoice) • carglumic acid (Carbaglu) • eltrombopag olamine (Promacta) • tafamidis meglumine (Vyndaqel, Vyndamax), plus any future branded tafamidis agent • emicizumab-kxwh (Hemlibra) • lanadelumab-flyo (Takhzyro) • pegvisomant (Somavert) • follotropin alfa, recombinant (Gonal-F, Gonal-F RFF, Gonal-F RFF Redi-ject) • follitropin beta, recombinant (Follistim AQ) • menotropins (Menopur) • vosoritide (Voxzogo) • belimumab (Benlysta)	

* The Expanded Military Treatment Facility (MTF)/Mail Pharmacy Initiative (EMMPI) implements 10 USC 1074g(a)(9), which requires beneficiaries generally to fill non-generic prescription maintenance medications at MTFs or the national mail order pharmacy.

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: January 29, 2024

Two weeks after signing: February 14, 2024

30 days after Signing: February 28, 2024

60 days after signing: April 3, 2024

90 days after signing: May 1, 2024

120 days after signing: June 12, 2024

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

Appendix H—Completely Excluded Agents and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Complete Exclusion Products	Formulary Alternatives	Implementation
November 2023	Cardiovascular Agents Miscellaneous	• colchicine low dose (LODOCO 0.5 mg tablets	• colchicine 0.6 mg tablets (generic Colcrys) • colchicine 0.6 mg caps (generic Mitigare	• 120 days

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE completely excluded agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with amended 32 CFR 199.21(e)(3) effective December 11, 2018. The Final Rule was published June 3, 2020 and is available at https://www.federalregister.gov/documents/2020/06/03/2020-10215/tricare-pharmacy-benefits-program-reforms.

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

The first complete exclusion products were designated at the February 2019 P&T Committee meeting, with implementation occurring on August 28, 2019. 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.

Appendix I—Table of Administrative Authorities

DoD P&T Committee Updates to Approval Authorities

Note that updates are in **bold** font on page 73

Table 1. Processes and Recommendation/Approval Authorities For the November 2023 DoD P&T Committee Meeting

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

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

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

	devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit. ▪ Designating "line extension" devices to retain the same formulary status and any applicable PA/step therapy or MN criteria as the "parent" or previous version device that have already been added to the TRICARE Pharmacy Benefit. Line extensions for devices will be reviewed by the DoD P&T Committee at the next meeting. Line extension devices are defined as having the same indication, being a newer version or model of an already covered device, same pricing, and must be from the same manufacturer.
Approval by Director, DHA, required based on DoD P&T Committee recommendations and UF BAP comments	▪ Classification of a medication as nonformulary on the Uniform Formulary (UF), and implementation plan (including effective date). ▪ Classification of a medication as Tier 4 (not covered) on the Uniform Formulary, for products selected for complete exclusion that provide very little or no clinical effectiveness relative to similar agents, and implementation plan (including effective date). ▪ Establishment of PA requirements for a medication or class of medications, a summary/outline of prior authorization criteria, and implementation plan (including effective date). ▪ Changes to existing PA (e.g., due to the availability of new efficacy or safety data). ▪ Discontinuation of PA requirements for a drug. ▪ Clarification of a medication as nonformulary due to NDAA Section 703 regulations, and implementation plan (effective date). ▪ Establishing pre-authorization criteria for drugs recommended as nonformulary due to NDAA Section 703 regulations. ▪ Addition or deletion of over-the-counter (OTC) drugs to the Uniform Formulary, and designating products recommended for a co-payment waiver. ▪ Removal of co-pays or reducing co-pays for an individual drug (e.g., branded product available at the Tier 1 co-pay). ▪ Designating individual generic drugs as nonformulary (Tier 3 co-pay). ▪ The Director may approve devices or supplies as recommended by the P&T Committee and the UF BAP; however, approval is not required. Even if excluded from the pharmacy benefit, devices or supplies continue to be covered under the TRICARE medical benefit. ▪ Devices or supplies approved for addition to the pharmacy benefit may be designated UF or NF with PA criteria and implementation plans as recommended by the DoD P&T Committee and UF BAP.
Approval by Director, DHA, required based on DoD P&T Committee recommendations (not required to be submitted to UF BAP for comments)	▪ Establishment of quantity limits for a medication, device or supply or class of medications, devices or supplies; deletion of existing quantity limits; or changing existing quantity limits based on clinical factors (e.g., new clinical data or dosing regimens). ▪ Establishment and changes of MN criteria for nonformulary drugs, devices or supplies. ▪ Addition or deletion of medications, devices or supplies listed on the Basic Core Formulary (BCF) or Extended Core Formulary (ECF). ▪ Addition or deletion of drugs or drug classes, devices or supplies on the Expanded MTF/Mail Order Pharmacy Initiative Program. ▪ For OTC products added or deleted from the UF, adding or removing the requirement for a prescription waiver.

	▪ Including or excluding drugs or drug classes, devices or supplies from the Mail Order Pharmacy auto refill program. ▪ Exempting NF medications, devices or supplies from the requirement for dispensing from the Mail Order Pharmacy (e.g., schedule II drugs, antipsychotics, oncology drugs, or drugs not suitable for dispensing from the Mail Order). ▪ Addition or deletion of drugs or drug classes from the Clinical Services Drug List, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies.