DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
August 2023

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on August 2nd and 3rd, 2023.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of May 2023 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the May 2023 DoD P&T Committee meeting on July 26, 2023.

B. Clarification of previous meeting minutes—May 2023

- **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors—adalimumab (Humira)—**The PA criteria for Humira were updated to allow for approval if the prescriber specialty is Rheumatology. The implementation has been delayed from the original implementation date of August 30, 2023.
- **Prenatal Vitamins: CitraNatal Medley—**CitraNatal Medley is not classified as a prenatal vitamin, but instead is classified as a multivitamin in FirstData Bank. Multivitamins are not a covered pharmacy benefit. Therefore, CitraNatal Medley is not covered.
- **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors Subclass: ibrutinib (Imbruvica) oral suspension—**The quantity limits were revised to 3 bottles/fill at Retail and 6 bottles/fill at Mail/MTFs (a 60-day supply).
- **Rapid Response/Safety Net program—**The direct-acting anticoagulant dabigatran pellets (Pradaxa pellets) and the Pegfilgrastim Stimufend were added to the program managed by the DoD's contracted Pharmacy Benefits Manager, Express Scripts, Inc. (ESI).

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 complete exclusion 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 pursuant to 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. Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists: Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty subclasses

Background—The P&T Committee evaluated the relative clinical effectiveness of the Luteinizing Hormone-Releasing Hormone (LHRH) Agonist-Antagonists. The class has three subclasses organized by labeled indications: Prostate Cancer, Endometriosis and Fibroids, and Central Precocious Puberty.

There are a total of 12 products in the class, however several contain the same active ingredient, leuprolide acetate. The drugs are administered via intramuscular (IM) injection, subcutaneous (SQ) injection, or orally. The IM depot injections have a variety of long-acting formulations, ranging from 1 month to 6 months duration of action.

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

Prostate Cancer

Products

- The prostate cancer drugs are comprised of LHRH agonists and LHRH antagonists. For the agonists, there are three leuprolide acetate products available in different formulations: Lupron Depot IM, leuprolide acetate IM (no brand name), and Eligard SQ. Leuprolide mesylate (Camcevi IM) has a different salt form. The two LHRH antagonists are degarelix SQ (Firmagon) and relugolix tablets (Orgovyx).

Clinical Practice Guidelines

- Current National Comprehensive Cancer Network (NCCN) guidelines for advanced hormone sensitive prostate cancer recommend androgen deprivation therapy (ADT) with either an LHRH agonist, LHRH antagonist, or surgical orchiectomy to achieve castration levels of testosterone (defined as <50 ng/dL). LHRH agonists have an initial testosterone flare prior to reaching castration levels, while LHRH antagonists and surgical orchiectomy as monotherapy have rapid onset of action and avoid the testosterone flare.
- Between the available LHRH antagonists and LHRH agonists, the guidelines do not recommend one product over another. The treatments are considered

equivalent in cancer control, although they have not been compared in large randomized controlled trials.

Efficacy

- There are limited direct comparative studies evaluating the effectiveness between leuprolide agents and between leuprolide agents and the LHRH antagonists, oral relugolix (Orgovyx) and SQ degarelix (Firmagon). Indirect comparison of efficacy data from the individual pivotal trials reveals similar rates of achieving testosterone castration levels between these products.
    - The LHRH agonists (Lupron Depot, Eligard, and Camcevi) take approximately 3-4 weeks to reach castration levels of testosterone regardless of administration route and salt form, while the LHRH antagonists (Firmagon and Orgovyx) show reduced testosterone levels in as early as 3 days.
    - Orgovyx was compared to leuprolide acetate 22.5 mg in the open-label HERO trial, which was used to obtain FDA approval. Treatment with Orgovyx for 48 weeks maintained testosterone castration levels in 96.7% of men, compared to 88.8% of men who received leuprolide. The FDA review of the HERO trial however, did not accept the non-inferiority comparison of castration rate between Orgovyx and leuprolide, and as such stated no claims of superiority could be made between the two products.
    - Firmagon was compared with leuprolide acetate 7.5 mg in the clinical trial used to gain FDA approval. Treatment with Firmagon resulted in sustained testosterone castration levels in 97.2% of men, compared with 96.4% of men receiving leuprolide.

Safety

- Products in this subclass have similar adverse reactions that are related to the reduced testosterone levels. Commonly reported adverse effects include hot flashes, injection site reactions, gastrointestinal (GI) symptoms, and testicular atrophy.
    - The LHRH agonists (Lupron Depot, Eligard, and Camcevi) carry similar warnings of tumor flare, hyperglycemia, diabetes, and cardiovascular disease.
    - The LHRH antagonists (Firmagon and Orgovyx) have similar warnings. In contrast to the LHRH agonists, cardiovascular disease is not listed as a warning with the antagonists.
        - There is conflicting evidence, but expert consensus that men with preexisting cardiovascular disease are at an increased risk of cardiovascular toxic effects when treated with androgen deprivation therapy (ADT). There is limited and conflicting data that LHRH antagonists may have a lesser effect on cardiovascular disease compared to LHRH agonists in patients treated with ADT.

In the HERO trial, Orgovyx demonstrated reduced major adverse cardiovascular events (MACE) compared to leuprolide. The MACE definition was very broad, and included nonfatal myocardial infarction, nonfatal stroke, and death due to any case. The FDA reviewers did not agree that the HERO study demonstrated an improved cardiac safety profile with Orgovyx compared to leuprolide.

- More data is needed to determine the full cardiovascular risk profile of Orgovyx.

Individual Product Characteristics

- LHRH agonists
  - **leuprolide acetate (Lupron Depot 7.5mg, 22.5mg, 30mg, 45mg) leuprolide acetate depot (no brand name), leuprolide acetate (Eligard), leuprolide mesylate (Camcevi)**: There is guideline and expert consensus that clinically, these products are generally considered equivalent. There is no data to suggest differences in efficacy or safety with the different leuprolide salt formulations, leuprolide acetate (Lupron) vs. leuprolide mesylate (Camcevi.)
  - **leuprolide acetate (Eligard)** is administered SQ, while Lupron Depot, leuprolide acetate depot, and Camcevi are administered IM. Eligard and Camcevi require refrigeration, while the other products are stable at room temperature.
- LHRH antagonists
  - **Relugolix (Orgovyx)** provides convenience to the patient, as it is the only oral product, however data are limited on long-term patient compliance. Orgovyx has a relatively short half-life of 61 hours compared to Firmagon. Military Health System (MHS) provider feedback supports Orgovyx as an option for short course ADT therapy. The full cardiovascular risk profile remains to be determined.
  - **degarelix (Firmagon**) is administered SQ and has a much longer half-life of 53 days compared to Orgovyx. There are no studies directly comparing Firmagon with Orgovyx.

Endometriosis and Fibroids

Products

- Injectable leuprolide acetate (Lupron Depot) and three oral tablet formulations of elagolix or relugolix combined with an oral contraceptive (Oriahnn or Myfembree, respectively) or elagolix alone (Orilissa) comprise the endometriosis and fibroid products.

Clinical Practice Guidelines

- *Endometriosis*: The European society of Human Reproduction and Embryology (ESHRE) 2020 updated guidelines for endometriosis recommend offering hormone treatment for endometriosis-related pain. First-line therapies include combined (estrogen and progestin) oral contraceptive tablets, given with or without nonsteroidal anti-inflammatory drugs (NSAIDs). Second-line therapies include progestins, LHRH agonists, LHRH antagonists, and androgens, due to the side effect profiles. No one LHRH agonist product is preferred over another agonist, and likewise no one LHRH antagonist product is preferred over another antagonist.
- *Uterine fibroids:* The 2022 American College of Obstetrics and Gynecology Practice Bulletin for treatment of symptomatic leiomyomas (fibroids) states there is insufficient comparative evidence to guide recommendations on first-line medical management options; treatment should be guided by symptoms. To address symptoms of heavy bleeding, options include LHRH antagonists, levonorgestrel intrauterine devices (e.g., Mirena), combined oral contraceptives and tranexamic acid. To address fibroid size and bleeding symptoms, options include LHRH agonists and selective progesterone receptor modulators (e.g., ulipristal).

Efficacy

- *Endometriosis:* No significant published trials directly comparing available agents for treatment of endometriosis-related pain were found. A 2020 Network Meta Analysis evaluating medication options found that the LHRH analogues, and elagolix were not superior to combined hormonal contraceptives. Additionally similar efficacy was seen between LHRH agonists and elagolix.
- *Fibroids:* There are no trials directly comparing available medical therapies for treatment of symptomatic fibroids. Indirect comparisons of Lupron Depot, Myfembree, and Oriahnn show that all three drugs met the primary endpoint of achieving a greater than 2 g/dL increase in hemoglobin compared to baseline.

Safety

- Products in this subclass have similar adverse reaction profiles and are mostly related to the hypoestrogenic state. Hot flashes, headaches, mood changes and changes in vaginal bleeding pattern are common side effects with all the products. All products carry the risk of bone mineral density loss. Elevated liver enzymes are listed as a warning for Myfembree, Oriahnn, and Orilissa.
- Myfembree and Oriahnn carry a black box warning for thromboembolic events, due to the estrogen and progesterone components.

Individual Product Characteristics

- LHRH agonists

    - **leuprolide acetate 3.75 mg and 11.25 mg IM (Lupron Depot)** advantages include its long marketing history and that it is the only LHRH agonist indicated for both medical management of endometriosis-related pain and symptomatic fibroids. It should be used with hormonal add-back therapy (e.g., with an estrogen and progestin). Treatment should not exceed 12 months of therapy due to concerns of bone mineral density loss.

- LHRH antagonists
    - **relugolix/estradiol/norethindrone acetate (Myfembree)** is combined with estrogen and progesterone. Advantages include that it is indicated for both treatment of endometriosis-related pain and symptomatic fibroids, and once daily dosing. Disadvantages include the black box warning for thromboembolic disease. Additionally, use is limited to 24 months due to the risk of continued bone mineral density loss which may not be reversible.
    - **elagolix/estradiol/norethindrone acetate (Oriahnn)** is combined with estrogen and progesterone solely indicated for treatment of heavy bleeding associated with fibroids. It carries a black box warning for thromboembolic disease as well as the unique warning of yellow dye. It is dosed twice daily, with the AM dose containing elagolix/estradiol/norethindrone while the PM dose contains only elagolix. Its use is limited to 24 months due to the risk of continued bone mineral density loss which may not be reversible.
    - **elagolix (Orilissa)** is indicated for treatment of endometriosis related pain. It is dosed either daily or twice daily based on coexisting conditions. Its duration of use is also limited due to coexisting conditions and risk of bone mineral density loss.

Central Precocious Puberty

Products

- This subclass is composed of two leuprolide acetate products; one is administered IM (Lupron Depot Ped), and one is administered SQ (Fensolvi).

Guidelines

- The American Academy of Pediatrics recommends LHRH agonists to treat Central Precocious Puberty. Guidelines do not prefer one product over another, although it is common to start a patient on a 1- or 3-month depot formulation.

Efficacy

- No significant published trials were found that directly compare Lupron Depot Ped with Fensolvi.. These products are considered similarly efficacious, based on indirect comparison of the clinical trial endpoints used to gain FDA approval.

Safety

- Products in this subclass have similar adverse reactions and commonly include injection site reactions and pain. Fensolvi alone carries the adverse reaction of bronchospasm.

Individual Product Characteristics

- **leuprolide acetate (Lupron Depot Ped)** is an LHRH agonist available in multiple strengths, with dosing for 1-month, 3-month, and 6-months. The 6-month formulation was recently approved in April 2023. It is approved for children as young as 1 year.
- **leuprolide acetate (Fensolvi)** is administered SQ and is available in one strength for a 6-month injection. It requires healthcare provider administration. FDA approval is in children down to the age of 2 years.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, a variety of agents are required to treat all indications of advanced prostate cancer, endometriosis, fibroids, and central precocious puberty.

Relative Cost Effectiveness Analysis and Conclusion—A cost minimization analysis (CMA), budget impact analysis (BIA) and sensitivity analysis were performed. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- CMA results showed that within the Prostate Cancer subclass, leuprolide acetate SQ (Eligard) is the most cost effective agent; within the Endometriosis and Fibroids subclass, relugolix/estradiol/norethindrone (Myfembree) is the most cost effective agent and within the Central Precocious Puberty subclass, leuprolide acetate (Fensolvi-Ped) is the most cost effective agent.
- Budge Impact Analysis (BIA) was performed to evaluate the potential impact of designating the LHRH agents as UF, NF, or completely excluded from the formulary. BIA results showed that designating agents in accordance with the formulary recommendation listed below demonstrated significant cost avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following. Note that the formulary recommendations do not apply to inpatient or in-clinic uses.

   Prostate Cancer Subclass

   - UF and step-preferred

    - leuprolide acetate SC 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month) (Eligard)
    - degarelix SC 80 mg, 120 mg (Firmagon)
- UF and non-step-preferred
    - leuprolide aetate IM 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month) (Lupron Depot)
    - leuprolide acetate depot IM 22.5 mg vial (no brand name)
    - leuprolide mesylate IM 42 mg (6 month) (Camcevi) – *moves from NF to UF*
    - relugolix tabs 120 mg (Orgovyx) – *moves from NF to UF*
    - Note that as part of this recommendation a trial of Eligard SQ is required before Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg, leuprolide acetate (no brand name) 22.5 mg and Camcevi 42 mg.
    - Note that as part of this recommendation a trial of Eligard SC or Firmagon SC is required before Orgovyx tablets.
- NF
    - None
- Complete exclusion
    - None

Endometriosis and Fibroids Subclass

- UF
    - leuprolide acetate IM 3.7 mg (1 month), 11.25 mg (3 month) (Lupron Depot)
    - elagolix/estradiol/norethindrone 300 mg/1 mg/0.5 mg tabs (Oriahnn)
    - relugolix/estradiol/norethindrone 40 mg/1 mg/0.5 mg tabs (Myfembree)
- NF
    - elagolix 150 mg, 200 mg tabs (Orilissa)
- Complete exclusion
    - None

Central Precocious Puberty Subclass

- UF

- leuprolide acetate IM 7.5 mg (1 month) 11.25 mg (1 month), 15 mg (3 month), 30 mg (4 month), 45 mg (6 month) (Lupron Depot-Ped)
- leuprolide acetate SQ 45 mg (6 month) (Fensolvi-Ped) – *moves from NF to UF*

- NF
  - None
- Complete exclusion
  - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following PA criteria for new users.

   Prostate Cancer Subclass: Eligard and Firmagon do not require PA. New PA criteria were recommended for Lupron Depot formulations used for prostate cancer (7.5 mg, 22.5 mg, 30 mg, and 45 mg) and leuprolide acetate IM in new users, requiring a trial of Eligard first, unless the patient has tried and failed or has a contraindication to Eligard. The current PA criteria for Camcevi was updated to require Eligard first, unless the patient had tried and failed or cannot tolerate Eligard.

   For Orgovyx tablets, the current PA criteria were updated to require a trial of Eligard or Firmagon in new users. Orgovyx will also be allowed in patients receiving short-term androgen deprivation therapy (ADT). Additionally, patients with significant cardiovascular risk can receive Orgovyx.

   Endometriosis and Fibroids Subclass: No changes were made to the current PA criteria for Oriahnn, Myfembree or Orilissa; PA is not required for Lupron Dept IM 3.7 mg and 11.25 mg.

   Central Precocious Puberty Subclass: PA criteria is not required for Lupron Depot-Ped or Fensolvi-Ped SC.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) maintaining the MN criteria currently in place for Orilissa. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for the LHRH Agonists-Antagonists, as outlined at the August 2022 meeting.

5. ***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) maintaining Orilissa on the EMMPI program. The prostate cancer LHRH drugs will be maintained on the EMMPI program. Additionally, from the May 2023 DoD P&T Committee meeting, Firmagon was added to the EMMPI program. The implementation date will be contingent on cost effectiveness and operational considerations.

6. ***COMMITTEE ACTION: TIER 1 COPAY FOR ELIGARD SC AND FENSOLVI-PED SC—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) lowering the current Tier 2 copay to the Tier 1 (generic) copay for Eligard and Fensolvi-Ped per 32 CFR 199.21(e)(3)(iii). Having Eligard and Fensolvi-Ped at the Tier 1 cost-share will provide a greater incentive for beneficiaries to use the most cost-effective prostate cancer and central precocious puberty drugs in the purchased care points of service.

7. ***COMMITTEE ACTION: UF, PA, MN, QL, EMMPI, TIER 1 COPAY and IMPLEMENTATION PERIOD—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. See Appendix G for the actual implementation date.

B. White Blood Cell Stimulants — Filgrastims and Pegfilgrastims

Background—The P&T Committee evaluated the relative clinical effectiveness of the White Blood Cell Stimulants (WBC) drug class, which is comprised of the filgrastims and pegfilgrastims. The class was last reviewed for formulary status at the August 2020 P&T Committee meeting, since then four new entrants were reviewed as newly approved drugs. Note that sargramostim (Leukine) is a WBC stimulant that was not included in the review; it will remain designated as UF.

The drugs in the WBC stimulants class include the original products and several biosimilars. The FDA definition of a biosimilar is a biological product that is approved based on data demonstrating it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

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

- The clinical conclusions from the August 2020 class review remain unchanged.

- There are now five FDA-approved filgrastims (Neupogen, Zarxio, Granix, Nivestym, and Releuko) and seven pegfilgrastims (Neulasta, Fulphila, Udenyca, Ziextenzo, Nyvepria, Fylnetra, and Stimufend). Both the filgrastim and pegfilgrastim subclasses are made up of a reference biologic (Neupogen, Neulasta) and multiple biosimilars.

Efficacy

- Per the definition of biosimilars, there are no clinically meaningful differences between the reference drug product and biosimilar, allowing for a high degree of therapeutic interchangeability. The 2023 NCCN Hematopoietic Growth Factors guidelines state that an FDA-approved biosimilar is an appropriate substitute for filgrastim and pegfilgrastim.

Safety

- Bone pain and pain in the extremities are commonly reported adverse reactions which are more commonly seen with the pegfilgrastims compared to the filgrastims.
- The filgrastim and pegfilgrastim products have a low potential for immunogenicity.

Other Factors

- All drugs in the subclasses are available as syringes; in addition, Neupogen, Granix, Nivestym, and Releuko are available as vials, and Udenyca is available as an auto-injector. Neulasta is the only product available as an on-body injector (OnPro device).
- Patients with a latex allergy cannot use syringes made with rubber (Neupogen, Zarxio, Neulasta, Neulasta OnPro, Ziextenzo, and Stimufend).

Individual Product Characteristics

Filgrastims

- **filgrastim (Neupogen)** is the reference biologic for the filgrastims. Advantages include availability in both a syringe and vial, and approval for both SC and IV administration. One disadvantage is that the syringe (but not the vial) contains latex, which is a concern in patients with latex allergy.
- **tbo-filgrastim (Granix)** is a follow-on biologic to Neupogen, which means it was approved via a different pathway than the biosimilars. Granix is available in both syringes and vials, which do not contain latex. Both formulations are only approved for SC administration.
- **filgrastim-sndz (Zarxiov)** disadvantages include that it is only available in a syringe, which contains latex, and that volumes smaller than 0.3 mL cannot be accurately measured due to limitations of the measuring units in the syringe.
- **filgrastim-aafi (Nivestym)** advantages include availability in both a syringe and vial, that it does not contain latex and can be administered by both SC and IV routes.

- **filgrastim-ayow (Releuko)** advantages include availability in both a syringe and vial, that it does not contain latex and can be administered by both SC and IV routes.

Pegfilgrastims

- **pegfilgrastim (Neulasta)** is the reference biologic for the pegfilgrastims. In addition to the syringe, it also comes in an on-body injector (Neulasta OnPro) which allows for delayed administration 27 hours after application. This provides a convenience for patients who cannot self-inject at home. Both formulations contain latex.
- **pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), and pegfilgrastim-apgf (Nyvepria)** are available as syringes that do not contain latex.
- **pegfilgrastim-cbqv (Udenyca)** does not contain latex and is available in a syringe and an auto-injector.
- **pegfilgrastim-bmez (Ziextenzo)** and **pegfilgrastim-fpgk (Stimufend)** have latex in the syringe.

Overall Clinical Conclusion

- According to FDA guidance, providers can interchange biosimilars at the time of prescribing, but the FDA requires further data for substitution by other than the prescriber (e.g., a pharmacist cannot substitute products at the pharmacy window). However, overall, there is a very high degree of interchangeability within the filgrastims subclass, and within the pegfilgrastims subclass.
- The overall choice for prescribing a particular filgrastim or pegfilgrastim should be based on the patient's chemotherapy regimen (e.g., cycle frequency and the risk for causing febrile neutropenia), convenience, and cost.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a cost minimization analysis (CMA), budget impact analysis (BIA), and sensitivity analysis. The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 0 absent) the following:

Filgrastims

- CMA results showed that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), filgrastim-sndz (Zarxio), filgrastim (Neupogen), and filgrastim-ayow (Releuko) 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 filgrastims in accordance with the formulary recommendation below demonstrated significant cost avoidance to the MHS.

Pegfilgrastims

- CMA results showed that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim (Neulasta and Neulasta OnPro), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) 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 pegfilgrastims in accordance with the formulary recommendation below demonstrated significant cost avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION*—**The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following. Note that the formulary recommendations do not apply to inpatient or in-clinic uses.

Filgrastims

- UF and step-preferred
  - tbo-filgrastim vial and syringe (Granix)
  - filgrastim-aafi vial and syringe (Nivestym)
  - filgrastim-sndz syringe (Zarxio)-*moves from UF and non-step-preferred to UF step-preferred*
- NF and non-step-preferred
  - filgrastim syringe and vial (Neupogen)-*moves from UF and non-step-preferred to NF and non-step-preferred*
  - filgrastim-ayow syringe and vial (Releuko)-*moves from UF and non-step-preferred to NF and non-step-preferred*
  - Note that as part of this recommendation a trial of Granix, Nivestym and Zarxio are required before Neupogen or Releuko.
- Complete exclusion
  - None

Pegfilgrastims

- UF and step-preferred
  - pegfilgrastim-jmdb syringe (Fulphila)
  - pegfilgrastim-pbbk syringe (Fylnetra)-*moves from UF and non-step-preferred to UF step-preferred*
  - pegfilgrastim-apgf syringe (Nyvepria)
  - pegfilgrastim-fpgk syringe (Stimufend)-*moves from UF and non-step-preferred to UF step-preferred*

        - pegfilgrastim-cbqv syringe and auto-injector (Udenyca) (see p 21 for the autoinjector)
        - pegfilgrastim-bmez syringe (Ziextenzo)-*moves from UF and non-step-preferred to UF step-preferred*
    - NF and non-step-preferred
        - pegfilgrastim syringe (Neulasta)-*moves from UF non-step-preferred to NF non-step-preferred*
        - pegfilgrastim on-body injector (Neulasta OnPro)-*moves from UF non-step-preferred to NF non-step-preferred*
        - Note that as part of this recommendation a trial of Udenyca, Fulphila, Ziextenzo, Nyvepria, Fylnetra, and Stimufend is required before Neulasta and Neulasta OnPro.
    - Complete exclusion
        - None

2. ***COMMITTEE ACTION: BASIC CORE FORMULARY (BCF) REMOVALS***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) removing tbo-filgrastim syringe and vial (Granix) and pegfilgrastim-cbqv syringe (Udenyca) from the BCF. This allows the MTFs to continue to select the most cost-effective product among the step-preferred agents if prices change in the future.

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria has been in place for the non-step-preferred products since the original class review in 2020. The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for the non-step-preferred WBC stimulants, requiring the step-preferred products first, unless the patient has had an inadequate response or could not tolerate the preferred WBC stimulants. For new users of Neupogen and Releuko, a trial of Granix, Nivestym, and Zarxio is required. New users of Neulasta, and Neulasta OnPro, are required to try Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca, and Ziextenzo first. Patients requiring a pegfilgrastim who cannot self-inject will be able to receive Neulasta OnPro. Note that as part of changes in the step-preferred drugs, the existing PAs for Zarxio, Fylnetra, Stimufend and Ziextenzo. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) MN criteria for the NF, non-step-preferred filgrastims (Neupogen and Releuko) and pegfilgrastims (Neulasta and Neulasta OnPro). See Appendix B for the full criteria.

5. ***COMMITTEE ACTION: EXPANDED MTF/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) exempting Neupogen, Releuko, Neulasta, and Neulasta Onpro from the non-formulary to mail requirement. As a result, none of the filgrastims or pegfilgrastims are included on the program.

6. ***COMMITTEE ACTION: TIER 1 COPAY***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) lowering the current Tier 2 copay to the Tier 1 (generic) copay for Nivestym (both syringe and vial) and Stimufend, maintaining the Tier 1 copay for Granix (both syringe and vial) and moving Nyvepria and Udenyca (both syringe and auto-injector) back to the Tier 2 copay per 32 CFR 199.21(e)(3)(iii).. Having Granix, Nivestym, and Stimufend available at the Tier 1 copay will provide a greater incentive for beneficiaries to use the most cost-effective WBC stimulant for the filgrastims and pegfilgrastims, in the purchased care points of service.

7. ***COMMITTEE ACTION: SAFETY NET/RAPID RESPONSE PROGRAM***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) adding the non-step-preferred filgrastims (Neupogen and Releuko) and pegfilgrastims (Neulasta and Neulasta Onpro) to the Safety Net/Rapid Response Program managed by ESI. The program targets beneficiaries who have not received a prescription fill for either a step-preferred or non-step-preferred drug, after the initial reject.

8. ***COMMITTEE ACTION: UF, BCF, PA, MN, EMMPI, TIER 1 COPAY and RAPID RESPONSE PROGRAM IMPLEMENTATION***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) 1) an effective date of the first Wednesday 90 days after signing of the minutes in all points of service; 2) DHA send letters to patients affected by the NF, non-step-preferred recommendation (Neupogen, Releuko, Neulasta, Neulasta OnPro), and 3) DHA send letters to those patients affected by the products returning to Tier 2 status from Tier 1 status (Udenyca syringe and auto-injector and Nyvepria). See Appendix G for the actual implementation date.

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

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (18 for, 0 opposed, 0 abstained, 2 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the

August 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 (18 for, 0 opposed, 0 abstained, 2 absent) the following:

    - UF
        - atropine sulfate 1% ophthalmic solution – Ophthalmic Miscellaneous: Mydriatics
        - deutetrabenazine extended-release tabs (Austedo XR) – Neurological Agents Miscellaneous: Movement Disorders
        - fecal microbiota spores, live-brpk capsules (Vowst) – Gastrointestinal-2 Agents Miscellaneous
        - fezolinetant (Veozah) – Gynecological Agents Miscellaneous
        - leniolisib (Joenja) – Immunological Agents Miscellaneous
        - omaveloxolone (Skyclarys) – Neurological Agents Miscellaneous
    - NF
        - perfluorohexyloctane 1.338 g/mL ophthalmic solution (Miebo) – Ophthalmic: Dry Eye Agents
        - sodium oxybate extended-release packets for oral suspension (Lumryz) – Sleep Disorders: Wakefulness Promoting Agents
        - somapacitan-beco injection (Sogroya) – Growth Stimulating Agents
        - sotagliflozin (Inpefa) – Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors
        - zavegepant nasal spray (Zavzpret) – Migraine Agents
    - Complete Exclusion: See Appendix H for additional detail regarding excluded agents and formulary alternatives.
        - sildenafil 10 mg/mL oral suspension (Liqrev)– Pulmonary Arterial Hypertension (PAH): PDE 5 Inhibitor
            - Liqrev was recommended for complete exclusion as it has little to no clinical benefit relative to other PDE-5 inhibitors for PAH, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include sildenafil tablets, sildenafil 10 mg/mL oral suspension (generic Revatio), and tadalafil oral suspension (Tadliq).
        - trientine tetrahydrochloride tablets (Cuvrior) – Binder-Chelators-Antidotes-Overdose

- Cuvrior was recommended for complete exclusion as it has little to no clinical benefit relative to other chelators for Wilson's disease, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include trientine hydrochloride capsules and penicillamine.

- zolpidem tartrate 7.5 mg capsules–Sleep Disorders: Insomnia
  - Zolpidem tartrate 7.5 mg capsules were recommended for complete exclusion as they have little to no clinical benefit relative to other insomnia drugs, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include zolpidem IR 5 mg and 10 mg tabs, zolpidem ER 6.5 and 12.5 mg tabs, and zaleplon.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) MN criteria for Miebo, Lumryz, Sogroya, Inpefa, and Zavzpret. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (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 Austedo XR, Joenja, Lumryz, Miebo, Skyclarys, Sogroya, Veozah, Vowst, and Zavzpret.
   - Applying manual PA criteria to Inpefa, similar to what is in place for the other non-step-preferred SGLT2 Inhibitors. New patients receiving Inpefa or one of the other non-step-preferred SGLT2 Inhibitors (Farxiga, Invokana, Steglatro) will be required to have a trial of Jardiance first.
   - Applying interim manual PA criteria for Liqrev, Cuvrior, and zolpidem tartrate 7.5 mg capsules prior to the complete exclusion implementation, 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 (18 for, 0 opposed, 0 abstained, 2 absent) QLs for Vowst, Lumryz and Zavzpret. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS***—The P&T Committee recommended (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. 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.

6. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 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 points of service; see Appendix G.
   - **New Drugs Recommended for Complete Exclusion Status:** 1) An effective date of the first Wednesday 120 days after signing of the minutes in all points of service, and 2) DHA send letters to beneficiaries who are affected by the complete exclusion recommendation at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

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

Manual PA criteria was recommended for one recently marketed drug which contains active ingredients that are widely available in low-cost generic formulations. Due to the pathway used to gain FDA approval, this product does not meet the criteria for an innovator. For the product listed below, PA criteria is recommended in new and current users, requiring a trial of all cost-effective generic formulary medications first.

a) **Vitamins: Prenatal— Natal PNV tablets—**Natal PNV is a prenatal dietary supplement manufactured by a single company. The primary ingredients of Natal PNV are similar to those found in Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, and Neonatal Plus which require manual PA and are very expensive. Several cost-effective prescription prenatal multivitamins are included in the TRICARE pharmacy benefit for women younger than the age of 45 and do not require prior authorization criteria.

COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) manual PA criteria for Natal PNV tablets in new and current users, due to the significant cost differences compared with numerous available alternative agents. The new PAs will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

2. Updated PA Criteria for New FDA-Approved Indications

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

a) **Anticonvulsant and Anti-Mania: topiramate ER capsule sprinkle (Qudexy XR) and topiramate ER capsule (Trokendi XR) —**For Qudexy XR, the manual PA criteria were updated for patients with partial-onset or primary generalized tonic clonic (GTC) seizures to include children 2 years of age and older. For Trokendi XR, the manual PA criteria were updated for patients with partial-onset or primary GTC seizures to include children 6 years of age and older. The PAs for both Qudexy XR and Trokendi XR were also updated to align with other topiramate PAs, including that a requirement for the medication to be prescribed by or in consultation with a neurologist was added.

b) **Migraine Agents: CGRP Antagonists Oral Agents Subclass—atogepant (Qulipta)—**The manual PA criteria were updated for Qulipta to allow for the new indication for the preventative treatment of migraine in adults to include chronic migraine. Previously, Qulipta was only indicated for the preventive treatment of episodic migraine.

c) **Gastrointestinal-2 Agents: Chronic Idiopathic Constipation/Constipation-predominant Irritable Bowel Syndrome (CIC/IBS-C)—linaclotide (Linzess)—**The manual PA criteria were updated to reflect the new expanded indication in children as young as 6 years old with functional constipation. The PA requires pediatric patients to try or have an intolerance to at least two other agents for constipation before Linzess.

d) **Continuous Glucose Monitoring Systems (CGMs): Therapeutic CGMs Freestyle Libre 2 and 3—**The manual PA criteria were updated for an expanded age indication. Freestyle Libre 2 and 3 systems are now indicated for use in children 2 years of age and older.

e) **Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)—upadacitinib (Rinvoq)**—The manual PA criteria were updated to include the new indication for adults with moderately to severely active Crohn's disease. A trial of adalimumab (Humira) is required before Rinvoq.

f) **Oncological Agents: Ovarian Cancer—olaparib (Lynparza)—**The manual PA criteria were updated to include the new indication for use in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer.

g) **Oncological Agents—dabrafenib (Tafinlar) and trametinib (Mekinist)—** The manual PA criteria were updated for Tafinlar and Mekinist to allow for use in pediatric patients 1 year of age and older with low-grade glioma with a BRAF V600E mutation and who require systemic therapy.

h) **Oncological Agents—avapritinib (Ayvakit)—**The manual PA criteria were updated to allow for a new indication for indolent systemic mastocytosis.

i) **Targeted Immunomodulatory Biologics (TIBs)—sarilumab (Kevzara)**—The manual PA criteria were updated to allow for a new indication for polymyalgia rheumatica in adults. The new PA criteria for this indication require that the prescription be written by or in consultation with a rheumatologist, and that the patient has tried glucocorticoids first unless the patient is not a candidate for them.

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 Qudexy XR, Trokendi XR, Qulipta, Linzess, Freestyle Libre 2 and 3, Rinvoq, Lynparza, Tafinlar, Mekinist, Ayvakit, and Kevzara 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.

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

a) **Neurological Agents Miscellaneous—risdiplam (Evrysdi)**—The Evrysdi PA was last reviewed at the February 2021 meeting. At that time, Evrysdi had not been studied in patients with hepatic impairment. Since then, studies have been conducted in patients with mild and moderate hepatic impairment. The P&T Committee recommended changing the existing PA criteria to allow for Evrysdi use in patients with hepatic impairment.

b) **Hematological Agents—avacopan (Tavneos)**—Tavneos was reviewed as an innovator drug at the February 2022 meeting for formulary status and PA criteria. The Tavneos PA required documentation of the Birmingham Vasculitis Activity Score (BVAS). Provider feedback supported removal of the BVAS requirement, as it is not commonly performed in clinical practice.

c) **Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors—adalimumab (Humira)—**The Humira PA in its current form required pediatric patients with non-fistulizing Crohn's disease to have an inadequate response to a non-biologic systemic therapy before they could try Humira. Based on provider feedback and a review of the available literature, the P&T committee recommended removing the requirement for pediatric Crohn's disease patients to try non-biologic systemic therapy before Humira.

d) **Weight Loss Agents—orlistat (Xenical)—**The medical necessity criteria for Xenical was updated to standardize required formulary alternatives across the weight loss drug class.

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 Evrysdi,

Tavneos, Humira, and medical necessity criteria for Xenical. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix B and Appendix C for the full criteria.

4. Quantity Limits

Self-monitoring blood glucose (SMBG) test strips: QL override criteria QLs for the blood glucose test strips were last updated in November 2014, limiting use to 100 strips per 30-day supply in the Retail Network and 300 strips per 90-day supply in the Mail Order and MTF points of service. Clinical override criteria were specified at the time, to allow for situations where a larger quantity was required and appropriate. Continuous glucose monitoring (CGM) systems were added to the TRICARE pharmacy benefit in November 2021, with an expectation that SMBG test strip utilization would decrease, given the reduced need for fingerstick testing with the CGMs.

COMMITTEE ACTION: SMBG TEST STRIP QL OVERRIDE CRITERIA AND IMPLEMENTATION—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) updating the QL override criteria to specifically exclude patients currently on a CGM, unless a supporting clinical rationale is provided. There was no change to the other clinical override criteria currently in place.

QLs for the SMBGS test strips may be exceeded in the following situations: patient is receiving insulin; using an insulin pump; has gestational diabetes; requires more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, non-islet cell tumor); or, has a history of poorly controlled blood glucose levels with adverse outcomes (e.g., ketoacidosis or hypoglycemic episode), requiring medical intervention. QL Implementation will occur the first Wednesday two weeks after signing of the minutes. See Appendix D for the test strip QL override criteria.

B. Line Extensions

The P&T Committee clarified the formulary status for five 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) **WBC Stimulants: Pegfilgrastims**—designating **pegfilgrastim-cbqv (Udenyca) autoinjector** with the same formulary status as the parent Udenyca syringe as determined by the recommendations presented in the WBC Stimulants: Pegfilgrastims class review (UF, step-preferred, and Specialty status) on page 14.

b) **Therapeutic CGMs**—designating **Dexcom 7 Sensor** with the same formulary status (UF), PA, and QL as the parent Dexcom 6 Sensor. In addition, the P&T committee recommended that the Dexcom 7 Sensor be added to the pharmacy benefit.

c) **Cystic Fibrosis Agents**—designating **elexacaftor/tezacaftor/ivacaftor (Trikafta) oral granules** with the same formulary status (UF), PA, QL, and Specialty status as the parent Trikafta tablets.

d) **Oncological Agents**—designating **dabrafenib (Tafinlar) tablets for oral suspension** with the same formulary status (UF), PA, QL, and Specialty status as the parent dabrafenib (Tafinlar) capsules.

e) **Oncological Agents**—designating **trametinib (Mekinist) solution** with the same formulary status (UF), PA, QL, and Specialty status as the parent trametinib (Mekinist) tablets.

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 changes for Udenyca autoinjector will occur at 90 days, with the implementation of the WBC Stimulants recommendations.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR DABIGATRAN (PRADAXA) CAPSULES

Dabigatran (Pradaxa) capsules are designated as UF. AB-rated generic versions have entered the market; however, these generic products are less cost-effective compared to the branded agent. Therefore, the branded Pradaxa capsules will continue to be dispensed at all three points of service, and the generic will only be available with prior authorization (i.e., the reverse of the current brand to generic policy). The Tier 1 copay for brand Pradaxa dose is recommended, and generic dabigatran capsules will be added to the Safety Net/Rapid Response program. Note that the Tier 1 copay does not apply to Pradaxa pellets for oral suspension, which was designated as NF when reviewed as a new drug at the May 2023 DoD P&T Committee meeting.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) requiring brand Pradaxa capsules over the generic in all new and current users at all points of service, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be used. The Tier 1 (generic) copayment will apply to brand Pradaxa capsules, and dabigatran capsules will be added to the Safety Net/Rapid Response program. The effective date will be no later than 60 days after the signing of the minutes at MTF and mail. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

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

Nonformulary medications are generally restricted to the Mail Order program pursuant to 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 several classes of medications for potential addition to the EMMPI program and agreed that branded maintenance medications in the following classes are generally suitable for inclusion on the EMMPI program. Specific agents in each subclass considered most likely to be suitable for the program are listed below.

- Oncological Agents: Colorectal Cancer
- Oncological Agents: Renal Cell Carcinoma
- Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors

COMMITTEE ACTION: EMMPI PROGRAM DRUG LIST—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) addition of appropriate agents in these three classes/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.

IX. COMPLETELY EXCLUDED DRUGS: ANNUAL REVIEW

The P&T Committee reviewed all drugs completely excluded from the pharmacy benefits program under 32 CFR 199.21(e)(3), which allows the Committee to recommend special Uniform Formulary actions "to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending." This specifically includes "a complete or partial exclusion from the pharmacy benefits program of any pharmaceutical agent the Director determines provides very little or no clinical effectiveness relative to similar agents to covered beneficiaries and DoD." Drugs designated as completely excluded are not available at the MTFs or Mail Order points of service, and beneficiaries are required to pay the full out-of-pocket cost at retail network pharmacies.

The Committee plans to review completely excluded drugs on an annual basis. Note: these medications were previously referred to as completely excluded drugs; the terminology has been changed to "completely excluded" to better align with the statutory authority.

The P&T Committee reviewed all the completely excluded drugs and found no new clinical data, guidelines, or indications for any of the completely excluded drugs that would change the previous conclusion that the drug offers little or no clinical effectiveness relative to similar agents. The Committee also found that with one exception (baclofen oral granules discussed below), all the completely excluded drugs remain substantially more costly than similar agents.

- **baclofen oral granules (Lyvispah) – Skeletal Muscle Relaxants:** After substantial wholesale acquisition cost (WAC) reductions by the manufacture, Lyvispah is now similar in price to baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy), both of which are designated as nonformulary.
- **dexlansoprazole (Dexilant, generics)- Proton Pump Inhibitors (PPIs):** The Committee also reviewed post-implementation pharmacy claims rejection rates and cost data for dexlansoprazole, noting that generic versions of the drug remain up to 2 orders of magnitude more costly compared to formulary proton pump inhibitors (PPIs).

COMMITTEE ACTION: UF RECOMMENDATION FOR PREVIOUSLY COMPLETE EXCLUDED DRUGS—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:

- Returning baclofen oral granules (Lyvispah) to the formulary, designated as nonformulary (Tier 3 copay), with an implementation date in all points of service of the first Wednesday 2 weeks after signing of the minutes.
- Applying the same prior authorization and medical necessity criteria to Lyvispah as is currently in place for baclofen oral solution (Ozobax) and baclofen oral suspension (Fleqsuvy) (See Appendix B and C).

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

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

A. ***COMMITTEE ACTION: DRUGS DESIGNATED NF***—The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) that the Section 703 non-compliant national drug code numbers (NDCs) of the following products be designated NF on the UF:

- Nabriva Therapeutics, Inc.: tidezolid (Sivextro) (*New Drug Application; NDC 72000-0310-06, 72000-0310-30*) 200 mg tabs

- Nabriva Therapeutics, Inc.: lefamulin (Xenleta) (*New Drug Application; NDC 72000-0110-10, 72000-0110-30*) 600 mg tabs

These NF drugs will be exempt from movement to the Mail Order POS due to the potential for acute use; and will remain available at the retail POS with pre-authorization.

B. ***COMMITTEE ACTION: PRE-AUTHORIZATION CRITERIA***—The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) the following pre-authorization criteria for the Section 703 non-compliant NDCs:

1. Use of the formulary alternatives are contraindicated.
2. Obtaining the product by home delivery would be detrimental to the patient.

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

C. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA—***The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) maintaining the MN criteria currently in place for Xenleta and updating the MN criteria for Sivextro. See Appendix B for the full criteria.

D. ***COMMITTEE ACTION: IMPLEMENTATION PERIOD***—The P&T Committee recommended (19 for, 0 opposed, 1 abstained, 0 absent) an effective date of two weeks after signing of the minutes for the non-compliant NDCs. Letters are not needed since these are acute use medications used to treat infections, and existing patients are unlikely to be continuing therapy once the implementation period has occurred.

XI. ITEMS FOR INFORMATION

A. MHS GENESIS OTC List Addition

The following products were added to the MHS GENESIS OTC test list, based on requests from the field and that similar generic code numbers (GCNs) are already included on the list.

- potassium citrate/citric acid 1100-334 mg/5 mL solution: GCN 14065—Niche use for pediatric patients with renal tubular acidosis-type 1 nephrocalcinosis; legend Urocit-K tabs available but liquid is needed for pediatrics
- DEKAS Plus capsules GCN 40257—Niche use in Cystic Fibrosis; adds the capsules; chew tabs and liquid were already on the list
- magnesium L-lactate GCN 04250—Niche use for Gitelman syndrome; magnesium L-lactate better tolerated

B. Ritlecitinib (Litfulo) and coverage for alopecia areata

Ritlecitinib (Litfulo) is an oral janus kinase 3 (JAK3) inhibitor (which falls under the TIB drug class) that was FDA-approved on June 24, 2023. Is it solely approved for treatment of severe alopecia areata in adults and adolescents 12 years and older. Medication intended to encourage hair regrowth for alopecia areata is excluded by federal regulation (32 CFR 199.4(g)(41)(ii)). Therefore, Litfulo is not covered, and will not be reviewed as an innovator (newly approved drug).

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

Amikacin liposome inhalation suspension (Arikayce) was reviewed as an innovator drug at the November 2018 meeting and designated as NF. At that time, a PA was recommended which required a provider to explain why the patient could not use IV amikacin. This question on the PA will be edited to clarify to ask why the patient cannot use IV amikacin via nebulizer. Additional information will be provided on how to arrange for IV amikacin and a nebulizer through the managed care support contractor.

XII. ADJOURNMENT

The meeting adjourned at 1600 hours on August 3rd. The next meeting will be in November 2023.

Appendix A—Attendance: August 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 August 2023 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Completely Excluded Agents and Therapeutic Alternatives

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

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

30 Oct 2023
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Paul Carby, MSC	DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO
Ed VonBerg, PharmD, CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
MAJ Ryan Burkhart MC, for LTC Charles Lynn, 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
Lt Col Brooke van Eeghen, for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	Physician at Large, DHA
LCDR Shira Paul, MC	Oncology Physician
Laura Au, RPh, BCOP	Oncology Pharmacist
CAPT Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA	TRICARE Health Plan Chief Medical Officer

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Eugene Moore, PharmD	Tpharm5 Clinical COR
CAPT Bill Kelly	Defense Logistics Agency
Pete Glassman, MD	Department of Veteran's Affairs
Guests	
CAPT Phung Thien Nguyen	POD Senior Executive Officer
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Juliane Canaly	DHA Contracting
Ms. Shiela Mirrelees	DHA Contracting
Julia Trang, PharmD	DHA Contracting
CDR Kendra Jenkins	Bureau of Prisons
CAPT Carl Olongo	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
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
Mr. David Folmar	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor
Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA Formulary Management Branch Contractor
Lt Col Brian Sydnor, MSC	DHA Direct Care Branch

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• elagolix (Orilissa) **Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists for Endometriosis**	• Patient has experienced or is likely to experience significant adverse effects from formulary agents • Formulary agents result or are likely to result in therapeutic failure **Formulary Alternatives:** leuprolide (Lupron Depot) intramuscular kit; nafarelin (Synarel) nasal solution
• filgrastim (Neupogen) • filgrastim-ayow (Releuko) **White Blood Cell Stimulants: filgrastims**	• Patient has experienced significant adverse effects from formulary agents **Formulary Alternatives:** tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio)
• pegfilgrastim (Neulasta) **White Blood Cell Stimulants: pegfilgrastims**	• Patient has experienced significant adverse effects from formulary agents **Formulary Alternatives:** pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo)
• pegfilgrastim (Neulasta OnPro) **White Blood Cell Stimulants: pegfilgrastims**	• No alternative formulary agent; patient requires an on-body injector and cannot use the formulary autoinjector **Formulary alternatives:** pegfilgrastim-cbqv autoinjector (Udenyca)
New Drugs MN Criteria	
• perfluorohexyloctane 1.338 g/mL ophthalmic solution (Miebo) **Ophthalmic: Dry Eye Agents**	• All formulary agents resulted in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis/Restasis Multidose), cyclosporine 0.09% (Cequa), lifitegrast (Xiidra)

Appendix B—Table of Medical Necessity Criteria

• sodium oxybate extended-release packets for oral suspension (Lumryz) **Sleep Disorders: Wakefulness Promoting Agents**	• All formulary agents resulted in therapeutic failure **Formulary alternatives:** sodium oxybate (Xyrem), sodium, calcium, magnesium, potassium, sodium oxybate (Xywav)
• somapacitan-beco injection (Sogroya) **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)
• sotagliflozin (Inpefa) **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)
• zavegepant nasal spray (Zavzpret) **Migraine 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:** triptans (sumatriptan), rimegepant (Nurtec ODT), ubrogepant (Ubrelvy)
Utilization Management MN Criteria	
• orlistat (Xenical) **Weight Loss Agents**	Updates from the August 2023 meeting are in **bold and ~~strikethrough~~** • Use of formulary agents and nonformulary agents {Qsymia, Contrave, ~~Belviq/ Belviq XR~~) are contraindicated • Use of formulary agents and nonformulary agents (Qsymia, Contrave, ~~Belviq/ Belviq XR~~) have resulted in therapeutic failure • No alternative formulary agent: The patient is between 12 and 18 years of age **Formulary alternatives and nonformulary:** phentermine, **~~diethylpropion, benzphetamine, phendimetrazine~~ Qsymia; Contrave**

Appendix B—Table of Medical Necessity Criteria

Section 703 Drugs MN Criteria	
• lefamulin (Xenleta) **Antibiotics – Misc.**	• Use of a formulary agent from each of the following three classes: macrolides, fluoroquinolones, and beta-lactams is contraindicated • Use of a formulary agent from each of the following three classes: lincosamide, sulfa, oxazolidinones and beta-lactams will result or is likely to result in therapeutic failure (e.g., due to local antimicrobial resistance rates) **Formulary alternatives:** azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, amoxicillin/clavulanate, cefpodoxime, and cefuroxime
• tidezolid (Sivextro) **Antiinfectives – Misc.**	• Use of a formulary agent from each of the following four classes: lincosamide, sulfa, oxazolidinones and beta-lactams is contraindicated • Use of a formulary agent from each of the following three classes: lincosamide, sulfa, oxazolidinones and beta-lactams will result or is likely to result in therapeutic failure (e.g., due to local antimicrobial resistance rates) • No alternative formulary agent. Patient has been stable on the Sivextro IV formulation and is transitioning to the oral formulation. **Formulary alternatives:** penicillin VK, cephalexin, cefazolin, nafcillin, dicloxacillin, clindamycin, linezolid and TMX/SMX
Previously Completely Excluded Drugs MN Criteria	
• baclofen oral granules (Lyvispah) **Skeletal Muscle Relaxants**	• No alternative formulary agent. Patient cannot swallow and crushed tablets are not an option. **Formulary alternatives**: baclofen tablets

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• leuprolide acetate (Lupron Depot) IM 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month) • leuprolide acetate IM 22.5 mg vial (no brand name) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	Manual PA criteria apply to all new users of Lupron Depot and leuprolide acetate (no brand name) Manual PA criteria: Coverage is approved if all criteria are met: • Provider is aware leuprolide acetate SQ (Eligard) is the preferred leuprolide product and does not require PA • Patient has tried and failed or has not been able to tolerate Eligard PA does not expire
• leuprolide mesylate SC 42 mg (6 month) injection (Camcevi Kit) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	Updates from the August 2023 meeting are in **bold** and ~~**strikethrough**~~ Manual PA criteria apply to all new users of Camcevi. Manual PA criteria: Coverage is approved if all criteria are met: • ~~**Patient is 18 years of age or older**~~ • ~~**Drug is prescribed by or in consultation with an oncologist or urologist**~~ • ~~**Patient has a diagnosis of advanced prostate cancer**~~ • The provider is aware that **leuprolide acetate** SQ (Eligard) is the preferred leuprolide product and does not require a PA • Patient has tried and failed or has not been able to tolerate Eligard ~~Patient has intolerability to, or has failed alternative formulary leuprolide injections (i.e. Lupron Depot, Eligard)~~ ~~**Non-FDA approved uses are NOT approved**~~ PA does not expire
• relugolix tablets (Orgovyx) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	Updates from the August 2023 meeting are in **bold and** ~~**strikethrough**~~ Manual PA criteria apply to all new users of Orgovyx Manual PA criteria: Coverage is approved if all criteria are met: • The provider is aware and acknowledges that ~~**leuprolide acetate IM (Lupron Depot),**~~ **leuprolide acetate SQ (Eligard), and degarelix SQ (Firmagon) are available to DoD beneficiaries without requiring prior authorization** • Patient is 18 years of age or older • Orgovyx is prescribed by or in consultation with an oncologist or urologist • Patient has a diagnosis of advanced prostate cancer • Patient has tried and failed or ~~**is unable to use injectable leuprolide formulation (i.e., subcutaneous injection or implant)**~~ **leuprolide acetate SQ (Eligard) or degarelix SQ (Firmagon) OR** • **The patient has significant cardiovascular risk factors as determined by their oncologist OR** • **The patient is prescribed short-term androgen deprivation therapy (ADT)** Non-FDA approved uses are NOT approved including cancers other than prostate cancer, and in women for endometrial thinning, endometriosis, and uterine leiomyomata (fibroids) PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• elagolix (Orilissa) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	No changes made at the August 2023 meeting Manual PA Criteria: Elagolix is approved if all criteria are met: • The patient is 18 years of age or older • Patient is a premenopausal woman with endometriosis • Patient has had inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, unless contraindicated • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have severe hepatic impairment (Child-Pugh Class C) • Patient does not have osteoporosis • Patient is on concurrent calcium supplementation. • Patient is not using Orilissa concomitantly with cyclosporine or gemfibrozil Non-FDA approved uses are not approved Prior authorization expires after 24 months (lifetime expiration). Cumulative treatment with Orilissa and Myfembree will not exceed 24 months during the patient's lifetime.
• relugolix/estradiol/ norethindrone (Myfembree) **Luteinizing Hormone Releasing Hormone (LHRH) Agonists-Antagonists**	No changes made at the August 2023 meeting Manual PA Criteria: Myfembree is approved if all criteria are met: • The patient is 18 years of age or older • Patient is a premenopausal woman • Patient has a diagnosis of: ▪ Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) OR ▪ Moderate to severe pain association with endometriosis AND • Patient has had inadequate relief after at least three months of first-line therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal contraceptives, unless contraindicated • Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD) • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant. Pregnancy test required. • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or a history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 years • Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs or if the patient has a sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions • Patient does not have uncontrolled hypertension • Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly • Patient does not have osteoporosis • Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes

	• Patient does not have a history of breast cancer or other hormonally-sensitive malignancies • Patient does not have known liver impairment or disease • Provider agrees to counsel patients on the signs and symptoms of liver injury • Patient does not have undiagnosed abnormal uterine bleeding • Patient is not using Myfembree concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors • Provider is aware of drug interactions with Myfembree and oral P-gp inhibitors (e.g., erythromycin) and combined P-gp and strong CYP3A inducers (e.g., rifampin) and will counsel patient on these interactions as appropriate Non-FDA approved uses are not approved, including contraception Prior authorization expires after 24 months (lifetime expiration). Cumulative treatment with Myfembree and Oriahnn will not exceed 24 months during the patient's lifetime.
• elagolix/estradiol/ norethindrone (Oriahnn) **Luteinizing Hormone-Releasing Hormone Agonists-Antagonists**	No changes made at the August 2023 meeting <u>Manual PA Criteria:</u> Oriahnn is approved if all criteria are met: • Patient is 18 years of age of older • Patient is a premenopausal woman with diagnosed heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • Patient has had inadequate relief after at least three months of first-line therapy with a hormonal contraceptive or Intrauterine Device (IUD) • Medication is prescribed by a reproductive endocrinologist or obstetrics/gynecology specialist • Patient is not pregnant confirmed by (-) HCG • Patient agrees to use non-hormonal contraception throughout treatment and for one week after discontinuation of treatment • Patient does not have current or history of thrombotic or thromboembolic disorders or an increased risk for these events • Patient is not a smoker over the age of 35 years • Provider agrees to discontinue treatment if a thrombotic, cardiovascular, or cerebrovascular event occurs; or if the patient has a sudden unexplained partial or complete loss of vision, proptosis (abnormal protrusion of the eye), diplopia (double vision), papilledema (optic disc swelling), or retinal vascular lesions • Patient does not have uncontrolled hypertension • Provider agrees to monitor blood pressure and discontinue treatment if blood pressure rises significantly • Patient does not have osteoporosis • Provider agrees to assess baseline and periodic bone mineral density • Provider agrees to advise the patient to seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety, or other mood changes • Patient does not have a history of breast cancer or other hormonally-sensitive malignancies • Patient does not have known liver impairment or disease • Provider agrees to counsel patients on the signs and symptoms of liver injury • Patient does not have undiagnosed abnormal uterine bleeding • Patient is not using Oriahnn concomitantly with cyclosporine or gemfibrozil or other organic anion transporting polypeptide [(OATP)1B1] inhibitors Non-FDA-approved uses are not approved including pain associated with endometriosis. Prior authorization expires after 24 months (lifetime expiration). Cumulative treatment with Myfembree and Oriahnn will not exceed 24 months during the patient's lifetime

Appendix C—Table of Prior Authorization (PA) Criteria

• filgrastim (Neupogen) • filgrastim-avow (Releuko) **WBC Stimulants Class: Filgrastim subclass**	Manual PA criteria apply to all new users of filgrastim (Neupogen) and filgrastim-ayow (Releuko) Note that Granix and Nivestym are available at the Tier 1 copay at the Mail Order and Retail Network pharmacies. <u>Manual PA Criteria:</u> Coverage will be approved if: • Provider acknowledges that tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) are the preferred filgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient has experienced an inadequate treatment response or intolerance to tbo-filgrastim (Granix), filgrastim-aafi (Nivestym), and filgrastim-sndz (Zarxio) and is expected to respond to filgrastim (Neupogen) or filgrastim-ayow (Releuko) PA does not expire
• pegfilgrastim (Neulasta) • pegfilgrastim (Neulasta OnPro) **WBC Stimulants Class: Pegfilgrastim subclass**	Manual PA criteria apply to all new users of pegfilgrastim (Neulasta) and pegfilgrastim (Neulasta OnPro) Note that Stimufend is available at the Tier 1 copay at the Mail Order and Retail Network pharmacies. <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Provider acknowledges that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) are the preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist/oncologist • Patient requires use of an on-body injector (Neulasta OnPro) because the patient/caregiver cannot self-inject and/or cannot reasonably attend multiple visits to the clinic for administration OR • Patient has experienced an inadequate treatment response or intolerance to pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) and is expected to respond to pegfilgrastim (Neulasta) PA does not expire
Newly Approved Drug PAs	
• deutetrabenazine extended-release tabs (Austedo XR) **Neurological Agents Miscellaneous: Movement Disorders**	Manual PA criteria apply to all new users of Austedo XR <u>Manual PA Criteria:</u> 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: monoamine oxidase inhibitors (MAOIs) within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine) <u>Huntington's Disease Chorea</u> • 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 XR.

Appendix C—Table of Prior Authorization (PA) Criteria

	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). ▪ is being monitored for depression and suicidal ideation.
• fecal microbiota spores, live -brpk capsules (Vowst) **Gastrointestinal-2 Agents: Misc.**	Manual PA criteria apply to all new users of fecal microbiota spores, live-brpk (Vowst) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient has had 3 or more episodes of *Clostridioides difficile* infection within the last 12 months that is refractory to standard antibiotic therapy • Patient's current episode of *Clostridioides difficile* infection must be controlled following 10 to 21 days of antibiotic therapy • Patient had a positive stool test for *Clostridioides difficile* within 30 days • Patient will start therapy within 2 to 4 days following completion of an antibiotic course for *Clostridioides difficile* treatment • Patient will undergo bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution on the day before the first dose of Vowst Non-FDA approved uses are NOT approved PA expires after each fill (new PA required for each treatment course)

Appendix C—Table of Prior Authorization (PA) Criteria

• fezolinetant (Veozah) **Gynecological Agents Misc.**	Manual PA criteria apply to all new users of fezolinetant (Veozah) Manual PA criteria: Coverage is approved if all criteria are met: • Patient has moderate to severe vasomotor symptoms due to menopause • Patient has a contraindication to menopausal hormone therapy (estrogens with or without progestins) OR • Patient has an intolerance to menopausal hormone therapy OR • Based on individual patient characteristics and risk factors, the provider has determined that the patient is not a candidate for menopausal hormone therapy • Patient has tried and failed or had an adverse reaction to at least one of the following non-hormonal treatments for vasomotor symptoms ▪ an SSRI (i.e. paroxetine, escitalopram, or citalopram) ▪ an SNRI (i.e. venlafaxine, desvenlafaxine, or duloxetine) ▪ gabapentin AND • Patient does not have severe renal impairment (eGFR of 15 to 30 mL/min/1.73m^2) or end-stage renal disease (eGFR less than 15 mL/min/1.73m^2) • Patient does not have cirrhosis • Provider acknowledges that patient's baseline hepatic function will be evaluated via bloodwork prior to therapy, at 3 months, at 6 months, at 9 months and when symptoms suggest hepatic injury 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 if the following applies: • Patient has had a positive response to therapy as noted by a decrease in the number of moderate to severe hot flashes
• leniolisib phosphate (Joenja) **Immunological Agents Misc.**	Manual PA criteria apply to all new users of leniolisib (Joenja) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 12 years of age or older and weighs 45 kg or greater • Medication is prescribed by a specialist who treats patients with primary immune deficiencies • Patient has a genetically confirmed diagnosis of phosphoinositide 3-kinase delta (PI3Kδ) mutation with a variant in PIK3CD and/or PIK3R1 genes • Patient has at least one clinical finding or manifestation consistent with activated phosphoinositide 3-kinase delta syndrome (APDS) Non-FDA approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• omaveloxolone (Skyclarys) **Neurological Agents Misc**	Manual PA criteria apply to all new users of omaveloxolone (Skyclarys) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 16 years of age or older • Medication is prescribed by a neurologist • Patient has genetic testing confirming the diagnosis of Friedreich's Ataxia • Provider is aware of the warnings, screening and monitoring precautions for Skyclarys. Non-FDA approved uses are NOT approved PA does not expire
• perfluorohexyloctane 1.338 g/mL ophthalmic solution (Miebo) **Ophthalmic: Dry Eye Agents**	Manual PA criteria apply to all new users of perfluorohexyloctane (Miebo) Manual PA criteria: Coverage is approved if all criteria are met: • Medication is prescribed by an ophthalmologist or optometrist • Patient is 18 years of age or older • Patient has a diagnosis of moderate to severe dry eye disease • Patient had positive symptomology screening for dry eye disease from an appropriate measure • Patient has at least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient has had at least 1 month of one ocular lubricant used at optimal dosing and frequency • Patient has had at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency • Patient has had at least a 3 month trial of cyclosporine (Restasis) or cyclosporine (Cequa) or lifitegrast (Xiidra) Non-FDA approved uses are NOT approved PA does not expire
• sodium oxybate extended-release packets for oral suspension (Lumryz) **Sleep Disorders: Wakefulness Promoting Agents**	Manual PA criteria apply to all new users of sodium oxybate (Lumryz) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Lumryz is prescribed by a neurologist, psychiatrist, or sleep medicine specialist • Lumryz is prescribed for the treatment of excessive daytime sleepiness or cataplexy in a patient with narcolepsy • Narcolepsy was diagnosed by polysomnogram or mean sleep latency time (MSLT) objective testing • The patient is not concurrently taking a central nervous system depressant, such as a narcotic analgesic, a benzodiazepine, or a sedative hypnotic • The patient has history of failure, contraindication, or intolerance of both of the following ▪ modafinil or armodafinil AND ▪ stimulant-based therapy (amphetamine-based therapy or methylphenidate) • Other causes of sleepiness have been ruled out or treated (including, but not limited to, obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders) Coverage is NOT provided for the treatment of other conditions not listed above or any non-FDA-approved use, including fibromyalgia, insomnia, and excessive sleepiness not associated with narcolepsy.

Appendix C—Table of Prior Authorization (PA) Criteria

	Prior Authorization expires after 1 year. Renewal PA criteria: Renewal not allowed. A new prescription will require a new PA to be submitted
• somapacitan-beco injection (Sogroya) **Growth Stimulating Agents**	Manual PA criteria apply to all new users of Sogroya Manual PA criteria: Sogroya is approved if all criteria are met: • Provider acknowledges that Norditropin is the Department of Defense's preferred somatropin agent. Pediatric patients • Patient is a pediatric patient between the ages of 2.5 to 17 years of age • Sogroya is being used for the indication of growth failure due to an inadequate secretion of endogenous growth hormone (GH) in pediatric patients • Sogroya is prescribed by or in consultation with a pediatric endocrinologist or nephrologist who recommends therapeutic intervention and will manage treatment Adult patients • Sogroya is being used for adult growth hormone deficiency as a result of pituitary disease, hypothalamic disease, trauma, surgery or radiation therapy that was acquired as an adult or diagnosed during childhood • The prescription was written by or in consultation with an appropriate specialty (endocrinologist, infectious disease specialist, general surgeon or gastroenterologist) All patients • Patient has a contraindication to Norditropin OR • Patient has experienced an adverse reaction(s) to Norditropin, Omnitrope, AND Zomacton not expected with Sogroya *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. Prior authorization expires in 1 year; provider must fill out a new PA.
• sotagliflozin (Inpefa) **Diabetes Non-Insulin: Sodium Glucose Co-Transporter-2 (SGLT2) Inhibitor**	Manual PA criteria apply to all new users of Inpefa. Manual PA Criteria: Inpefa 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), empagliflozin/metformin (Synjardy, Synjardy XR) and empagliflozin/linagliptin (Glyxambi) are DoD's preferred SGLT2 inhibitor, and that PA is not required for empagliflozin • Provider acknowledges that empagliflozin is approved for patients with heart failure with all levels ejection fraction • Provider acknowledges that empagliflozin is approved for patients with chronic kidney disease • Inpefa is prescribed to reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visits in patients heart failure, type 2 diabetes, chronic kidney disease and other cardiovascular risk factors

	• Patient has experienced significant adverse reactions or has a contraindication to empagliflozin • Prescription is written by or in consultation with a cardiologist • Patient is receiving appropriate guideline-directed medical therapy including the following: angiotensin-converting enzyme inhibitor (ACEI), angiotensin II receptor blocker (ARB), or angiotensin receptor neprilysin inhibitor (ARNI); beta blocker; and aldosterone antagonist, unless contraindicated or if the patient has experienced adverse effects or could not tolerate these therapies Non-FDA-approved uses are not approved, including type 1 diabetes mellitus Prior authorization does not expire.
• zavegepant nasal spray (Zavzpret) **Migraine Agents oral CGRP**	Manual PA criteria apply to all new users of Zavzpret. Manual PA criteria: Zavzpret is approved if all criteria are met: • The patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any other small molecule CGRP targeted medication (i.e., Nurtec ODT or Ubrelvy) is not allowed • Patient has a diagnosis of acute treatment of migraine headache AND • Patient has a contraindication to, intolerability to, or has failed a trial of BOTH of the following medications ▪ sumatriptan (Imitrex) nasal spray AND ▪ Nurtec ODT or Ubrelvy tabs 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 the following criteria is met • Acute Treatment: Patient has a documented positive clinical response to therapy
Newly Approved Drug Interim PAs for Completely Excluded Drugs	
• sildenafil 10 mg/mL oral suspension (Liqrev) **Pulmonary Arterial Hypertension (PAH): PDE 5 Inhibitor**	Interim Manual PA criteria apply to all users of sildenafil 10 mg/mL oral suspension (Liqrev) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Liqrev will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the August 2023 DoD P&T Committee meeting minutes by the Director, DHA • Provider acknowledges that generic sildenafil 10 mg/mL oral suspension (generic Revatio) is available to TRICARE beneficiaries • Patient has diagnosis of World Health Organization (WHO) group 1 pulmonary arterial hypertension (PAH) • Prescriber is cardiologist or pulmonologist • Patient had a right heart catheterization • Patient has documentation that patient had right heart catheterization that results confirm diagnosis of World Health Organization (WHO)Group 1 pulmonary arterial hypertension (PAH) • Patient is not receiving other PDE-5 inhibitors, nitrates, or riociguat concomitantly • Patient requires a liquid formulation due to swallowing difficulty Non-FDA approved uses are NOT approved PA does not expire (until complete exclusion status implementation)

Appendix C—Table of Prior Authorization (PA) Criteria

• trientine tetrahydrochloride tabs (Cuvrior) **Binders-Chelators-Antidotes-Overdose Agents**	Interim Manual PA criteria apply to all users of Cuvrior tabs Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges Cuvrior will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the August 2023 DoD P&T Committee meeting minutes by the Director, DHA • Provider acknowledges that generic trientine hydrochloride capsules are available without prior authorization • Patient has tried and failed generic trientine hydrochloride capsules • The provider must document why the patient cannot use generic trientine hydrochloride capsules ▪ Acceptable responses include that the patient has a contraindication/intolerance to an inactive ingredient in the generic trientine hydrochloride capsules Non-FDA approved uses are NOT approved PA does not expire (until complete exclusion status implementation)
• zolpidem 7.5 mg capsules (no brand name) **Sleep Disorders: Insomnia Agents**	Interim Manual PA criteria apply to all users of zolpidem 7.5 mg capsules Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges zolpidem 7.5 mg capsules will be completely excluded from the TRICARE pharmacy benefit 120 days after the signing of the August 2023 DoD P&T Committee meeting minutes by the Director, DHA • Provider acknowledges that generic zolpidem IR 5 mg and 10 mg tabs, zolpidem ER 6.25 mg and 12.5 mg tabs, zaleplon 5 mg and 10 mg caps; and eszopiclone 1 mg, 2 mg and 3 mg tabs are available without requiring PA. Please consider changing the prescription to one of these other products. • The provider must provide a clinical rationale to document why the patient cannot take any of the drugs listed above, including zolpidem IR 5 mg and 10 mg tabs or zolpidem ER 6.25 mg or 12.5 mg tabs ▪ Acceptable responses include that the patient has tried and failed ALL of the following: zolpidem IR 5 mg and 10 mg tabs; zolpidem ER 6.25 mg and 12.5 mg tabs; zaleplon 5 mg and 10 mg caps; and eszopiclone 1 mg, 2 mg and 3 mg tabs Non-FDA approved uses are NOT approved No refills allowed; new prescription is required for each fill until complete exclusion status implementation.
Utilization Management New PAs	
• prenatal MVI (Natal PNV) **Vitamins: Prenatal**	Manual PA criteria applies to new and current users of prenatal MVI (Natal PNV). Manual PA Criteria: Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, Neonatal Plus, or Natal PNV is approved if all criteria are met: • The provider is aware and acknowledges that Prenatal Vitamins Plus Low I, Prenatal Plus, Preplus, Prenatal, Prenatal Vitamins, Prenatal Multi plus DHA, Prenatal Vitamin plus Low Iron, or Prenatal Plus DHA are the preferred products over Azesco, Zalvit, Trinaz, Neonatal-DHA, Neonatal FE, Neonatal Complete, Neonatal Plus, and Natal PNV. The preferred vitamins listed above are covered without a PA for women who are under the age of 45 years and planning to become pregnant or who are pregnant. Please consider changing the prescription to one of these agents. • The provider must explain why the patient requires Natal PNV and cannot take one of the cost-effective formulary alternatives (fill-in blank) Non-FDA-approved uses are NOT approved Prior Authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management Updated PAs	
• topiramate ER capsule sprinkle (Qudexy XR) • topiramate ER capsule (Trokendi XR) **Anticonvulsant and Anti-Mania**	**Updates from the August 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of topiramate ER capsule sprinkle (Qudexy XR) or topiramate ER capsule (Trokendi XR) Manual PA criteria: Qudexy XR or Trokendi XR are approved if all criteria are met: • **The drug is prescribed by or in consultation with an adult or pediatric neurologist** • **Patient has a diagnosis of one of the following:** ▪ **Epilepsy monotherapy** ○ **Qudexy XR: For epilepsy monotherapy: Partial onset seizure or primary generalized tonic-clonic seizures in patients 2 years or age or older** ○ **Trokendi XR: For epilepsy monotherapy: Partial onset seizure or primary generalized tonic-clonic seizures in patients 6 years or age or older** ▪ **Epilepsy adjunctive therapy** ○ **Qudexy XR: Partial-onset seizures, primary generalized tonic clonic seizures, or seizures associated with Lennox-Gastaut Syndrome in patients 2 years of age and older** ○ **Trokendi XR: For epilepsy adjunctive therapy: Partial-onset seizures, primary generalized tonic clonic seizures, or seizures associated with Lennox-Gastaut Syndrome in patients 6 years of age and older** ▪ **For Qudexy XR and Trokendi XR: For Migraine: Preventive treatment of migraine in patients 12 years of age and older** • ~~**Partial onset seizure and 1° generalized tonic-clonic seizures in patients > 10 years**~~ • ~~**Lennox-Gastaut seizures in patients > 6 years for Trokendi XR and age > 2 years for Qudexy XR.**~~ • ~~**Adjunctive therapy for partial onset seizure or primary generalized tonic clonic seizure in patients 2 years of age or older (Qudexy XR) or 6 years and older (Trokendi XR).**~~ • ~~**Migraine prophylaxis in adults (Trokendi XR and Qudexy XR)**~~ • Patient is required to try topiramate first, unless the following has occurred: ▪ Inadequate response not expected to occur with Qudexy XR or Trokendi XR ▪ Patient has contraindication or adverse reaction to a component of generic topiramate not expected to occur with Qudexy XR or Trokendi XR Non-FDA-approved uses are not approved Prior Authorization does not expire
• atogepant (Qulipta) **Migraine Agents oral CGRP**	**Updates from the August 2023 meeting are in bold.** **Note that there were no changes to the current Qulipta criteria for episodic migraine** Manual PA criteria apply to all new users of Qulipta. Manual PA criteria: Qulipta is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by or in consultation with neurologist • Concurrent use with any small molecule CGRP targeted medication (i.e., Ubrelvy, Nurtec ODT or another gepant) is not allowed • **Patient has a diagnosis of chronic migraine OR** • Patient has Episodic Migraine as defined by the following:

	▪ 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 ▪ 8 to 14 migraine days per month for 3 months • 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 • Patient has a contraindication to, intolerability to, or has failed a 2-month trial of at least ONE of the following CGRP injectable agents ▪ erenumab-aooe (Aimovig) ▪ fremanezumab-vfrm (Ajovy) ▪ galcanezumab-gnlm (Emgality) Non-FDA-approved uses are not approved Prior Authorization expires after 6 months Renewal Criteria: (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
• linaclotide (Linzess) **Gastrointestinal-2 Agents: CIC/IBS-C**	**Updates from the August 2023 meeting are in bold.** Manual PA is required for all new users of Linzess. Manual PA Criteria: Linzess 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 Non-FDA-approved uses other than OIC are NOT approved

Appendix C—Table of Prior Authorization (PA) Criteria

	Prior authorization expires after 1 year Renewal PA Criteria: Coverage will be approved 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).
• Freestyle Libre 2 and 3 and Dexcom G6 and G7 **CGM: Therapeutic Continuous Glucose Monitoring Systems**	**Updates from the August 2023 meeting are in bold** Manual PA criteria apply to all new users of Abbott FreeStyle Libre 2 and 3 and Dexcom G6 and G7. Manual PA criteria: Coverage is approved if all criteria are met: • *Patients that have previously received a CGM under the medical benefit must still fill out prior authorization criteria* • Patient has a diagnosis of diabetes • Patient is using basal and prandial insulin injections; OR patient is using a continuous subcutaneous insulin infusion (i.e., insulin pump) OR patient is on insulin therapy with a history of severe hypoglycemia episodes requiring medical intervention (grade 2 or higher) • Device is prescribed by an endocrinologist or diabetes management expert ▪ Diabetes management expert is defined as: licensed independent practitioner experienced in the management of insulin dependent diabetics requiring basal and bolus dosing or a pump and familiar with the operation and reports necessary for proper management of continuous glucose monitoring systems. This is a self-certification. • Documentation is required of all the following: ▪ Diagnosis ▪ Medication history ▪ Completion of a comprehensive diabetes education program ▪ Patient agrees to wear CGM as directed ▪ Patient agrees to share device readings with managing healthcare professional for overall diabetes management • Patient meets the age requirement (≥ two years if Dexcom G6 and Dexcom G7, ≥ **two** ~~**four**~~ years if FreeStyle Libre 2, or FreeStyle Libre 3) • Provider and patient will assess the usage of self monitoring of blood glucose (SMBG) test strips with the goal of minimizing/discontinuing use Initial PA Expiration: annual Renewal expiration: annual Annual renewal criteria: • Confirm patient has seen endocrinologist or diabetes specialist within past year • Patient has utilized CGM daily • Provider and patient will assess the usage of self monitoring of blood glucose (SMBG) at every visit with the goal of minimizing/discontinuing use • Patients with T2DM continue to require basal and prandial insulin injections daily • Patient continues to share data with managing healthcare professional for the purposes of clinical decision making

• upadacitinib (Rinvoq) **Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)**	**Note that there were no changes to the current Rinvoq criteria for the other indications (RA, PsA, Ulcerative Colitis, Ankylosing Spondylitis, or Atopic Dermatitis – see the August 2022 P&T Committee meeting minutes for the full criteria)** Manual PA apply to all new users of Rinvoq Manual PA criteria: Coverage for Crohn's disease is approved if all criteria are met: • **Provider acknowledges that Humira is the Department of Defense preferred targeted biologic agent for Crohn's disease** • **The patient is 18 years of age or older** • **The patient has moderately to severely active Crohn's disease** • **Patient has had an inadequate response to Humira OR** • **Patient has experienced an adverse reaction to Humira and that is not expected to occur with the requested agent OR** • **Patient has a contraindication to Humira AND** For all indications • Patient has no evidence of active TB infection within the past 12 months • Patient has no history of venous thromboembolic (VTE) disease • Provider is aware of the FDA safety alerts AND Boxed Warnings • Patient has no evidence of neutropenia (ANC < 1000) • Patient has no evidence of lymphocytopenia (ALC < 500) • Patient has no evidence of anemia (Hgb < 8) • Patient is not taking Rinvoq concomitantly with other TIBs agents except for Otezla and other potent immunosuppressant's (e.g., azathioprine, cyclosporine) Non-FDA-approved uses are not approved **PA does not expire for Crohn's disease**
• olaparib (Lynparza) **Oncological Agents: Ovarian Cancer**	**Updates from the August 2023 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Lynparza. Manual PA Criteria: Lynparza is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist or urologist • Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test *see prostate diagnosis below for exception* • Lynparza will be prescribed as treatment for one of the following diagnoses: ▪ Recurrent or Stage IV Triple negative breast cancer ▪ Recurrent or Stage IV hormone receptor (+) (ER, PR, or both) HER2(-) breast cancer AND was either: – Previously treated with prior endocrine therapy OR – Was not an appropriate candidate for endocrine therapy ▪ Recurrent advanced ovarian cancers (platinum-sensitive or platinum resistant), fallopian tube or primary peritoneal cancers AND – Patient has received at least 3 prior lines of therapy AND – Lynparza will not be used as a single agent

	▪ Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene (e.g. BRCA, ATM)-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior androgen receptor-directed therapy ~~**and taxane-based chemotherapy**~~ – Of note, a patient does not require both a BRCA mutation and another separate HRR mutation; any HRR mutation satisfies requirement – this is an exception to the initial requirement that a patient have a BRCA mutation specifically ▪ **Deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) in combination with abiraterone and prednisone or prednisolone** ▪ Deleterious or suspected deleterious gBRCAm, (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy • OR Lynparza will be prescribed as maintenance therapy for one of the following diagnoses: ▪ Platinum-sensitive, relapsed, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND – Patient has received 2 or more lines of platinum-based chemotherapy – Patient was in objective response (either complete or partial) to most recent treatment regimen – Lynparza will not be combined with bevacizumab (Avastin) ▪ Newly diagnosed, advanced, high-grade, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer AND – Patient has had a complete or partial response to primary therapy with a platinum-based therapy ▪ Metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen 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: _____. • Female patients are not pregnant or planning to become pregnant and will use highly effective contraception while taking Lynparza and for 6 months after the last dose • Female patients will not breastfeed during treatment and for at least 1 month after the cessation of treatment • Male patients will use effective contraception while taking Lynparza and for at least 3 months after cessation of therapy Other non-FDA-approved uses are NOT approved PA does not expire
• dabrafenib (Tafinlar) **Oncological Agents**	**Updates from the August 2023 meeting are in bold** Manual PA criteria applies to all new users of Tafinlar <u>Manual PA criteria</u>**:** 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 • **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
• trametinib (Mekinist) **Oncological Agents**	**Updates from the August 2023 meeting are in bold** Manual PA criteria apply to all new users of Mekinist. <u>Manual PA criteria</u>: Mekinist is approved if all criteria are met: • 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 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 Prior Authorization does not expire
• avapritinib (Ayvakit) **Oncological Agents**	**Updates from the August 2023 meeting are in bold.** Manual PA criteria apply to all new users of avapritinib (Ayvakit). <u>Manual PA criteria</u>: Ayvakit is approved if all criteria are met: • Patient is 18 years of age or older • Must be prescribed by or in consultation with a hematologist/oncologist • Patient has: ▪ Pathologically confirmed unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation with or without the D842V mutation OR

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	▪ Advanced systemic mastocytosis (includes patients with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia) OR ▪ **Indolent Systemic Mastocytosis (ISM) with a platelet count ≥ 50 x 10^9/L** • Provider agrees to monitor for intracranial bleeding and other central nervous system (CNS) adverse effects • 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: _____. • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 6 weeks after the cessation of therapy Other Non-FDA-approved uses are not approved Prior authorization does not expire
• sarilumab (Kevzara) **Targeted Immunomodulatory Biologics**	**Note that there were no changes to the current Kevzara criteria for RA – see the August 2017 P&T Committee meeting minutes for the full criteria** Manual PA criteria apply to all new users of Kevzara Manual PA criteria: Kevzara is approved for Polymyalgia Rheumatica if all criteria are met: • **Patient is 18 years of age or older** • **Kevzara is prescribed by or in consultation with a rheumatologist** • **Patient has tried and/or failed ONE systemic corticosteroid; OR the patient is not a candidate for corticosteroid therapy** • Patient does not have platelets less than 150,000/mm3 or liver transaminases above 1.5 times upper limit of normal (UNL) • Patient has evidence of a negative TB test result in the past 12 months (or TB is adequately managed) • Patient will not be receiving other targeted immunomodulatory biologics with Kevzara, including but not limited to the following: Actemra, Cimzia, Cosentyx, Enbrel, Humira, Ilumya, Kineret, Olumiant, Orencia, Otezla, Remicade, Rituxan, Siliq, Simponi, Stelara, Taltz, Tremfya, Xeljanz or Xeljanz XR Non-FDA-approved uses are not approved **Prior authorization for PMR expires after 12 months** **Renewal Criteria for PMR: (Initial TRICARE PA approval is required for renewal) Kevzara will be approved indefinitely if:** • **The patient has had a positive response to therapy**
• risdiplam (Evrysdi) **Neurological Agents Miscellaneous**	**Updates from the August 2023 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of risdiplam (Evrysdi). Manual PA Criteria: Evrysdi is approved if all criteria are met: • The drug is prescribed by a pediatric or adult neurologist • Patient has genetic confirmation of homozygous deletion or compound heterozygosity predictive of loss of function of the SMN1 gene (documentation required)

	• Patient has confirmation of at least two SMN2 gene copies (documentation required) • Patient has a confirmed diagnosis of Spinal Muscular Atrophy Types 1, 2, or 3 (Fill-in-the-blank) • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients of childbearing potential have been counseled to use effective contraception during treatment and for at least 1 month after the cessation of therapy • Male patients of reproductive potential are counseled about the potential effects on fertility • ~~**Patient does not have evidence of hepatic impairment**~~ • Patient does not have permanent ventilator dependence • Patient does not have complete paralysis of all limbs • Evrysdi will not be used concurrently with Spinraza (nusinersen injection for intrathecal use) • Patient weight must be documented (Fill-in-the-blank) – (Any answer acceptable) • Patient dose in total mg/day and mg/kg per day must be documented (Fill-in-the blank) • The dose must be 0.2 mg/kg if the patient is 2 months to < 2 years of age; OR 0.25 mg/kg for patients ≥ 2 years of age who weigh < 20 kg; OR 5 mg for patients ≥ 2 years of age who weigh ≥ 20 kg Non-FDA-approved uses are not approved Prior authorization expires in 6 months Renewal criteria: (Initial TRICARE PA approval is required for renewal) • According to the prescriber, the patient's level of disease has improved or stabilized to warrant continuation on Evrysdi as determined by an objective measurement and/or assessment tool and/or clinical assessment of benefit. (documentation required) Renewal criteria expires in 1 year.
• avacopan (Tavneos) **Hematological Agents**	**Updates from the August 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to new users of Tavneos. <u>Manual PA criteria</u>: Tavneos is approved initially for 6 months if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a rheumatologist • Patient has a documented diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's) and microscopic polyangiitis (MPA) • Patient meets one of the following criteria (either a or b): ▪ a. Positive ELISA test for anti-proteinase-3 (PR-3) ▪ b. Positive ELISA test for anti-myeloperoxidase (MPO) • ~~**Patient has documentation of baseline Birmingham vasculitis activity score (BVAS), with at least one of the following criteria (at least a, b, or c):**~~ ▪ ~~**a. At least 1 major item (i.e. gangrene, scleritis/episcleritis, hearing loss, massive hemoptysis/alveolar hemorrhage, respiratory failure, ischemic abdominal pain, rise/fall in serum creatinine, meningitis, CVA);**~~

	~~▪ b. At least 3 non-major items;~~ ~~▪ c. At least 2 renal items of proteinuria and hematuria~~ • Patient has experienced or has a high probability to experience significant adverse effect from prednisone • Tavneos is prescribed in combination with cyclophosphamide or rituximab, unless clinically significant adverse effects are experienced or both cyclophosphamide or rituximab are contraindicated Non-FDA-approved used are not approved including Immunoglobulin A nephropathy, Hidradenitis suppurativa, acne inversa, and C3 Glomerulopathy (C3G) Prior Authorization expires after 6 months Renewal criteria (Initial TRICARE PA approval required for renewal) Coverage will be approved indefinitely for continuation of therapy if one of the following apply: • Patient has responded positively to therapy as evidenced by **a reduction in symptoms** ~~**at least a 50% reduction in BVAS from baseline**~~ or remission ~~**(BVAS of zero)**~~ AND If request is for a dose increase, new dose does not exceed 60 mg (2 tabs) per day
• adalimumab (Humira) **Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors**	**Updates from the August 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of adalimumab (Humira) Manual PA criteria: Coverage is approved if all criteria are met: • If patient is less than 18 years old coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease ▪ If indication is moderate to severe moderate to severe polyarticular juvenile idiopathic arthritis patient must be greater than or equal to 2 years old ▪ If indication is moderate to severe Crohn's disease patient must be greater than or equal to 6 years old ~~**AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease**~~ • If patient is greater than or equal to 18 years old coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa ▪ If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease ▪ If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months • Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has been not been reported with TNF blockers, including Humira.

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	• 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 PA does not expire
Previously Completely Excluded Drugs That Are Returned to NF Status PA Criteria	
• baclofen oral granules (Lyvispah) **Skeletal Muscle Relaxants & Combinations**	Manual PA criteria apply to all new users of baclofen oral granules (Lyvispah) <u>Manual PA criteria:</u> baclofen oral granules are approved if all criteria are met: • Baclofen will be used for spasticity • Patient requires baclofen and cannot use the tablet formulation due to some documented medical condition – dysphagia, systemic sclerosis, etc. and not due to convenience Non-FDA-approved uses are not approved Prior authorization does not expire

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• fecal microbiota spores, live-brpk (Vowst) **Gastrointestinal-2 Agents: Miscellaneous**	▪ Retail/MTF/Mail: 1 treatment course per fill
• sodium oxybate ER packets for oral suspension (Lumryz) **Sleep Disorders: Wakefulness Promoting Agents**	▪ Retail/MTF/Mail: 30-day supply
• zavegepant (Zavzpret) **Migraine Agents**	▪ Retail: 6 bottles/30 days ▪ MTF and Mail Order:18 bottles/90 days
• **Self-Monitoring Blood Glucose Test Strips (all products)**	**Changes from the August 2023 meeting are outlined in bold (no changes made to the QL; changes made to the override criteria)** ▪ Retail Network: 100 strips/30-day supply ▪ Mail Order and MTF: 300 strips/90-day supply Override criteria include the following situations: ▪ receiving insulin ▪ using an insulin pump ▪ gestational diabetes ▪ requires more frequent testing due to endocrine disorders (e.g., insulinoma, endogenous hyperinsulinism, non-islet cell tumor) ▪ history of poorly-controlled blood glucose levels with history of adverse outcomes (e.g., ketoacidosis or hypoglycemic episode) requiring medical intervention ▪ **Patient is not using a continuous blood glucose monitoring (CGM) system, unless a clinical explanation is provided: _____ (write-in)**

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

Generic (Trade) Name UF Class	Comparators	Dosage Form/ Dosing	Indications	Adverse Events (Aes)	Clinical Summary	Recommendation
• atropine sulfate ophthalmic solution **Ophthalmic Miscellaneous: Mydriatics**	• cyclopentolate 1% • Isopto Atropine 1% • Cyclomydril 0.2%-1% • tropicamide 1%	Formulation • 1% ophthalmic solution Dosing • 1 drop in affected eye 40 minutes prior to max dilation time	• Mydriasis • Cycloplegia • Penalization of the healthy eye in the treatment of amblyopia	• eye pain • blurred vision • photophobia • superficial keratitis • decreased lacrimation • drowsiness • increased heart rate and blood pressure	• Preservative-free formulation of atropine sulfate ophthalmic solution • No new clinical studies; approved via 505(b)(2) • Atropine sulfate is available generically as a 1% ophthalmic solution and a 1% ophthalmic ointment, however they contain the preservative benzalkonium chloride in multi-dose dropper bottles • Provides no compelling clinical advantage over existing agents	• UF • Add to EMMPI List
• deutetra-benazine XR tabs (Austedo XR) **Neurological Agents Misc: Movement Disorder**	• deutetraben-azine (Austedo) • tetrabenazine (Xenazine) • valbenazine (Ingrezza)	Formulation • 6, 12, 24 mg tab Dosing • 12 mg QD • Max 48 mg/day	• Treatment of Chorea associated with Huntington's disease • Treatment of Tardive dyskinesia	<u>> 8%</u> • somnolence • fatigue, • diarrhea • dry mouth <u>> 4%</u> • insomnia • nasopharyngitis	• extended-release formulation of deutetrabenazine (Austedo) • Approval via 505(b)(2) with no new clinical data • Similar half-life and clearance to Austedo • Provides another treatment option for Huntington's Chorea and Tardive dyskinesia	• UF • Do not add to EMMPI List
• fecal microbiota spores, live - brpk caps (Vowst) **GI-2 Agents: Misc**	• fecal microbiota live (Rebyota) (medical benefit) • bezlotoxumab (Zinplava) (medical benefit)	Formulation • capsules Dosing • 4 caps daily x 3 consecutive days	• Prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI	≥5% • abdominal distension • fatigue • constipation • chills • diarrhea	• Fecal microbiota spores to prevent the recurrence of *Clostridioides difficile* infection (CDI) • Phase 3 study demonstrated 88% of patients were recurrence free at 8 weeks following treatment vs. placebo with a sustained effect up to 24 weeks • Most common adverse effects are abdominal distension, fatigue, constipation, chills and diarrhea • Rebyota must be administered by a healthcare provider and needs to be kept in an ultracold freezer while Vowst can be kept at room temperature and self-administered • No head-to-head studies with Rebyota and Vowst • Vowst provides another treatment option to prevent the recurrence of CDI	• UF • Do not add to EMMPI List

• fezolinetant (Veozah) **Gynecological Agents Misc**	• estradiol & Medroxyprogesterone tab • paroxetine caps (Brisdelle)	Formulation • 45 mg tab Dosing • 45 mg daily	• Treatment of moderate to severe vasomotor symptoms (VMS) due to menopause	≥2% • abdominal pain • diarrhea • insomnia • back pain • hot flush • hepatic transaminase elevation	• 1st neurokinin 3 receptor antagonist for treatment of moderate to severe VMS due to menopause • Although Veozah demonstrated statistically significant improvements in VMS frequency and severity vs. placebo, it only met MCID for one of the two studies on VMS severity, and it did not reach MCID for improvement in VMS frequency or for improvement in MENQoL • Overall, it is well tolerated; however, there are warnings for elevations in serum transaminases, and lab monitoring at baseline, 3, 6, and 9 months is recommended • Not studied against other VMS medications and no long-term data beyond 1 year • NAMS 2023 guidelines give Veozah a level 1 recommendation along with other non-hormonal options: SSRIs/SNRIs and gabapentin • ICER rates the net health benefit of Veozah vs. no treatment as "promising but inconclusive" due to modest benefits observed in trials and uncertainty about long-term benefits and safety • Provides another non-hormonal option for vasomotor symptoms in women who are not candidates for menopausal hormone therapy	• UF • Add to EMMPI List
• Leniolisib (Joenja) **Immunological Agents Misc**	• N/A	Formulation • 70 mg tab Dosing • 70 mg BID	• Treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in patients 12 years of age and older and ≥45 kg	≥10% • headache • sinusitis • atopic dermatitis	• Specialty, orphan drug for the treatment of activated phosphoinositide 3-kinase delta syndrome (APDS) in adult and pediatric patients 12 years of age and older • Single phase 3 study demonstrated statistically significantly reduction of lymphadenopathy and an increase in naïve B cells compared to placebo after 12 weeks • Generally well tolerated, with most common AE reported as atopic dermatitis, headache and sinusitis • Joenja provides another treatment option for this rare primary immunodeficiency disorder	• UF • Do not add to EMMPI list

• omaveloxolone (Skyclarys) **Neurological Agents Misc**	• N/A	Formulation • 50 mg cap Dosing • 150 mg BID	• Treatment of Friedreich's Ataxia in adults and adolescents aged 16 and older	≥20% • ↑ liver enzymes • headache • nausea • abdominal pain • fatigue • diarrhea • musculoskeletal pain	• Specialty, orphan drug for the treatment of Friedreich's Ataxia in adults and adolescents 16 years and older • Phase 2 study demonstrated statistically significant improvement in modified Friedreich's Ataxia scale (mFARS) scores vs. placebo • Most common adverse effects are reversible transaminitis, headache, nausea, abdominal pain, fatigue, diarrhea, MSK pain • Skyclarys provides a pharmacologic treatment option for this rare disorder	• UF • Do not add to EMMPI list
• perfluorohexyloctane ophthalmic (Miebo) **Ophthalmic: Dry Eye Agents**	• cyclosporine 0.05% unit dose • Cequa 0.09% • Xiidra 5% • Eysuvis 0.05%	Formulation • ophthalmic solution Dosing • 1 drop OU QID	• Treatment of the signs and symptoms of dry eye disease	• Blurred vision	• Ophthalmic semifluorinated alkane indicated • Miebo is the first and only product that was specifically studied in patients with meibomian gland disorder (MGD)-related dry eye disease • Two phase 3 studies demonstrated statistically significant improvement in change from baseline to Week 8 in total corneal fluorescein staining (tCFS) score and eye dryness score vs. saline • Adverse reactions with Miebo are mostly mild to moderate in nature • Miebo was not studied in patients with dry eye disease not due to MGD • Cequa, Restasis, Tyrvaya, and Xiidra are effective in treating dry eye disease, regardless of presence of MGD • No head-to-head studies with other agents for dry eye disease • Provides an alternative to other products for dry eye disease	• NF • Add to EMMPI List

• sildenafil 10 mg/mL oral suspension (Liqrev) **Pulmonary Arterial Hypertension: PDE 5 Inhibitor**	• sildenafil tab • Adcirca tab • Revatio oral susp • Tadliq oral susp	Formulation • 10 mg/ml oral susp Dosing • 20 mg PO TID	• Treatment of pulmonary arterial hypertension, WHO Group I, in adults to improve exercise ability and delay clinical worsening	• headache • dyspepsia • flushing • pain in limb • myalgia • back pain • diarrhea	• Another formulation of sildenafil • No new clinical studies; approved via 505(b)(2) application • Sildenafil powder for oral suspension (Revatio) is now generic, and in the same concentration as Liqrev ▪ FDA-approved for patients as young as 1 year of age, as well as adults ▪ Once reconstituted requires refrigeration, with a shelf-life of 60 days; grape flavored • Sildenafil oral suspension (Liqrev) • Only approved in adults • Can be stored at room temperature; shelf-life of 90 days once opened; strawberry flavored • Tadalafil 20 mg/5 mL oral suspension (Tadliq) is NF, and allows for an alternative formulation for children other than sildenafil • Provides no compelling clinical advantage over existing agents	• Complete Exclusion
• sodium oxybate extended release packets for oral suspension (Lumryz) **Sleep Disorders: Wakefulness Promoting Agents**	• Xyrem • Xywav	Formulation • 4.5 g, 6 g, 7.5 g, 9 g packets for extended-release oral suspension Dosing • 4.5 g QHS; max 9 g/night	• Treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy	≥5% • nausea • dizziness • enuresis • headache • vomiting	• Specialty, schedule III, extended-release formulation of sodium oxybate • Phase 3 study demonstrated statistically significant improvement for all three primary endpoints compared to placebo; these endpoints assessed mean sleep latency on a Maintenance of Wakefulness Test, Clinical Global Impression-Improvement and average weekly number of cataplexy attacks • Adverse reactions with Lumryz are mostly mild to moderate; however Lumryz carries a black box warning for CNS depression and abuse/misuse requiring REMS monitoring • Provides an additional treatment option for cataplexy or excessive daytime sleepiness in adults with narcolepsy	• NF • Do not add to EMMPI list

• sotagliflozin (Inpefa **Diabetes Non-Insulin: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	• Jardiance tab • Steglatro tab • Farxiga tab • Invokana tab	Formulation • 200 mg tab • 400 mg tab Dosing • 200 – 400 mg daily	• Reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes, chronic kidney disease and other cardiovascular risk factors	≥5% • UTI • volume depletion • diarrhea • hypoglycemia	• SGLT2/SGLT-1 inhibitor • Although was only studied in pts with T2DM, the FDA-approved indication does not limit tx to diabetics • Two phase 3 studies demonstrated a 33% (SOLOIST-WHF) and 26% (SCORED) decreased risk for the composite endpoint of hospitalization for heart failure, urgent visits for heart failure and CV mortality versus placebo • Primary composite endpoint results were driven by the reduction in HF hospitalization, which has been seen with numerous other HF drugs (empagliflozin, dapagliflozin, sacubitril/valsartan, ARBs) • No effect seen on rate of decline in CKD progression • Neither trial was sufficiently powered for cardiovascular death alone, since both trials ended prematurely owing to loss of funding at the onset of the Covid-19 pandemic • Advertised as an “SGLT2 inhibitor for cardiologists” • Does not have a glycemic control indication for T2DM • Provides no compelling advantage over the other SGLT-2 inhibitors	• NF non-step-preferred • Add to EMMPI list
• zolpidem 7.5 mg capsules **Sleep Disorders: Insomnia**	• zolpidem tab • zolpidem ER tab • zaleplon • eszopiclone	Formulation • 7.5 mg cap Dosing • 7.5 mg QHS	• Short-term treatment of transient insomnia	• headache • drowsiness • dizziness diarrhea	• Zolpidem tartrate capsules are not recommended for geriatric patients • The capsule cannot be opened and must be swallowed whole • No new clinical studies; approved via 505(b)(2) • Provides no compelling clinical advantage over existing agents	• Complete Exclusion

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

• trientine tetra-HCl (Cuvrior) **Binders-Chelators-Antidotes-Overdose Agents**	• trientine hydrochloride • penicillamine	Formulation • 300 mg tab Dosing • 300 – 3000 mg in divided doses	• Treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine	≥5% • abdominal pain • change of bowel habits • rash • alopecia • mood swings	• New salt formulation of trientine HCl • Phase 3 study demonstrated non-inferiority to penicillamine via mean difference in non-ceruloplasmin copper levels • Trientine has fewer side effects than penicillamine • Trientine hydrochloride must be refrigerated and has a max dose 2 grams per day while Cuvrior can be kept at room temperature and has a max dose of 3 grams per day • Trientine hydrochloride should be used when continued primary/maintenance treatment with penicillamine is no longer possible because of intolerable or life endangering side effects • Cuvrior should be used in maintenance treatment in patients who are tolerant to penicillamine • Provides no compelling clinical advantage over existing agents	• Complete Exclusion
• zavegepant nasal spray (Zavzpret) **Migraine Agents**	• Ubrelvy • Nurtec ODT • Sumatriptan NS	Formulation • 10 mg nasal spray Dosing • 10 mg PRN; Max 10 mg/day	• Acute treatment of migraine with or without aura in adults	≥2% • dysgeusia • nausea • nasal discomfort • vomiting	• Zavzpret is a calcitonin gene-related peptide (CGRP) antagonist for the acute treatment of migraine with or without aura in adults • Two studies demonstrated statistically significant findings in freedom from pain and freedom from the most bothersome symptoms (MBS) at 2 hours post-dose vs. placebo • Adverse effects were mild to moderate in nature • Zavzpret is an additional treatment option available for the acute treatment of migraine	• NF • Do not add to EMMPI list

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)
August 2023	**Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** ***Designated UF*** • atropine sulfate ophthalmic solution 1% (Bausch & Lomb) ***Designated NF*** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • perfluorohexyloctane ophthalmic solution (Miebo) • sotagliflozin (Inpefa) **Drug Class Reviews** **Luteinizing Hormone-Releasing Hormone (LHRH) Agonists-Antagonists** *(Note: LHRH agonists/antagonists are already designated as generally suitable for inclusion on the EMMPI program)* ***Designated UF*** **Prostate Cancer subclass** *Remains on EMMPI program* • leuprolide acetate injection (Lupron Depot, Cipla unbranded product) all strengths • leuprolide acetate SQ (Eligard) • leuprolide mesylate injection (Camcevi) • relugolix (Orgovyx) *Added to contingent list (based on cost effectiveness and operational considerations) in May 2023* • degarelix SC injection (Firmagon) **Endometriosis/Fibroid subclass** *Remains on EMMPI program* • leuprolide acetate injection (Lupron Depot) all strengths *Added to the EMMPI program* • elagolix/estradiol/norethindrone (Oriahnn) • relugolix/estradiol/norethindrone (Myfembree)	**Drug Class Reviews** **White Blood Cell Stimulants: Filgrastims and Pegfilgrastims** ***Designated UF*** *Acute or limited duration of use* • tbo-filgrastim (Granix) • filgrastim-aafi (Nivestym) • filgrastim-sndz (Zarxio) • pegfilgrastim-jmdb (Fulphila) • pegfilgrastim-pbbk (Fylnetra) • pegfilgrastim-apgf (Nyvepria) • pegfilgrastim-fpgk (Stimufend) • pegfilgrastim-cbqv (Udenyca), • pegfilgrastim-bmez (Ziextenzo) ***Designated NF*** *Acute or limited duration of use exception* • filgrastim (Neupogen) • filgrastim-ayow (Releuko) • pegfilgrastim (Neulasta, Neulasta OnPro) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF** *Acute or limited duration of use* • fecal microbiota spores, live-brpk (Vowst) • fezolinetant (Veozah) *Not yet clear if feasible to provide through Mail* • deutetrabenazine (Austedo XR) • leniolisib (Joenja) • omaveloxolone (Skyclarys) **Designated NF** *Acute or limited duration of use exception* • zavegepant (Zavzpret) *Not yet clear if feasible to provide through mail* • sodium oxybate extended-release oral suspension (Lumryz)

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)
August 2023	**Central Precocious Puberty subclass** *Remains on EMMPI program:* • leuprolide acetate depot injection (Lupron Depot Ped) • leuprolide acetate SC injection (Fensolvi) ***Designated NF*** **Endometriosis/Fibroid subclass** *No reason to exempt from NF-2-Mail requirement, remains on list:* • elagolix 150 mg & 200 mg tabs (Orilissa)	

* 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)

August 2023	**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:
	• somapacitan-beco injection (Sogroya)
	
	Drug Classes Designated by the P&T Committee as Generally Suitable for Inclusion
	Specific agents listed within subclasses are those most likely to be feasible at mail order)
	
	Designated UF
	• Oncological Agents: Colorectal Cancer
	  • trifluridine/tipiracil (Lonsurf)
	• Oncological Agents: Renal Cell Carcinoma
	  • axitinib (Inlyta)
	  • cabozantinib s-malate (Cabometyx)
	  • lenvatinib (Lenvima)
	  • pazopanib (Votrient)
	
	• Breast Cancer Agents: Cyclin Dependent Kinase Inhibitors
	  • abemaciclib (Verzenio)
	  • palbociclib (Ibrance)
	  • ribociclib (Kisqali)
	  • ribociclib/letrozole (Kisqali Femara Co-Pack)	

* 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: October 30th, 2023

Two weeks after signing: November 15th, 2023

30 days after Signing: December 6th, 2023

60 days after signing: January 3rd, 2024

90 days after signing: January 31st, 2024

120 days after signing: February 28th, 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 Excluded Products	Formulary Alternatives	Implementation
August 2023	PAH: PDE-5 inhibitors	• sildenafil 10 mg/mL oral suspension (Liqrev)	• sildenafil tabs • sildenafil 10 mg/mL oral suspension (generic Revatio) • tadalafil oral suspension (Tadliq)	• 120 days
August 2023	Binders Chelators Antidotes	• trientine tetrahydrochloride tabs (Cuvrior)	• trientine hydrochloride caps • penicillamine	• 120 days
August 2023	Sleep Disorders: Insomnia Agents	• zolpidem 7.5 mg caps	• zolpidem IR 5 mg, 10 mg tabs • zolpidem ER 6.25 mg, 12.5 mg tabs • zaleplon 5 mg and 10 mg caps • eszopiclone 1 mg, 2 mg and 3 mg tabs	• 120 days

*The P&T Committee may recommend complete exclusion of any pharmaceutical agent from the TRICARE pharmacy benefits program the Director determines provides very little or no clinical effectiveness relative to similar agents. All TRICARE complete exclusion agents that are not eligible for cost-sharing were reviewed for clinical and cost-effectiveness in accordance with 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 DoD P&T Committee quarterly meeting minutes, found on the heatlh.mil website.