DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

February 2023

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on February 8th and 9th, 2023.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of November 2022 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the November 2022 DoD P&T Committee meeting on January 31, 2023

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 (not covered/tier 4) 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), 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 non-formulary (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. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass

Background—The P&T Committee evaluated the relative clinical effectiveness of the dual orexin receptor antagonists (DORAs), which are used to treat insomnia. The DORA agents include suvorexant (Belsomra), lemborexant (Dayvigo), and

daridorexant (Quviviq). Belsomra and Dayvigo were previously reviewed as part of the insomnia drug class review in May 2021, while daridorexant (Quviviq), was evaluated as a new drug in August 2022.

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (20 for, 0 opposed, 0 abstained, 2 absent) the following:

Clinical Practice Guidelines

- Non-pharmacological therapy, specifically cognitive behavioral therapy for insomnia (CBT-I), is recommended as a first-line treatment for chronic insomnia. This was supported most recently in 2021 by the 'Endorsement of European Guideline for the Diagnosis and Treatment of Insomnia by the World Sleep Society.'
- Pharmacologic treatment can be used in addition to non-pharmacologic therapies for patients who continue to have insomnia symptoms.
- Guidelines recommend treating insomnia with pharmacologic therapies for the shortest possible treatment course.
- No single medication is recommended as a first line treatment option for insomnia.

DORA Efficacy

- No direct comparative data are available between the DORA agents.
- A 2022 Sleep Medicine Review network meta-analysis concluded that the DORAs, to include Belsomra, Dayvigo, and Quviviq, are superior to placebo in terms of both efficacy and safety. Efficacy outcomes included a variety of objective and subjective sleep endpoints, such as sleep latency, time to sleep onset, total sleep time, and wake after sleep onset.

DORA Safety

- All three agents have similar label information, including warnings, contraindications, drug interactions, and adverse drug reactions.
- All three agents have similar recommendations regarding special populations. No dosing modifications are required for geriatric patients or those with renal impairment; and all three agents should be avoided in severe hepatic impairment.
- Longer term extension studies for all three agents reveal a slightly higher incidence of somnolence for Belsomra and Dayvigo compared to Quviviq.
- All three agents have data reported for the elderly population. Efficacy and safety endpoints in this population include assessing wake after sleep onset, falls, driving performance, rebound insomnia, and withdrawal effects.

Belsomra and Dayvigo have clinical trial data involving patients with Alzheimer's dementia, whereas Quviviq does not.

DORA Other Factors

- Dayvigo has the longest half-life (17-19 hours), followed by Belsomra (12 hours), then Quviviq (8 hours).
- The 2022 Sleep Medicine Review network meta-analysis involving the three DORA agents notably reported on the Insomnia Severity Index (ISI) for all three agents. The ISI includes measures of the impact of insomnia on an individual, such as daytime functioning, dissatisfaction with sleep, and quality of life. Notably, all three DORA agents did not meet the minimally clinical important difference threshold for ISI scores.
- Military Health System (MHS) sleep medicine physicians provided feedback, with a general consensus that no one DORA agent is preferred over another.

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:

- CMA results showed that daridorexant (Quviviq), lemborexant (Dayvigo), and suvorexant (Belsomra) were all cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of designating selected agents as formulary or NF on the UF. BIA results showed that designating daridorexant (Quviviq), lemborexant (Dayvigo), and suvorexant (Belsomra) as UF generated significant cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the following:
    - UF and step-preferred brand
        - lemborexant (Dayvigo)
        - suvorexant (Belsomra)
        - daridorexant (Quviviq)
        - Note that as part of the formulary recommendation for Belsomra, Dayvigo, and Quviviq, a trial of zolpidem ER or eszopiclone is required.
        - The step therapy allows for new entrants to come to market and be placed non-preferred, if recommended by the Committee.

- NF
  - None
- Tier 4 (complete exclusion)
  - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) maintaining the current manual PA criteria for Belsomra, Dayvigo and Quviviq. A trial of a non-pharmacologic therapy (i.e., CBT-I) is required first, along with a trial and failure or adverse effect to zolpidem extended release or eszopiclone. Renewal criteria will include a continued requirement for trial and failure of a non-pharmacologic therapy. The patient should also demonstrate a response to the requested drug for renewal. See Appendix C for the full criteria

3. ***EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (18 for, 0 opposed, 2 abstained, 0 absent) excluding Belsomra, Dayvigo, and Quviviq from the EMMPI program.

4. ***COMMITTEE ACTION: UF, PA, EMMPI and IMPLEMENTATION PERIOD—*** The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first Wednesday 30 days after signing of the minutes in all points of service. See Appendix G for the actual implementation date.

B. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass

Background—The Androgens-Anabolic Steroids: Testosterone Replacement Therapy class was last reviewed for formulary status in August 2012. At that time, the class was solely comprised of the topical testosterone products; the oral (PO) and the intramuscular (IM) injectable products were not included in the original review. Step-therapy, requiring a trial of testosterone 2% gel (Fortesta) prior to other topical products, has been in place since 2012.

Testosterone products are available in a variety of formulations including topical gels, a topical solution, a transdermal patch, a nasal spray, oral capsules and tablets, IM injections, and a subcutaneous autoinjector. Testosterone pellets (Testopel) and testosterone undecanoate injection (Aveed) are part of the TRICARE medical benefit and were not included in the formulary review.

The current review included the topicals, IM injectable products (testosterone cypionate and testosterone enanthate), SC product (Xyosted), oral testosterone undecanoate

formulations (Jatenzo and Tlando) and oral methyltestosterone products. A third recently approved oral testosterone undecanoate product, Kyzatrex, was also reviewed.

The P&T Committee evaluated the relative clinical effectiveness of the testosterone replacement therapy agents for the FDA-labeled indications of primary hypogonadism, hypogonadotropic hypogonadism, delayed puberty, and metastatic mammary cancer.

- All agents in the class have indications for primary hypogonadism and hypogonadotropic hypogonadism.
- The testosterone enanthate IM injections and the methyltestosterone products are the only products that are also approved for treating delayed puberty and metastatic mammary cancer.
- With the exception of the IM injections and methyltestosterone products, the package labeling for all other testosterone replacement therapy agents contains a limitation of use noting the lack of safety and efficacy data to support use in males less than 18 years of age.

Off-label uses of testosterone were also evaluated, including for treating age-related decline in testosterone levels, gender dysphoria (use in transgender males), and hypoactive sexual desire disorder.

- Topical and injectable testosterone products are commonly used off-label for men with age-related hypogonadism, although the safety and efficacy of these products are limited. Notably, the four most recently approved agents, Xyosted SC injection, and the orally administered products Jatenzo, Tlando, and Kyzatrex, are contraindicated for use in men with age-related hypogonadism.
- Testosterone replacement therapy agents are used by patients with gender dysphoria to achieve the desired virilization effects of testosterone.
- Women with hypoactive sexual desire disorder typically use one-tenth of the standard male dose of a 1% transdermal gel product.

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

Efficacy

- The clinical conclusions from the 2012 review remain largely unchanged.
- The testosterone products have all demonstrated efficacy in normalizing testosterone levels in the majority of patients. Comparative efficacy data among the available testosterone replacement therapies is limited. Drugs in this class are considered similarly efficacious for treating hypogonadism; however, expert opinion suggests that methyltestosterone products may be less effective.
- The 2018 Endocrine Society Guidelines on hypogonadism state that the choice of testosterone therapy can be based on patient preference, pharmacokinetics, formulation-specific adverse effects, treatment burden, and cost.

- The 2017 Endocrine Society Guidelines on gender dysphoria were reviewed by the P&T Committee. The recent update to the TRICARE Gender Dysphoria Policy references the 2017 Endocrine Society guidelines and states, "Gender-affirming hormone therapy, also known as cross-sex hormone treatment, for adult or adolescent beneficiaries is covered when all of the following criteria are met: The beneficiary meets the eligibility criteria outlined in the most current version of the Endocrine Society Clinical Practice Guidelines for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons; and the beneficiary has no contraindications to gender-affirming hormone therapy."

  Notably, the Endocrine Society Guidelines states the following with regard to initiation of gender affirming hormone therapy: "In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs [mental health professionals] has confirmed the persistence of gender dysphoria/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with gender dysphoria/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment."

Safety

- Testosterone products differ in their adverse reactions, precautions, and warnings in the product labeling. Some differences include transference risk, flammability, application site reactions, and hypertension.
- The American Urological Association Guidelines recommend that clinicians should not prescribe methyltestosterone, as it is associated with hepatic safety concerns.

Individual Product Characteristics

Topical

- *Androderm* is the only available testosterone patch. It is applied once daily and is associated with skin irritation at the application site.
- *Androgel, Fortesta, Testim, Vogelexo, and generics* are all available in a testosterone gel formulation. Fortesta is available as a 2% gel, Androgel is formulated as a 1% and 1.62% gel, while the remaining products are available as 1% gels. The gels are used once daily and can be applied to the shoulders or upper arms, with the exception of Fortesta which is applied to the front and inner thighs. The transdermal gels contain a black box warning for the risk of virilization of children from secondary exposure. Precautions must be taken to prevent testosterone transference to close-contact partners and children.
- *Axiron* is available as a 2% solution and is applied to the axilla once daily. Similar to the gels, it has a black box warning on the risk of transference.

Nasal

- *Natesto* is a nasal spray administered three times daily and is associated with nasal adverse effects.

Injectable

- *testosterone cypionate IM and testosterone enanthate IM injections* are typically administered once every two weeks. These formulations are associated with peaks and valleys in serum testosterone which may lead to fluctuations in symptoms.
- *testosterone enanthate SC (Xyosted)* is a once weekly, subcutaneous autoinjector; it has a black box warning for increases in blood pressure.

Oral

- *testosterone undecanoate capsules (Jatenzo, Tlando, and Kyzatrex)* are typically administered twice daily. Each drug is available at a slightly different dose and requires dose titration, with the exception of Tlando which does not allow for dose titration. The oral products have black box warnings for increases in blood pressure. Provider feedback stated a preference for using the topical and injectable products first before trying an oral agent.
    - *Kyzatrex* was recently FDA-approved and is the 3rd testosterone undecanoate capsule. In one open-label, single-arm study, 88% of patients receiving Kyzatrex met the primary outcome of a specified testosterone concentration.
    - There are numerous alternative testosterone formulations available, and overall, Kyzatrex has no compelling clinical advantages over existing testosterone formulary agents.
- *methyltestosterone* is an older testosterone replacement therapy agent. Guidelines and provider feedback support avoiding use due to hepatic side effects.

Overall Clinical Conclusion

- There is a high degree of therapeutic interchangeability among the testosterone products with regards to efficacy. There are some subtle differences in safety based on differences in formulation, but overall, the testosterone products are highly interchangeable.
- In order to meet the needs of MHS patients, at least one topical and one injectable testosterone product are required on the formulary.

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

- CMA results showed that the injectable testosterone products are more cost effective than the topical formulations, followed by the oral products.
- BIA was performed to evaluate the potential impact of designating the testosterone replacement agents as UF, NF, or Tier 4 (complete exclusion) on the formulary. BIA and sensitivity analysis results showed that maintaining the agents in the respective formulary status as stated below demonstrated significant cost avoidance to the MHS.

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

- UF
  - testosterone 2% gel (Fortesta) (step-preferred)
  - testosterone 1% gel *(generic to AndroGel)* (step-preferred)
  - testosterone cypionate IM
  - testosterone enanthate IM
  - Androderm patch (non-step-preferred)
  - Natesto spray (non-step-preferred)
  - Striant (non-step-preferred) *(discontinued)*
  - Testim 1% gel, generic (non-step-preferred)
  - Vogelxo 1% gel; 1% gel metered dose pump (MDP) (non-step-preferred)
  - Xyosted SC auto-injector
  - methyltestosterone oral capsule and tablet
- NF
  - AndroGel 1% gel brand (non-step-preferred)
  - AndroGel 1.62% gel packet (non-step-preferred)
  - AndroGel, generic 1.62% gel MDP (non-step-preferred)
  - Axiron, generic 30 mg MDP (non-step-preferred)
  - Jatenzo oral capsule
  - Tlando oral capsule
  - Kyzatrex oral capsule
- Tier 4 (complete exclusion) - none

- Note that Fortesta 2% gel and generic Androgel 1% are step-preferred and must be tried before the other topical testosterone formulations.

2. ***COMMITTEE ACTION: BCF RECOMMENDATION—***The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current BCF status for testosterone 2% gel (Fortesta, generics).

3. ***COMMITTEE ACTION: MANUAL PA CRITERIA FOR INDICATIONS OTHER THAN TRANSGENDER USE***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) manual PA criteria for all agents in the class. Efforts were made to streamline and simplify the PAs. The oral testosterone undecanoate products will now require a trial of both a preferred topical and an injectable testosterone replacement therapy first. New manual PA criteria will apply to methyltestosterone in new and current users. The PA updates for all products other than methyltestosterone will affect new users only. See Appendix C for the full criteria.

4. ***COMMITTEE ACTION: MANUAL PA CRITERIA FOR TRANSGENDER USE***—The P&T Committee recommended (13 for, 3 opposed, 3 abstained, 1 absent) manual PA criteria for transgender use of the testosterone replacement therapies. The age limit for the gender dysphoria indication was updated to allow for use in adolescents down to age 14 years. Product preference for IM testosterones and testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel) applies to Transgender Use criteria. See Appendix C for the full criteria.

5. ***COMMITTEE ACTION: ACTION: MEDICAL NECESSITY (MN) CRITERIA***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the MN criteria currently in place for Tlando, adding MN for Kyzatrex to match Tlando, and updating the MN criteria for all other NF drugs to match Tlando. See Appendix B for the full criteria.

6. ***COMMITTEE ACTION: QUANTITY LIMITS (QL)***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) maintaining the current quantity limits for Xyosted injection which were originally recommended at the February 2019 DoD P&T Committee meeting. See Appendix D.

7. ***COMMITTEE ACTION: EMMPI PROGRAM REQUIREMENTS***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) adding Kyzatrex and maintaining all other branded and NF agents on the EMMPI list.

8. ***COMMITTEE ACTION: UF, BCF, MN, PA, QL, EMMPI and IMPLEMENTATION PERIOD***—The P&T Committee recommended

(19 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service. DHA will send letters to patients affected by the new PA criteria for oral methyltestosterone. See Appendix G for the actual implementation date.

C. Nephrology Agents Miscellaneous Drug Class

Background—The P&T Committee evaluated the relative clinical effectiveness of the drugs in the Nephrology Agents Miscellaneous drug class. Currently there is only one product in the class, a new formulation of budesonide in a delayed-release (DR) capsule (Tarpeyo), however additional drugs are in the pipeline. *(Note following the meeting sparsentan (Filspari) was FDA-approved for treating IgAN and will be reviewed as a new drug at an upcoming P&T Committee meeting.)*

Relative Clinical Effectiveness Conclusion—The P&T Committee concluded (18 for, 0 opposed, 0 abstained, 2 absent) the following:

- Tarpeyo is FDA-approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN). Approval was based on a surrogate outcome; however, the Kidney Disease Improving Global Outcomes (KDIGO) 2021 guidelines do recognize reduction in proteinuria as a valid surrogate outcome.
- It has not been established to what extent Tarpeyo's efficacy is mediated via local effects in the ileum vs. systemic effects.
- FDA-approval for Tarpeyo was granted using the accelerated approval process, and a confirmatory trial is required (currently ongoing).
- Other glucocorticoids, including prednisone and methylprednisolone, lack formal FDA-approval for IgAN but have been evaluated in randomized controlled trials, including the STOP-IgAN and TESTING trials.
- Current professional guidelines (KDIGO 2021) outline considerations for using glucocorticoids in patients with IgAN who are at high risk of progressive chronic kidney disease despite maximal supportive care.
- The Tarpeyo package insert contains the usual warnings for glucocorticoids, including hypercortisolism and adrenal axis suppression, immunosuppression, and other corticosteroid effects.
- Comparative efficacy and safety of Tarpeyo vs. other glucocorticoids (e.g., prednisone, methylprednisolone), and other immunosuppressants (e.g., cyclophosphamide, mycophenolate mofetil) is currently unknown.
- There is no direct comparative clinical data showing how Tarpeyo would compare clinically to other budesonide formulations that are released in the ileum.

- Tarpeyo's place in therapy for IgAN remains to be established.

Relative Cost-Effectiveness Analysis and Conclusion—The Committee conducted a CMA, BIA, and sensitivity analysis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 3 absent) the following:

- CMA results showed that budesonide 4 mg delayed release (Tarpeyo) was not cost effective.
- A BIA and a sensitivity analysis were performed to evaluate the potential impact of formulary status for budesonide 4 mg DR (Tarpeyo). BIA and sensitivity results showed that designating Tarpeyo as Tier 4 (complete exclusion) demonstrated significant cost avoidance for the MHS

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) that Tarpeyo be designated as Tier 4 (complete exclusion), as other than the formal FDA-approval for IgAN, it provides little to no clinical advantages relative to other drugs used off-label for IgAN.

2. ***COMMITTEE ACTION: INTERIM MANUAL PA CRITERIA***—In order to minimize the impact on affected beneficiaries, the P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) interim PA criteria for Tarpeyo prior to the Tier 4 (complete exclusion) implementation. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: UF, INTERIM PA, AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 3 absent) an effective date of the first Wednesday 180-days after signing of the minutes in all points of service and that DHA send letters to patients affected by the formulary decision. See Appendix G for the actual implementation date.

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

The products were divided into three groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Lytgobi, Ermeza, Rezlidhia, Fylnetra, and Noxafil; Group 2 was comprised of Furoscix, Auvelity and Relyvrio; and Group 3 included Xelstrym, Leuprolide, Basaglar Tempo pen, Lyumjev Tempo pen, and Humalog Tempo pen. Please note the Kyzatrex review can be found in the testosterone class review.

*Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—*The P&T Committee agreed (group 1: 19 for, 0 opposed, 0 abstained, 1 absent; group 2: 19 for, 0

opposed, 0 abstain, 1 absent; and group 3: 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 February 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 for group 1: (19 for, 0 opposed, 0 abstained, 1 absent) and group 2: (19 for, 0 opposed, 0 abstained, 1 absent); and for group 3 (18 for, 0 opposed, 0 abstained, 2 absent) the following:

    - UF
        - futibatinib (Lytgobi) – Oncological agent for intra-hepatic cholangio-carcinoma
        - insulin lispro (Humalog Tempo Pen) – Rapid acting insulin.
        - leuprolide acetate depot injection (no brand name) - Luteinizing hormone-releasing hormone (LHRH) agonists-antagonists for prostate cancer
        - olutasidenib (Rezlidhia) – Oncological agent for acute myeloid leukemia (AML) with isocitrate dehydrogenase-1 (IDH1) mutation
        - pegfilgrastim-pbbk (Fylnetra) – White Blood Cell (WBC) stimulants – pegfilgrastims. Note that as part of this recommendation, Fylnetra will be non-step-preferred
        - posaconazole DR oral suspension (Noxafil Powdermix Kit) – Antifungal for prophylaxis of invasive Aspergillus and Candida
        - sodium phenylbutyrate/sodium taurursodiol powder for oral suspension (Relyvrio) – miscellaneous neurological agent for amyotrophic lateral sclerosis (ALS)
    - NF
        - dextroamphetamine transdermal system (Xelstrym) – Attention deficit hyperactivity disorder (ADHD) Stimulant
        - dextromethorphan hydrobromide/bupropion hydrochloride (Auvelity) – Antidepressants and non-opioid pain syndrome agents
        - insulin glargine (Basaglar Tempo Pen) – Basal insulin; note that as part of this recommendation the Basaglar TEMPO pen will be non-step-preferred
        - insulin lispro-aabc (Lyumjev Tempo Pen) – Rapid acting insulin; note that as part of this recommendation the Lyumjev TEMPO pen will be non-step-preferred

        - levothyroxine sodium 150 mcg/5 mL oral solution (Ermeza) – Thyroid agent
        - Note that for the three TEMPO pens (Basaglar, Lyumjev and Humalog) the actual Tempo Smart button and app are not a covered TRICARE pharmacy benefit at this time.
    - Tier 4 (complete exclusion): See Appendix H for additional detail regarding excluded agentss and formulary alternatives.
        - furosemide SC injection (Furoscix) – Diuretic
            - Furoscix was recommended for (complete exclusion) as it has little to no clinical benefit relative to other diuretics, and the needs of TRICARE beneficiaries are met by alternative agents. Formulary alternatives include furosemide, bumetanide, ethacrynic acid and torsemide tablets.

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (group 1: 19 for, 0 opposed, 0 abstained, 1 absent; group 2: 19 for, 0 opposed, 0 abstain, 1 absent; and group 3: 18 for, 0 opposed, 0 abstained, 2 absent) MN criteria for Xelstrym, Auvelity, Basaglar Tempo Pen, Lyumjev Tempo Pen, and Ermeza. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (group 1: 19 for, 0 opposed, 0 abstained, 1 absent; group 2: 19 for, 0 opposed, 0 abstain, 1 absent; and group 3: 18 for, 0 opposed, 0 abstained, 2 absent) the following PA criteria (see Appendix C for the full criteria):
    - Oncologic drugs: Applying manual PA criteria to new users of Lytgobi and Rezlidhia
    - Applying manual PA criteria to new users of Xelstrym patch, Auvelity, Basaglar Tempo pen, Lyumjev Tempo pen, Humalog Tempo pen, Relyvrio and Ermeza oral solution
    - Applying manual PA criteria to Fylnetra, similar to what is in place for the other non-step-preferred pegfilgrastims. New patients receiving Fylnetra or one of the other non-step-preferred pegfilgrastims (Neulasta, Neulasta Onpro, and Ziextenzo) will be required to have a trial of Nyvepria, Udenyca and Fulphila first.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (19 for, 0 opposed, 0 abstained, 1 absent) QLs for Lytgobi, Rezlidhia, leuprolide acetate depot and Relyvrio. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI***—The P&T Committee recommended (group 1: 19 for, 0 opposed, 0 abstained, 1 absent; group 2: 19 for, 0 opposed, 0 abstain, 1 absent; and group 3: 18 for, 0 opposed, 0 abstained, 2 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

6. ***COMMITTEE ACTION: UF, MN, AND PA IMPLEMENTATION PERIOD***—The P&T Committee recommended (group 1: 19 for, 0 opposed, 0 abstained, 1 absent; group 2: 19 for, 0 opposed, 0 abstain, 1 absent; and group 3: 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 Tier 4 (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 Tier 4 (complete exclusion) recommendation at 30 days and 60 days prior to implementation; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA Criteria

1. New Manual PA Criteria and Formulary Status

mifepristone 200 mg tablet (Mifeprex)—On January 3, 2023, the FDA approved a modification of the mifepristone Risk Evaluation and Mitigation Strategies (REMS) program which permanently removed the in-person (e.g., clinic, medical office, hospital setting) dispensing requirement and allowed for the addition of pharmacy certification for dispensing. The revised REMS program prompted a review of mifepristone for addition to the TRICARE pharmacy benefit and for PA criteria. PA criteria were recommended to allow for use of mifepristone for termination of pregnancy abiding by 10 U.S. Code 1093 requirements (limited to cases of rape, incest, or if the life of the mother would be endangered if the fetus were carried to term) and allow for off-label use for pregnancy loss. Provider feedback, randomized controlled trial data, and guidelines support the off-label use for pregnancy loss.

A) ***COMMITTEE ACTION: MIFEPRISTONE 200 MG TABLET (MIFEPREX)—TRICARE PHARMACY BENEFIT ADDITION, UNIFORM FORMULARY STATUS AND PA CRITERIA FOR PREGNANCY LOSS AND IMPLEMENTATION PERIOD—***The P&T

Committee recommended (14 for, 1 opposed, 2 abstained, 3 absent) addition of mifepristone 200 mg tablets (Mifeprex) to the TRICARE pharmacy benefit, UF status, and manual PA criteria for every use (one tablet and no refills) for pregnancy loss. The new PA will become effective the first Wednesday 30 days after the signing of the minutes. See Appendix C for the full criteria.

b) ***COMMITTEE ACTION: MIFEPRISTONE 200 MG TABLET (MIFEPREX)—PA CRITERIA FOR PREGNANCY TERMINATION IN ACCORDANCE WITH 10 U.S. CODE 1093 —***The P&T Committee recommended (14 for, 2 opposed, 1 abstained, 3 absent) PA criteria for Mifeprex for every use (one tablet and no refills) for the indication of termination of pregnancy. See Appendix C for the full criteria.

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

Manual PA criteria were recommended for two recently marketed drugs which contain active ingredients that are widely available in low-cost generic formulations. These products are usually produced by a single manufacturer. Due to the pathway used to gain FDA approval, these products do not meet the criteria for innovators. These drugs all have numerous cost-effective formulary alternatives available that do not require prior authorization. For the products listed below, PA criteria is recommended in new and current users, requiring a trial of cost-effective generic formulary medications first.

a) Antigout Agents—allopurinol 200 mg tablet—Allopurinol 200 mg is manufactured by a single company and is not cost-effective relative to allopurinol 100 mg and 300 mg formulations. Allopurinol 100 mg and 300 mg are on the uniform formulary and do not require prior authorization criteria.

b) Skeletal Muscle Relaxants and Combinations—methocarbamol 1000 mg tablet—Methocarbamol 500 mg and 750 mg tablets are available on the formulary as generics and do not require a prior authorization. A new methocarbamol 1000 mg tablet that is manufactured by a single company is markedly not cost-effective relative to methocarbamol 500 mg and methocarbamol 750 mg tablets.

COMMITTEE ACTION: NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) manual PA criteria for allopurinol 200 mg tablets and methocarbamol 1000 mg 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 90 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

3. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 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) Neurological Agents Miscellaneous—amifampridine (Firdapse)—The manual PA criteria were updated for Firdapse, allowing for use in children 6 to 17 years of age for the treatment of Lambert-Eaton myasthenic syndrome.

b) Oncological Agents: Melanoma—cobimetinib (Cotellic)—Includes the new indication for the treatment of histiocytic neoplasms as a single agent in adults.

c) Oncological Agents—elpercatinib (Retevmo)—Includes the new indication for adult patients with locally advanced or metastatic solid tumors in adults with a rearranged during transfection gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.

d) Osteoporosis Agents: Parathyroid Hormone Analogs—abaloparatide (Tymlos)—The manual PA criteria were updated for Tymlos to allow for use in men at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

e) Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)—upadacitinib (Rinvoq)—The manual PA criteria were updated to include the new indication for non-radiographic axial spondyloarthritis. The new PA criteria requires a trial of two NSAIDs, Humira, and Cosentyx before Rinvoq for this indication.

f) Atopy Agents—dupilumab (Dupixent)—The manual PA criteria were updated to allow for Dupixent use in patients with prurigo nodularis if a patient has a contraindication to, intolerability to, or has failed treatment with a topical glucocorticoid.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Firdapse, Cotellic, Retevmo, Tymlos, Rinvoq, and Dupixent in new users. Implementation will be effective the first Wednesday 90 days after signing of the minutes. See Appendix C for the full criteria.

4. Updated PA Criteria for Safety Information

a) Oral Oncologic Agents: Ovarian Cancer—niraparib (Zejula) In September 2022, the FDA label for Zejula was updated to remove the indication for the treatment of advanced ovarian, fallopian tube or primary peritoneal cancer in adults who have been treated with three or more prior chemotherapy regimens and who cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious breast

cancer susceptibility gene (BRCA) mutation, or genomic instability and who have progressed more than 6 months after response to the last platinum based chemotherapy. This was based on a consultation with the FDA and the totality of information from PARP inhibitors in late-line ovarian cancer which suggests a negative effect on overall survival.

COMMITTEE ACTION: MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Zejula removing the indication for treatment of advanced HRD positive ovarian after three or more lines of chemotherapy. Implementation will be effective the first Wednesday 90 days after signing of the minutes. See Appendix C for the full criteria.

5. Updated PA Criteria for Reasons other than new Indications

a) Targeted Immunomodulatory Biologics: Tumor Necrosis Factor Inhibitors—adalimumab

i. biosimilars to Humira—Based on provider feedback, manual PA criteria were updated to allow use of adalimumab biosimilar if a patient has an intolerance or contraindication to non-biologic systemic therapy. See Appendix C.

ii. adalimumab plaque psoriasis update—MHS provider feedback relayed that it is now common practice to start Humira in patients with moderate to severe psoriasis who have failed topical treatments. The manual PA criteria were revised to allow use of Humira for plaque psoriasis if a patient has an inadequate response, intolerance or contraindication to non-biologic systemic therapy, including methotrexate, aminosalicylates, corticosteroids, immunosuppressants (e.g., azathioprine, cyclosporine), acitretin or phototherapy.

b) Insulins: Miscellaneous Insulin Devices—Omnipod, Omnipod Dash, Omnipod 5—Based on a MTF provider request, the manual PA criteria were updated to remove the current requirement of multiple daily injection therapy for six months for type 1 diabetics for all the Omnipod devices. However, the multiple daily injection therapy for six months requirement will remain for other diabetic patients for Omnipod and Omnipod Dash.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for biosimilar adalimumab, and Omnipod, Omnipod Dash, and Omnipod 5 in new users. Implementation will be effective the first Wednesday 90 days after signing of the minutes. See Appendix C for the full criteria.

5. Updated PA Criteria for Weight Loss Drugs

The weight loss drugs were evaluated for formulary status at the November 2017 P&T Committee Meeting. Since then, several updates to the PAs were recommended to account for expanded age ranges, recommendations from clinical practice guidelines as to the appropriate place in therapy, and to increase the initial approval period to account for dosage titration schedules.

Recent guidelines from the American Gastroenterological Association now recommend against the use of orlistat (Xenical), due to low efficacy and increased incidence of adverse effects. The ICER 2022 obesity report concluded that the fixed dose phentermine/topiramate ER (Qsymia) demonstrated greater weight loss than liraglutide (Saxenda) and bupropion/naltrexone (Contrave).

Specific requirements for Active Duty Service Members (ADSM) have referenced individual service polices for weight loss; there are inconsistences between the services. The recommendation from the Committee was to remove the service policy requirements, contingent on the Pharmacy Consultants coordinating the request with their respective Surgeons General.

The specific PA updates are listed below:

a) liraglutide (Saxenda)—Multiple edits were made to the manual PA criteria for Saxenda. Patients are no longer required to have a trial of Xenical first, adolescents 16 to 17 years of age are no longer required to try phentermine first, and adolescents between the ages of 12 to 17 years of age must now try Qsymia first or have a contraindication to its use. The initial approval period for the PA was increased from four months to six months to allow for adequate time for dose titration.

b) phentermine/ topiramate ER (Qsymia)—The manual PA criteria were updated to include the new indication allowing use in children 12 to 17 years of age for weight management.

c) semaglutide (Wegovy)— The manual PA criteria were updated allowing for use in children 12 to 17 years of age per the current FDA label**.** Patients are no longer required to have a trial of Xenical first, and adolescents between the ages of 12 to 17 years of age must now try Qsymia first or have a contraindication to it. The initial approval period for the PA was increased from four months to six months to allow for adequate time for dose titration.

COMMITTEE ACTION: WEIGHT LOSS DRUGS UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for the weight loss drugs in new users. Implementation will be effective the first Wednesday 90 days after signing of the minutes. See Appendix C for the full criteria.

B. Line Extensions

The P&T Committee clarified the formulary status for one product line extension 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.

Multiple Sclerosis: Miscellaneous Oral Agents—fingolimod 0.5 mg orally dissolving tablets (Tascenso ODT)—Tascenso 0.25 mg ODT was reviewed as a new drug at the November 2022 P&T meeting, with the PA criteria limiting use to the indications in the label at that time, which were only for treating patients who were ten years of age and older and weighing no more than 40 kg. A new 0.5 mg ODT dosage strength has now been approved, which no longer has the weight restriction. The manual PA criteria were updated to remove the weight limit. A trial of fingolimod 0.5 mg capsules will be required first, based on cost effectiveness. Tascenso 0.5 mg ODT will be designated as NF, similar to the formulary status of the 0.25 mg ODT formulation. See Appendix C.

COMMITTEE ACTION: TASCENSO 0.5 mg ODT LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD— The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) clarifying the formulary status of the line extension product, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. SLEEP DISORDERS: WAKEFULNESS PROMOTING AGENT: SODIUM OXYBATE (XYREM) AUTHORIZED GENERIC PA CRITERIA:

The Sleep Disorders: Wakefulness Promoting Agents class was last reviewed in August 2020, and sodium oxybate (Xyrem) was designated as UF with a PA. Xyrem is indicated for treatment of narcolepsy with cataplexy. Prior authorization (PA) criteria for authorized generic sodium oxybate requiring a trial of Xyrem first were recommended.

COMMITTEE ACTION: AUTHORIZED GENERIC PA REQUIREMENT FOR XYREM AND IMPLEMENTATION PERIOD—
The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent), requiring brand Xyrem in all new and current users for the authorized generic sodium oxybate at all points of service, based on cost effectiveness. The prescriber will provide patient-specific justifications as to why brand Xyrem cannot be used over the authorized generic. The effective date will be the first Wednesday 90 days after signing of the minutes. The "brand over authorized generic" requirement will be removed administratively when it is no longer cost-effective compared to AB-rated generics.

VIII. REFILLS OF PRESCRIPTION MAINTENANCE MEDICATIONS THROUGH MTF PHARMACIES OR THE MAIL ORDER PROGRAM

Newly Approved Drugs per 32 CFR 199.21(g)(5)
See Appendix F for the mail order status of medications designated UF or NF during the November 2021 P&T Committee meeting. Note that the Add/Do Not Add recommendations listed in the appendix pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement. The implementation period for all the recommendations from the February 2023 meeting listed in Appendices E and F, including those for newly approved drugs, will be effective upon the first Wednesday two weeks after the signing of the minutes.

> ***COMMITTEE ACTION: NEWLY APPROVED DRUGS PER 32 CFR 199.21(g)(5) RECOMMENDED FOR UF OR NF STATUS—*** The P&T Committee recommended (for group 1: 19 for, 0 opposed, 0 abstained, 1 absent; group 2: 19 for, 0 opposed, 0 abstained, 1 absent; and group 3: 18 for, 0 opposed, 0 abstain, 2 absent) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. See Appendix F.

IX. ITEMS FOR INFORMATION

A. Annual Review of TRICARE Pharmacy Benefit Medications

The Committee was briefed on the utilization and cost trends for the newly approved drugs per 32 CFR 199.21(g)(5) that were evaluated since program implementation in August 2015.

The Committee was also briefed on trends in the FDA's accelerated approval pathway, where drugs enter the market based on surrogate outcomes. Concerns raised by the accelerated approval pathway include holding the manufacturer responsible to complete confirmatory trial requirements within the designated time, and when warranted, timely withdrawal of the product from the market when confirmatory trials are negative or produce harms. (https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals)

The Committee also noted that more reformulated medications are being approved, rather than new molecular entities. Many of the drugs approved in the past year provide slight or no improvement in therapeutic benefit over currently available therapies. Updates for the newly approved drugs will be presented periodically at upcoming P&T Committee meetings.

B. Notice to MTF Pharmacies Regarding Continual Surveillance of Drug Classes

The Formulary Management Branch (FMB) reviews all drug classes included on the DoD Pharmacy Benefit annually for updates to formulary management status. MTFs can submit requests for formulary status updates and, if criteria are met, these changes will be considered by the DoD Pharmacy and Therapeutics Committee.

Criteria used to update the formulary status includes relevant clinical updates (i.e., safety, efficacy, etc.), humanistic information, and economic data. The Department of Defense Pharmacy and Therapeutics Committee's mission is to uniformly, consistently, and equitably provide appropriate drug therapy to meet the clinical needs of DoD beneficiaries in an effective, efficient, and fiscally responsible manner.

C. Baricitinib (Olumiant) and coverage for alopecia areata

The P&T Committee reviewed an MTF request to update the baricitinib (Olumiant) PA criteria to allow use for a new FDA-approved indication to treat adult patients with severe alopecia areata. Medication intended to encourage hair regrowth for alopecia areata is excluded by federal regulation (32 CFR 199.4(g)(41)(ii)). Therefore, no update to coverage for this indication was recommended. Olumiant remains covered for treatment of rheumatoid arthritis.

D. Retrospective Review: Weight Loss Agents

The Committee reviewed utilization and cost trends for the Weight Loss Agents, which were reviewed for formulary placement in November 2017, with implementation occurring in May 2018. Formulary management tools such as step therapy, PA, and tier status help ensure appropriate patient selection and medication utilization. The weight loss drugs class review created formulary conditions (including step therapy, PA, and NF) which have successfully managed utilization, and also allows placement of future marketed drugs as non-step-preferred.

X. ADJOURNMENT

The meeting adjourned at 1630 hours on February 9th. The next meeting will be in May 2023.

Appendix A—Attendance: February 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 February 2023 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Tier 4 Agents (completely excluded) 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
1 May 2023
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
Col Paul Hoerner BSC, for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, 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
CDR Kellye Donovan, MSC, for CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Col Larissa Weir, MC	Air Force, OB/GYN Physician
Capt Courtney Clutter, MC, for Lt Col Jeffrey Colburn, MC Day #1	Air Force, Internal Medicine Physician
Lt Col John Oberlin, MC, for Lt Col Jeffrey Colburn, MC Day #2	Air Force, Internal Medicine Physician
Maj Jennifer Dunn, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	Physician at Large, DHA
LCDR Shira Paul	Oncology Physician
Laura Au, RPh, BCOP	Oncology Pharmacist
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
COL Yang Xia	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Members Present	
Megan Gemunder, DHA	Attorney Advisor, Contract Law
Dennis Dyke, DHA	Attorney Advisor, Contract Law
Eric Parsons, RPh	Tpharm5 Clinical COR
Eugene Moore, PharmD	Tpharm5 Clinical COR
CPT Hope Shen, PharmD	Defense Logistics Agency
Guests	
Ms. Marsha Peterson	DHA Contracting Officer
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Sydney Roman	DHA Contracting
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
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Julia Trang, PharmD	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

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• testosterone undecanoate capsule (Jatenzo) • testosterone undecanoate capsule (Tlando) • testosterone undecanoate capsule (Kyzatrex) • testosterone transdermal solution (Axiron) • testosterone transdermal gel (AndroGel 1% brand, Androgel 1.62% brand, 1.62% gel generic) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	• Patient has experienced significant adverse effects from ALL listed formulary agents • ALL listed formulary agents resulted in therapeutic failure **Formulary alternatives:** Androderm patch, testosterone 2% gel (Fortesta), testosterone 1% gel (generic to Androgel), and Testim 1% gel
New Drugs MN Criteria	
• dextroamphetamine transdermal system (Xelstrym) **ADHD Agents: Stimulants**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure • No alternative formulary agent **Formulary alternatives:** extended-release methylphenidate (e.g., Concerta, Metadate CD, Ritalin LA), extended-release mixed amphetamine salts (Adderall XR)
• dextromethorphan hydrobromide/bupropion hydrochloride (Auvelity) **Antidepressants and Non-Opioid Pain Syndrome Agents**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents • Formulary agents resulted in therapeutic failure • Patient previously responded to non-formulary agent and changing to a formulary agent would incur unacceptable risk **Formulary alternatives:** SSRIs, SNRIs, TCAs, mirtazapine (Remeron), bupropion (Wellbutrin), trazodone, nefazodone, MAOIs
• insulin glargine (Basaglar Tempo Pen) **Basal Insulin**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents **Formulary alternatives:** Lantus

Appendix B—Table of Medical Necessity Criteria

• insulin lispro-aabc (Lyumjev Tempo Pen) **Rapid Acting Insulin**	• Use of formulary agents is contraindicated • Patient has experienced significant adverse effects from formulary agents **Formulary alternatives:** Novolog Flex Pen, Humalog Kwikpen and Lyumjev Kwikpen
• levothyroxine sodium 150 mcg/5 mL oral solution (Ermeza) **Thyroid & Antithyroid Agents**	• No alternative formulary agent: patient is not able to swallow capsule or sprinkle capsule on food or chew a tablet **Formulary alternatives:** levothyroxine sodium tablets, levothyroxine sodium liquid filled capsules, levothyroxine sodium oral solution (Tirosint-Sol)

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	
• suvorexant (Belsomra) • lemborexant (Dayvigo) • daridorexant (Quviviq) **Sleep Disorders: Insomnia**	**Note there were no changes to the PA criteria from the May 2021 and August 2022 P&T meetings.** Manual PA criteria apply to all new users of Quviviq, Belsomra, and Dayvigo. Manual PA Criteria: Quviviq, Belsomra, Dayvigo is approved if all criteria are met: • Provider acknowledges the following agents are available without prior authorization: zolpidem IR and ER, zaleplon, eszopiclone • Patient has documented diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance • Non-pharmacologic therapies have been inadequate in improving functional impairment, including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), sleep hygiene, and the patient will continue with non-pharmacologic therapies throughout treatment • Patient has tried and failed or had clinically significant adverse effects to zolpidem extended-release OR eszopiclone • Patient has no current or previous history of narcolepsy • Patient has no current or previous history of substance and/or alcohol use disorder Non FDA-approved uses are not approved Prior authorization expires in 1 year Renewal criteria: Note that initial TRICARE PA approval is required for renewal. PA will be renewed for an additional 1 year if the renewal criteria are met: • Patient has not adequately responded to non-pharmacologic therapies • Patient agrees to continue with non-pharmacologic therapies including but not limited to relaxation therapy, cognitive behavioral therapy for insomnia (CBT-I), and/or sleep hygiene • Patient continues to respond to the drug
• transdermal 2% gel pump (Fortesta) • transdermal patch (Androderm) • transdermal 1% gel tubes (Testim) • transdermal 1% gel (Vogelxo) • transdermal gel and gel pump 1%, 1.62% (AndroGel) • transdermal solution (Axiron) • nasal gel (Natesto) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the February 2023 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Androderm, Androgel, Fortesta, Natesto, Testim, Testosterone 1.62% gel, Vogelxo, and Axiron. Manual PA Criteria: Androderm, Androgel, Fortesta, Natesto, Testim, Testosterone 1.62% gel, Vogelxo, and Axiron are approved if ALL criteria are met: Coverage approved for Hypogonadism if: • Patient is ~~**greater than 17 years of age**~~ **a male 18 years of age or older** • Patient has a **confirmed** diagnosis of hypogonadism as evidenced by ~~**2 or more**~~ morning total serum testosterone levels below 300 ng/dL **taken on at least two separate occasions OR testosterone is prescribed by an endocrinologist or urologist who has made the diagnosis of hypogonadism based on unequivocally and consistently low serum total testosterone or free testosterone levels** • Patient is experiencing signs and symptoms ~~**usually**~~ associated with hypogonadism • Provider has investigated the etiology of the low testosterone levels **and has assessed the risks versus benefits of initiating testosterone therapy in this patient. Provider** acknowledges that testosterone therapy is clinically appropriate and needed. OR

	Coverage approved for female-to-male gender**-affirming hormone therapy in a natal female patient (assigned female at birth)** ~~**reassignment (endocrinologic masculinization)**~~ if: • **Patient is 14 years of age or older** • Patient has diagnosis of Gender Dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) • **Prescription if prescribed by an endocrinologist or a physician who specializes in the treatment of transgender patients** • Patient is an adult, or is **an adolescent** ~~**16 years or older who has experienced puberty to at least Tanner stage 2**~~ **with sufficient mental capacity to give informed consent for this partially irreversible treatment** • **Patient has experienced puberty to at least Tanner stage 2** • ~~**Patient has no signs of breast cancer**~~ • For gender dysphori**ac,** biological**ly** female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment) OR **If indication is not listed above, please write in requested indication and rationale for use: _____ (blank write-in)** **AND** • **Is the requested prescription for testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel),** – **Yes, approve. No, answer below questions** • Patient has tried **and failed a 3-month trial, experienced a clinically significant adverse reaction, or had a contraindication or relative contraindication to one of the following:** – **Testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel)** – **OR does the patient require a testosterone replacement therapy that has a low risk of skin-to-skin transfer (option only for Androderm and Natesto)** • ~~**Fortesta or Androgel 1% for a minimum of 90 days failed to achieve total serum testosterone levels > 400 ng/dL AND without improvement in symptoms [For hypogonadism indication only not transgender indication]**~~ • ~~**Patient has a CI or relative CI to Fortesta or Androgel that does not apply to requested agent**~~ • ~~**Patient has experienced a clinically significant skin reaction to Fortesta or Androgel not expected to occur with the requested agent**~~ • ~~**Fortesta or Androgel not expected to occur with the requested agent**~~ • ~~**Is the requested med Androderm or Natesto?**~~ – ~~**Patient requires a testosterone replacement therapy that has a low risk of skin-to-skin transfer between family members**~~ • Not approved for concomitant use with other testosterone products ~~**Non-FDA-approved uses are NOT approved.**~~ **Testosterone will not be approved to enhance athletic performance.** ~~**Prior Authorization does not expire**~~ **PA expires in 1 year** **Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply:** • **The patient has had a positive response to therapy** • **The risks of continued therapy do not outweigh the benefits**

Appendix C—Table of Prior Authorization (PA) Criteria

• testosterone cypionate IM injection
• testosterone enanthate IM injection
• testosterone enanthate SC injection (Xyosted)
 	
Androgens-Anabolic **Steroids: Testosterone Replacement Therapies**
	Updates from the February 2023 meeting are in bold and strikethrough.
	
	PA does not apply to patients less than 1 year of age (age edit **for testosterone cypionate or enanthate IM only)**
	
	Manual PA criteria applies to new users of testosterone cypionate **IM,** testosterone enanthate IM**, and testosterone enanthate (Xyosted)** injections
	
	Manual PA Criteria: testosterone cypionate **IM, ~~and~~** testosterone enanthate IM, **and testosterone enanthate (Xyosted)** injections are approved if all criteria are met:
	• Coverage approved for male patients (patients male at birth) if:
	  • Patient is younger than 18 years of age AND
	  • **Prescription is for testosterone cypionate IM or testosterone enanthate IM**
	  • Prescription is written by or in consultation with a pediatric endocrinologist **or pediatric urologist** OR
	  • Patient is 18 years of age or older AND
	  • Patient has **a confirmed** diagnosis of hypogonadism as evidenced by two or more morning total **serum** testosterone levels below 300 ng/dL **taken on at least two separate occasions OR testosterone is prescribed by an endocrinologist or urologist who has made the diagnosis of hypogonadism based on unequivocally and consistently low serum total testosterone or free testosterone levels**
	  • Patient is experiencing **signs and** symptoms **~~usually~~** associated with hypogonadism
	  • Provider has investigated the etiology of the low testosterone levels and **has assessed the risks versus benefits of initiating testosterone therapy in this patient. Provider** acknowledges that testosterone therapy is clinically appropriate and needed.
	  • **~~The patient does not have prostate cancer~~**
	OR
	
	Coverage approved for female-to-male gender**-affirming hormone therapy in a natal female patient (assigned female at birth)~~ reassignment (endocrinologic masculinization)~~** if:
	  • **Patient is 14 years of age or older**
	  • Patient has diagnosis of Gender Dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM)
	  • **Prescription if prescribed by an endocrinologist or a physician who specializes in the treatment of transgender patients**
	  • Patient is an adult, or is **an adolescent ~~16 years or older who has experienced puberty to at least Tanner stage 2~~ with sufficient mental capacity to give informed consent for this partially irreversible treatment**
	  • **Patient has experienced puberty to at least Tanner stage 2**
	  • **~~Patient has no signs of breast cancer~~**
	  • For gender dysphori**~~a~~c,** biological**~~l~~y** female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding
	  • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment)
	OR
	Coverage approved for females if:
	  • Patient has diagnosis of breast cancer
	  • Prescription is written by or in consultation with an oncologist
	OR
	If indication is not listed above, please write in requested indication and rationale for use: _____ (blank write-in)
	AND
	  • **Is the requested prescription for testosterone cypionate IM or testosterone enanthate IM?**
	  ○ **Yes, approve. No need to answer below questions**

	• **If requested prescription is for Xyosted, has the patient tried and failed a 3-month trial, experienced a clinically significant adverse reaction, or had a contraindication or relative contraindication to one drug from each of the following two categories?**
	  ○ **testosterone cypionate IM injection or testosterone enanthate IM injection**
	  ○ **testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel)**
	• **Not approved for concomitant use with other testosterone products.**
	
	~~**Non-FDA-approved uses are NOT approved.**~~ **Testosterone will not be approved to enhance athletic performance.**
	Prior Authorization expires in 1 year
	Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved in:
	• **Children for one additional year if one of the following apply**
	  – The patient has had a positive response to therapy
	  – The risks of continued therapy do not outweigh the benefits
	OR
	• Adults will be approved indefinitely for continuation of therapy **if both of the following apply**
	  – The patient has had a positive response to therapy
	  – The risks of continued therapy do not outweigh the benefits

• testosterone undecanoate oral capsule (Jatenzo) • testosterone undecanoate oral capsule (Tlando) • testosterone undecanoate oral capsule (Kyzatrex) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	**Updates from the February 2023 meeting are in bold.** Manual PA criteria applies to new users of Jatenzo, Tlando**, and Kyzatrex** Manual PA Criteria: Jatenzo, Tlando, **or Kyzatrex** is approved if all criteria are met: Coverage approved for hypogonadism if: • Patient is a male age 18 years of age or older • Patient has a confirmed diagnosis of hypogonadism as evidenced by morning total serum testosterone levels below 300 ng/dL taken on at least two separate occasions **OR testosterone is prescribed by an endocrinologist or urologist who has made the diagnosis of hypogonadism based on unequivocally and consistently low serum total testosterone or free testosterone levels** • Patient is experiencing signs and symptoms associated with hypogonadism • Provider has investigated the etiology of the low testosterone levels and **has assessed the risks versus benefits of initiating testosterone therapy in this patient. Provider** acknowledges that testosterone therapy is clinically appropriate and needed. OR Coverage approved for female-to-male gender**-affirming hormone therapy in a natal female patient (assigned female at birth)** ~~**reassignment (endocrinologic masculinization)**~~ if: • **Patient is 14 years of age or older** • Patient has diagnosis of Gender Dysphoria made by a TRICARE-authorized mental health provider according to most current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) • **Prescription if prescribed by an endocrinologist or a physician who specializes in the treatment of transgender patients** • Patient is an adult, or is **an adolescent** ~~**16 years or older who has experienced puberty to at least Tanner stage 2**~~ **with sufficient mental capacity to give informed consent for this partially irreversible treatment** • **Patient has experienced puberty to at least Tanner stage 2** • ~~**Patient has no signs of breast cancer**~~ • For gender dysphori~~a~~**,** biological**ly** female patients of childbearing potential, the patient IS NOT pregnant or breastfeeding • Patient has no psychiatric comorbidity that would confound a diagnosis of gender dysphoria or interfere with treatment (e.g., unresolved body dysmorphic disorder; schizophrenia or other psychotic disorders that have not been stabilized with treatment)

Appendix C—Table of Prior Authorization (PA) Criteria

	OR **If indication is not listed above, please write in requested indication and rationale for use: _____ (blank write-in)** AND • Patient has tried **and failed a 3-month trial, experienced a clinically significant adverse reaction, or had a contraindication or relative contraindication to one drug from each of the following two categories: ~~for a minimum of 90 days AND failed to achieve total serum testosterone levels above 400 ng/dL (labs drawn 2 hours after use of the agent) AND without improvement in symptoms~~** **1. testosterone cypionate IM injection or testosterone enanthate IM inje** **2. testosterone 2% gel (Fortesta) OR testosterone 1% gel (Androgel generic)** **~~OR~~** **~~• The patient requires a testosterone replacement therapy (TRT) that has a low risk of skin-to-skin transfer between family members~~** **~~OR~~** **~~• Patient does not have any of the following:~~** **~~• Hypogonadism conditions not associated with structural or genetic etiologies (e.g. "age-related" hypogonadism), carcinoma of the breast or suspected carcinoma of the prostate~~** **~~• Uncontrolled hypertension or is at risk for cardiovascular events (e.g., myocardial infarction or stroke) prior to start of Jatenzo or Tlando therapy or during treatment (based on the product's boxed warning of increased risk of major adverse cardiovascular events and hypertension)~~** • Not approved for concomitant use with other testosterone products **~~Non-FDA-approved uses are NOT approved.~~ Testosterone will not be approved to enhance athletic performance.** **~~Prior Authorization does not expire~~** **PA expires in 1 year** **Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply:** • **The patient has had a positive response to therapy** • **The risks of continued therapy do not outweigh the benefits**
• methyltestosterone oral tablet or capsule **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	Manual PA Criteria apply to all new and current users of methyltestosterone Manual PA criteria: Methyltestosterone is approved if ALL criteria are met Patient has a diagnosis of hypogonadism, delayed puberty, or metastatic mammary cancer • This agent has been identified as having safer, more effective, and more cost-effective alternatives. The provider must explain why the patient requires methyltestosterone and cannot take the formulary alternatives. (blank write-in) • Not approved for concomitant use with other testosterone products Non-FDA-approved uses are not approved. PA expires in 1 year Renewal Criteria: Initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if both of the following apply: • The patient has had a positive response to therapy • The risks of continued therapy do not outweigh the benefits

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• budesonide delayed release 4 mg caps (Tarpeyo) **Nephrology Agents Miscellaneous**	Interim Manual PA criteria apply to all new users of Tarpeyo until implementation of the Tier 4 (complete exclusion) recommendation. Manual PA Criteria: Coverage is approved if all criteria are met: • Provider will be notified that Tarpeyo will no longer be available 180 days after signing of the minutes • Tarpeyo is prescribed by a nephrologist • The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) • The patient has a urine protein-to-creatinine ratio UPCR greater than or equal to 1.5 g/g • The patient is receiving a stable dose of a Renin-Angiotensin inhibitor [ACE inhibitor or ARB (such as lisinopril, losartan, irbesartan)] at a maximally tolerated dose. Note: prior use will be verified • Patient is not currently receiving dialysis or has not undergone kidney transplant • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 35 ml/min/1.73m^2 • The patient has had a trial of an alternate oral glucocorticoid regimen for 6 months or immunosuppressive therapy and has failed therapy or the patient has a contraindication to oral glucocorticoid therapy or immunosuppressive therapy. Examples include methylprednisolone, prednisolone/prednisone, and Entocort EC or Uceris budesonide formulations • The provider has considered use of an SGLT-2 inhibitor Non-FDA-approved uses are not approved, including ulcerative colitis or Crohn's disease PA expires in 9 months; no renewal allowed
Newly Approved Drug PAs	
• dextroamphetamine transdermal system (Xelstrym) **ADHD Agents: Stimulants**	Manual PA criteria apply to all new users of dextroamphetamine transdermal system (Xelstrym) Manual PA criteria: Xelstrym is approved if all criteria are met: • Patient is 6 years of age and older. • Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) that has been appropriately documented in the medical record. • Provider is aware of the warnings, screening and monitoring precautions for Xelstrym. • Patient must have tried and failed or have a contraindication to one medication from each of the following categories: ▪ amphetamines (single or mixed salt medications) ▪ methylphenidate • Patient has documented swallowing dysfunction requiring alternative formulation for treatment Non-FDA approved uses are NOT approved. PA does not expire.

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• dextromethorphan hydrobromide and bupropion hydrochloride (Auvelity) **Antidepressants and Non-Opioid Pain Syndrome Agents**	Manual PA criteria apply to all new users of Auvelity. <u>Manual PA criteria:</u> Auvelity is approved if all criteria are met: • The patient is 18 years of age or older • The patient does not have a history of seizure disorder or conditions that increase the risk of seizure (e.g., bulimia, anorexia nervosa, severe head injury) • Provider acknowledges that patient and provider have discussed that non-pharmacologic interventions (i.e., CBT, sleep hygiene) are encouraged to be used in conjunction with this medication • The patient is being treated for depression • Patient has tried and failed generic bupropion extended release at maximally tolerated dose AND • The patient has a contraindication to, intolerability to, or has failed a trial of TWO other formulary antidepressant medications (note: failure of medication is defined as a minimum treatment duration of 4-6 weeks at maximally tolerated dose) Non-FDA-approved uses are not approved. Prior Authorization does not expire.
• futibatinib (Lytgobi) **Oncological Agent**	Manual PA criteria apply to all new users of futibatinib (Lytgobi) <u>Manual PA criteria:</u> Lytgobi is approved if all criteria are met: • Patient is 18 years of age or older • The drug is prescribed by or in consultation with a hematologist or oncologist • Patient has previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test • The patient will be monitored for retinal pigment epithelial detachment, hyperphosphatemia, and soft-tissue mineralization • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: Non-FDA approved uses are NOT approved. PA does not expire.
• insulin glargine (Basaglar Tempo Pen) **Basal Insulin**	Manual PA criteria apply to all new users of insulin glargine (Basaglar Tempo Pen) <u>Manual PA criteria</u>: Basaglar Tempo pen is approved if all criteria are met: • Provider acknowledges that Lantus is the DoD's preferred basal insulin and preferred insulin glargine. No prior authorization is required for Lantus. Lantus is available at the lowest Tier 1 copay. • The patient must have tried and failed Lantus. • The provider must document why the patient cannot use the Basaglar Kwikpen version. (blank write-in) Non-FDA approved uses are NOT approved. PA does not expire.

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• insulin lispro (Humalog Tempo Pen) **Rapid Acting Insulin**	Manual PA criteria apply to all new users of insulin lispro (Humalog Tempo Pen) Manual PA criteria: Humalog Tempo pen is approved if all criteria are met: • Provider acknowledges that Novolog Flex Pen, Humalog Kwikpen and Lyumjev Kwikpen are TRICARE's preferred rapid-acting insulins and are available to TRICARE beneficiaries without requiring prior authorization. • The provider must document why the patient cannot use the Humalog Kwikpen version. Non-FDA approved uses are NOT approved. PA does not expire.
• insulin lispro-aabc (Lyumjev Tempo Pen) **Rapid Acting Insulin**	Manual PA criteria apply to all new users of insulin lispro-aabc (Lyumjev Tempo Pen) Manual PA criteria: Lyumjev Tempo pen is approved if all criteria are met: • Provider acknowledges that Novolog Flex Pen, Humalog Kwikpen and Lyumjev Kwikpen are TRICARE's preferred rapid-acting insulins and are available to TRICARE beneficiaries without requiring prior authorization. • The provider must document why the patient cannot use the Lyumjev Kwikpen version. (blank write-in) Non-FDA approved uses are NOT approved. PA does not expire.
• levothyroxine sodium 150 mcg/5 mL oral solution (Ermeza) **Thyroid & Antithyroid Agents**	Manual PA criteria apply to all new users of levothyroxine sodium oral solution (Ermeza) PA does not apply to patients younger than 6 years of age (Age edit) Manual PA criteria: Ermeza is approved if all criteria are met: • The patient is 6 years of age or older • Patient is not able to chew a levothyroxine tablet • Patient is not able to swallow a levothyroxine capsule or tablet • Ermeza is prescribed by or in consultation with an endocrinologist Non-FDA approved uses are NOT approved. PA expires after 12 months. No renewal allowed; must fill out a new PA
• olutasidenib (Rezlidhia) **Oncological Agent**	Manual PA criteria apply to all new users of olutasidenib (Rezlidhia) Manual PA criteria: Rezlidhia is approved if all criteria are met: • Patient is 18 years of age or older • Rezlidhia is prescribed by or in consultation with a hematologist or oncologist • The patient has laboratory evidence of relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test 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, please list the diagnosis:_____. • The patient will be monitored for differentiation syndrome • The patient will be monitored for hepatotoxicity Other non-FDA approved uses are NOT approved. PA does not expire.
• pegfilgrastim-pbbk (Fylnetra) **WBC Stimulants/ Pegfilgrastims**	Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta OnPro), pegfilgrastim-bmez (Ziextenzo) and **pegfilgrastim-pbbk (Fylnetra)** Note that Udenyca and Nyvepria are available at the Tier 1 copay at the Mail Order and Retail Network pharmacies. Manual PA criteria: **Fylnetra** is approved if all criteria are met:

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	• Provider acknowledges that pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) and pegfilgrastim-apgf (Nyvepria) are the preferred pegfilgrastims and are available without a PA • Fyletra is prescribed by or in consultation with a hematologist/oncologist • For Neulasta OnPro, the 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-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) or pegfilgrastim-apgf (Nyvepria) and is expected to respond to pegfilgrastim (Neulasta), pegfilgrastim-bmez (Ziextenzo), or **pegfilgrastim-pbbk (Fylnetra)** PA does not expire
• sodium phenylbutyrate and taurursodiol (Relyvrio) **Neurological Agent**	Manual PA criteria apply to all new users of Relyvrio. Manual PA criteria: Relyvrio is approved if all criteria are met: • Patient is 18 years of age or older. • Relyvrio is prescribed by a neurologist. • The patient has a diagnosis of amyotrophic lateral sclerosis (ALS) Non-FDA approved uses are NOT approved. PA does not expire.
Utilization Management New PAs	
• mifepristone 200 mg tablets (Mifeprex)	Manual PA criteria apply to every use (one tablet and no refills) of mifepristone (Mifeprex). Manual PA criteria: Mifeprex is approved if all criteria are met: • The patient and provider are enrolled in the Mifeprex Risk Evaluation and Mitigation Strategies (REMS) program • Mifeprex used for termination of pregnancy: ▪ Patient is terminating a pregnancy through 70 days of gestation. Documentation will indicate date of patient's last menstrual period: _____ and anticipated date of treatment initiation: _____ AND ▪ One of the two following criteria must apply: 1. Patient is seeking to terminate pregnancy due to an act of rape or incest. It is the provider's good faith belief, based on all of the information available to the provider, that the patient was the victim of rape or incest (the provider should maintain medical records that support the provider's good faith belief). OR 2. Patient is seeking to terminate pregnancy because the patient's life would be endangered by carrying the fetus to term. Provider certifies that the mother's life would be at risk if the fetus was carried to term (the provider should maintain medical records that support the provider's certification). • Mifeprex used for Pregnancy Loss: ▪ Patient has experienced a pregnancy loss and requests medical management ▪ Provider certifies that the medication will be used to manage a pregnancy loss and will not be used for termination of a pregnancy (medical abortion) (the provider should maintain medical records that support the provider's certification). Other non-FDA-approved uses are not approved PA renewal is not allowed; no refills allowed; each course of therapy requires a new PA

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• allopurinol 200 mg tablet **Antigout Agents**	Manual PA criteria apply to all new and current users of allopurinol 200 mg tablets. Manual PA criteria: allopurinol 200 mg tablets are approved if all criteria are met: • Provider acknowledges other allopurinol formulations, including allopurinol 100 mg and 300 mg tablets are available without requiring prior authorization. • The provider must explain why the patient can't take a different allopurinol formulation. (*write-in*) Non-FDA-approved uses are not approved. Prior authorization does not expire.
• methocarbamol 1000 mg tablet **Skeletal Muscle Relaxants and Combinations**	Manual PA criteria apply to all new and current users of methocarbamol 1000 mg tablet. Manual PA criteria: methocarbamol 1000 mg tablet is approved if all criteria are met: • Provider acknowledges other formulations of methocarbamol, including methocarbamol 500 mg and 750 mg are available without requiring prior authorization. • The provider must explain why the patient can't take a different formulation of methocarbamol. (*write-in)* Non-FDA-approved uses are not approved. Prior authorization does not expire.
Utilization Management Updated PAs	
• amifampridine (Firdapse) **Neurological Agents Miscellaneous**	**Updates from the February 2023 meeting are in bold and strikethrough.** Manual PA apply to all new users of Firdapse. Manual PA Criteria: Firdapse is approved if: • Patient is **6** ~~**18**~~ years of age or older • Firdapse is prescribed by an oncologist or neurologist • The patient has laboratory evidence of Lambert-Eaton myasthenic syndrome (LEMS) Non-FDA-approved uses are not approved. PA does not expire.
• cobimetinib (Cotellic) **Oncological Agents: Melanoma**	**Updates from the February 2023 meeting are in bold.** Manual PA apply to all new users of Cotellic. Manual PA Criteria: Cotellic is approved if: • The patient is 18 years of age or older. • **Patient has one of the following:** ▪ Unresectable metastatic melanoma AND has confirmed BRAF V600E or V600K mutation by an FDA-approved test AND Cotellic is being taken in combination with vemurafenib (Zelboraf) AND Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), dabrafenib (Tafinlar), nor trametinib (Mekinist) OR ▪ **histiocytic neoplasms** • Prescribed by or in consultation with an oncologist Non-FDA-approved uses are NOT approved. Prior authorization does not expire.

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• elpercatinib (Retevmo) **Oncological Agents**	**Updates from the February 2023 meeting are in bold.** Manual PA apply to all new users of Retevmo. Manual PA Criteria: Retevmo is approved if all criteria are met: • Retevmo is prescribed by or in consultation with a hematologist/oncologist • Patient has one of the following indications: ▪ Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) ▪ Patients 12 years and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy ▪ Patients 12 years and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine refractory (if radioactive iodine is appropriate) ▪ **Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options** • Patient will be monitored for hepatotoxicity and QT prolongation • Patient does not have uncontrolled hypertension • Provider is aware and has counseled patient that Retevmo can cause life threatening hemorrhage and allergic reactions • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. Non-FDA approved uses are NOT approved except as noted above. Prior authorization does not expire.
• abaloparatide (Tymlos) **Osteoporosis Agents: Parathyroid Hormone Analogs**	**Updates from the February 2023 meeting are in bold.** Manual PA apply to new users of Tymlos. Manual PA criteria: Tymlos is approved if **ALL** of the following criteria are met: • The drug is prescribed for treatment of osteoporosis, and not for prevention of osteoporosis. • The patient is a **male or** postmenopausal female with osteoporosis at high risk for fracture as defined by one of the following: ▪ history of osteoporotic fracture ▪ multiple risk factors for fracture (e.g., a history of vertebral fracture or low-trauma fragility fracture of the hip, spine or pelvis, distal forearm or proximal humerus) ▪ documented bone mineral density (BMD) T-score of -2.5 or worse ▪ has one of the following: has tried and experienced an inadequate response to, therapeutic failure with, is intolerant to (unable to use or absorb), or has contraindications to at least one formulary osteoporosis therapy (e.g., alendronate, ibandronate) AND ▪ The patient will continue to take calcium and vitamin D supplementation during PTH analog therapy if dietary intake is inadequate AND ▪ Cumulative treatment with Tymlos, Forteo and/or other Parathyroid Hormone Analogs formulations used more than 24 months during the patient's lifetime should be used in extreme caution AND

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	• The patient is not at increased risk for osteosarcoma (e.g., Paget's disease, unexplained elevations of alkaline phosphatase, patients with open epiphyses, prior external beam or implant radiation therapy involving the skeleton) AND • The patient cannot comply with the refrigeration requirement for Tymlos Off-label uses are not approved unless supporting documentation is provided. Prior Authorization expires in 24 months. Prior Authorization may not be renewed.
• fingolimod orally dissolving tablets (Tascenso ODT) **Multiple Sclerosis: Miscellaneous Oral Agents**	**Updates from the February 2023 meeting are in bold and strikethrough.** Manual PA apply to all new users of Tascenso ODT. Manual PA Criteria: Coverage is approved if all criteria are met: • Patient is ≥ 10 years **~~and weighs ≤ 40 kg~~** • Patient has a documented diagnosis of a relapsing form of multiple sclerosis (MS) • Medication is prescribed by a neurologist • Patient has tried and failed or has a contraindication (i.e. swallowing difficulties) to fingolimod capsule • Patient is not concurrently using a disease-modifying therapy (e.g., beta interferons [Avonex, Betaseron, Rebif, Plegridy, Extavia], glatiramer [Copaxone, Glaptopa], dimethyl fumarate [Tecfidera], diroximel fumarate [Vumerity], monomethyl fumarate [Bafiertam], cladribine [Mavenclad], teriflunomide [Aubagio]) • Patients of childbearing potential agree to use effective contraception during treatment and for 2 months after stopping therapy • Patient has not failed a course of another S1p receptor modulator (e.g., Gilenya, Mayzent, Zeposia, Ponvory) • Provider acknowledges that all recommended Tascenso ODT monitoring has been completed and the patient will be monitored throughout treatment as recommended in the package insert. Monitoring includes complete blood count (CBC); liver function tests (LFT), varicella zoster virus (VZV) antibody serology, electrocardiogram (ECG), pulmonary function tests (PFTs), blood pressure, skin assessments and macular edema screening as indicated. Non-FDA approved uses are not approved**~~, including for patients weighing > 40 kg~~** PA does not expire.

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• niraparib (Zejula) **Oral Oncologic Agents: Ovarian Cancer**	Manual PA criteria apply to all new users of Zejula. Manual PA Criteria: Coverage will be approved if all criteria are met: • Zejula is prescribed by or in consultation with a hematologist/oncologist • Patient is 18 years of age or older • ~~**Patient has a deleterious or suspected deleterious BRCA mutation as detected by an FDA-approved test**~~ • Niraparib will be prescribed as a maintenance therapy for one of the following diagnoses: o Platinum-sensitive, relapsed, high-grade, ovarian cancers: OR o Recurrent epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer AND o Patient has received 2 or more lines of platinum-based chemotherapy AND o Patient was in objective response (either complete or partial) to most recent treatment regimen AND o Zejula will not be combined with bevacizumab (Avastin) OR o 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 take highly effective contraception while taking Zejula and for 6 months after the last dose. • Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• upadacitinib (Rinvoq ER) **Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)**	Manual PA apply to all new users of Rinvoq Note that there were no changes to the current PA requirements for indications other than atopic dermatitis (e.g., a trial of Humira is still required before Rinvoq in patients with rheumatoid arthritis; no changes were made to the indications of PsA, Ulcerative Colitis or Ankylosing Spondylitis – see the August 2022 P&T Committee meeting minutes for the full criteria Manual PA criteria: Coverage for **non-radiographic axial spondyloarthritis** is approved if all criteria are met: • Provider acknowledges that Humira is the Department of Defense preferred targeted biologic agent for active non-radiographic axial spondyloarthritis • The patient is 18 years of age or older • The patient has active non-radiographic axial spondyloarthritis • Patient has had an inadequate response to Humira and Cosentyx OR • Patient has experienced an adverse reaction to Humira and Cosentyx that is not expected to occur with the requested agent OR • Patient has a contraindication to Humira and Cosentyx AND • Patient has had an inadequate response to at least two NSAIDs over a period of 2 months 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)

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	Non-FDA-approved uses are not approved. PA does not expire for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis
• dupilumab (Dupixent) **Atopy Agents**	Manual PA apply to all new users of Dupixent. Note that there were no changes to the PA criteria for the indications of asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis, or eosinophilic esophagitis; see the August 2022 P&T Committee meeting minutes for the full criteria <u>Manual PA criteria</u>: Coverage for Prurigo Nodularis is approved if all criteria are met: • Patient is 18 years of age or older • Dupixent is prescribed by an allergist, immunologist, or dermatologist • Patient has 20 or more identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk • Patient has experienced pruritus for 6 weeks or longer • Patient's prurigo nodularis is NOT medication-induced or secondary to a non-dermatologic condition OR the patient has a secondary cause of prurigo nodularis that has been identified and adequately managed • The patient has a contraindication to, intolerability to, or has failed treatment with one high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream) • The patient has a contraindication to, intolerability to, inability to access treatment, or has failed treatment with phototherapy Non-FDA approved uses are NOT approved. Prior authorization does not expire.
• adalimumab biosimilars to Humira **Targeted Immunomodulatory Biologics**	Manual PA apply to all new and current users of biosimilar formulations of adalimumab Manual PA Criteria: Biosimilar adalimumab is approved if all criteria are met: • The provider acknowledges that the originator Humira formulation is preferred over biosimilar adalimumab formulations for the DoD • The provide must document a patient-specific justification as to why the originator Humira formulation cannot be used in this patient: _____(write-in) Non-FDA approved uses are not approved. Prior Authorization does not expire**.**

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• Omnipod 5 **Insulins: Miscellaneous Insulin Devices**	**Updates from the February 2023 meeting are in bold and strikethrough.** Manual PA applies to new users of Omnipod 5 Pods and Kits Manual PA criteria: Omnipod 5 Pods are approved if all criteria are met: • Note: Current utilization of Omnipod 3 and 4 is not automatic approval for Omnipod 5. A new PA is required • Written by or in consultation with an endocrinologist • The patient has a documented diagnosis of Type 1 DM • ~~**The patient is on an insulin regimen of 3 or more injections per day using both basal and prandial insulin and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy or is currently on an insulin pump**~~ • The patient has completed a comprehensive diabetes education program **(to include teaching patient and caregiver how to administer insulin via syringe)** • The patient has demonstrated willingness and ability to play an active role in diabetes self-management PA expires after 1 year Renewal criteria: (coverage will be approved for 1 year if all criteria are met); Note that initial TRICARE PA approval is required for renewal: • Patient has been successful with therapy as shown by increased time in range (TIR), improved A1c, or has seen decreases in hypoglycemic episodes.
• Omnipod DASH (4) and Omnipod 3 **Insulins: Miscellaneous Insulin Devices**	**Updates from the February 2023 meeting are in bold.** Manual PA applies to new users of Omnipod/Omnipod DASH Manual PA criteria: Omnipod/Omnipod DASH is approved if all criteria are met: • The patient has diabetes mellitus AND requires insulin therapy • **Patient has one of the following** o **The patient has a documented diagnosis of Type 1 DM OR** o The patient **has diabetes** and is on an insulin regimen of 3 or more injections per day and has failed to achieve glycemic control after six months of Multiple Daily Injection (MDI) therapy • The patient performs 4 or more blood glucose tests per day or is using a Continuous Glucose Monitoring (CGM) system • The patient has completed a comprehensive diabetes education program **(to include teaching patient and caregiver how to administer insulin via syringe)** • The patient has demonstrated willingness and ability to play an active role in diabetes self-management Initial prior authorization expires after 1 year. Renewal criteria: Note that initial TRICARE PA approval is required for renewal. Omnipod or Omnipod DASH is approved for 1 year for continuation of therapy if all criteria are met: • Patient has been successful with therapy
• phentermine/ topiramate ER (Qsymia) **Weight Loss Agents**	**Updates from the February 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Qsymia. Manual PA Criteria: Agent is approved if all criteria are met: • **Patient is 12 years of age or older** ~~**and is managed by an obesity specialist**~~ • Patient does not have a history of cardiovascular disease (e.g., arrhythmias, coronary artery disease, heart failure, stroke, uncontrolled hypertension), hyperthyroidism, or other significant contraindication to the above agent. • Patient has a BMI ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) **OR**

Appendix C—Table of Prior Authorization (PA) Criteria

	patient is a pediatric patient 12 years of age or older with BMI ≥ 95th percentile standardized for age and sex • Patient has engaged in a trial of behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss and will remain engaged throughout course of therapy. • ~~**For Active Duty Service Members: The individual must be enrolled in a Service specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy.**~~ • Patient is not pregnant. • **Provider agrees to monitor the rate of weight loss in pediatric patients. If weight loss exceeds 2 lbs (0.9 kg)/week, consider dosage reduction.** • Prescriber will abide by and the patient has been informed of the REMS and safety concerns associated with this agent: • Use in combination with other products intended for weight loss has not been established • Use in patients with increased cardiovascular risk has not been established • Qsymia is pregnancy category X and is associated with increased risk of teratogenicity • If patient has **impaired glucose tolerance** or diabetes, must have tried **metformin** first or is concurrently taking metformin. Non-FDA-approved uses are not approved. Prior authorization expires after 4 months. Renewal PA Criteria: Qsymia will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • The patient has lost ≥ 5% of baseline body weight since starting medication • For patients initially receiving Qsymia 7.5 mg/46 mg: discontinue Qsymia or escalate to 15 mg/92 mg if a 3% reduction in baseline body weight is not achieved **or a pediatric patient has not experienced a reduction of at least 3% of baseline BMI** at 12 weeks • For patients receiving Qsymia 15 mg/92 mg: discontinue if a 5% reduction in baseline body weight is not achieved **or a pediatric patient has not experienced a reduction of at least 5% of baseline BMI** at 12 weeks • The patient is not pregnant.
• semaglutide (Wegovy) **Weight Loss Agents**	**Updates from the February 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Wegovy. Manual PA criteria: Coverage is approved if all criteria are met: • ~~**Patient is ≥ 12 years old and <18 years old with BMI ≥ 95th percentile standardized for age and sex and is managed by an obesity specialist**~~ • **Has tried and Qsymia or has a contraindication to Qsymia (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** Qsymia: Date_____ Duration of therapy _____ **Or** • Patient is 18 years of age or older and patient has tried and failed all of the following (generic phentermine, Qsymia, ~~**Xenical,**~~ and Contrave) or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) Phentermine: Date_____ Duration of therapy _____ Qsymia: Date_____ Duration of therapy _____ ~~**Xenical: Date _____ Duration of therapy _____**~~ Contrave: Date _____ Duration of therapy _____

	• If the patient is diabetic, must have tried and failed metformin and the DoD's preferred GLP1Ras (Trulicity) • Concomitant use of Wegovy with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ to 30, or a BMI ≥ to 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • ~~**If active duty, the individual is enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy**~~ • Patient is not pregnant Non-FDA approved uses are NOT approved including diabetes mellitus. Initial prior authorization expires after **6 4** months and then annually. Renewal PA Criteria: Wegovy will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Wegovy will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks **or pediatric patient has not experienced a reduction of at least 5% of baseline BMI** • The patient is not pregnant ~~**Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.**~~

Appendix C—Table of Prior Authorization (PA) Criteria

• liraglutide (Saxenda) **Weight Loss Agents**	**Updates from the February 2023 meeting are in bold and strikethrough.** Manual PA apply to all new users of Saxenda. Manual PA criteria: Coverage is approved if all criteria are met: • **Patient is ≥ 12 years old and <18 years old with BMI ≥ 95th percentile standardized for age and sex ~~and is managed by an obesity specialist~~** • **Has tried and Qsymia or has a contraindication to Qsymia (Note: provider must include the date of use and duration of therapy or contraindication to the drug)** **Qsymia: Date**_____ **Duration of therapy** _____ **OR** • Patient is 18 years of age or older and patient has tried and failed all of the following (generic phentermine, Qsymia, **~~Xenical,~~** and Contrave) or has a contraindication to all of the following weight loss medications (Note: provider must include the date of use and duration of therapy or contraindication to the drug) Phentermine: Date_____ Duration of therapy _____ Qsymia: Date_____ Duration of therapy _____ **~~Xenical: Date _____ Duration of therapy _____~~** Contrave: Date _____ Duration of therapy _____ • If the patient is diabetic, must have tried and failed metformin and the DoD's preferred GLP1Ras (Trulicity) • Concomitant use of Wegovy with another GLP1RA is not allowed (e.g., Bydureon, Trulicity, Byetta, Adlyxin, Victoza, Soliqua, Xultophy) • The patient does not have a history of or family history of medullary thyroid cancer or multiple endocrine neoplasia syndrome type 2 • Patient has a BMI ≥ to 30, or a BMI ≥ to 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) • Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss, and will remain engaged throughout course of therapy • **~~If active duty, the individual is enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy, AND will remain engaged throughout course of therapy~~** • Patient is not pregnant Non-FDA approved uses are NOT approved including diabetes mellitus. Initial prior authorization expires after **6 ~~4~~**-months and then annually. Renewal PA Criteria: Saxenda will be approved for an additional 12 months if the following are met: • The patient is currently engaged in behavioral modification and on a reduced calorie diet • Wegovy will be discontinued if a 4% decrease in baseline body weight is not achieved at 16 weeks **or pediatric patient has not experienced a reduction of at least 5% of baseline BMI** • The patient is not pregnant **~~Additionally, for Active Duty Service Members: The individual continues to be enrolled in a Service-specific Health/Wellness Program AND adheres to Service policy AND will remain engaged throughout course of therapy.~~**

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• testosterone enanthate (Xyosted) **Androgens-Anabolic Steroids: Testosterone Replacement Therapies**	▪ Retail: 4 syringes per fill and 28-day supply ▪ MTF/Mail: 12 syringes per fill and 84-day supply
• futibatinib (Lytgobi) **Oncological Agent**	▪ Retail/MTF/Mail: 60-day supply
• leuprolide acetate (Leuprolide Depot – unbranded) **LHRH Agents**	▪ Retail/MTF/Mail: 1 kit per fill
• olutasidenib (Rezlidhia) **Oncological Agent**	▪ Retail/MTF/Mail: 60-day supply
• sodium phenylbutyrate and taurursodiol (Relyvrio) **Neurological Agent**	▪ Retail/MTF/Mail: 60-day supply

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
dextro-amphet-amine transdermal system (Xelstrym) **ADHD Agents: Stimulants**	• Vyvanse cap • Daytrana patch • Adzenys XR-DT	• Formulation: 4.5, 9, 13.5, 18 mg patch • Dosing: Patch worn up to 9 hours	• Treatment of ADHD in patients ≥ 6 years old	Pediatric (≥ 2%): • Anorexia • Headache • Insomnia • Tic • Abdominal pain • Vomiting • Nausea • Irritability • Hypertension, • Tachycardia Adults (≥ 5%): • Anorexia • Insomnia • Dry mouth • Diarrhea • Nausea • Anxiety	• Xelstrym is the 2nd transdermal formulation approved for ADHD in patients 6 years of age and older • It is one amongst numerous alternate formulations available for ADHD patients unable to swallow a capsule or tablet • Xelstrym was approved via 505(b)(2) • A single phase 2 study demonstrated statistically significant improvement vs. placebo in ADHD symptoms on SKAMP scores for patients ages 6-17 years • Xelstrym provides little to no compelling clinical advantage over existing agents	• NF • Do not add to EMMI list
dextro-methorphan hydrobromide / bupropion hydrochloride (Auvelity) **Antidepress-ants and non-opioid pain syndrome: Norepinephrine-dopamine releasing**	• Wellbutrin XL tab • Aplenzin tab • Delsym tab • Lexapro tab • Effexor XR tab	• Formulation: dextro-methorphan HBr IR 45 mg and bupropion HCl XR 105 mg tablet • Dosing: Initial is 1 tab PO QAM x3 days, then 1 tab PO BID	• Treatment of Major Depressive Disorder (MDD)in adults	≥5% • Dizziness • Headache • Diarrhea • Somnolence • Dry mouth • Sexual dysfunction • Hyperhidrosis	• Auvelity is indicated for the treatment of adults with major depressive disorder • Clinical trial results demonstrated statistically significant reduction in total MADRS score relative to placebo; antidepressant effect was observed within 1 week with sustained improvement over the 6-week timeframe • Multiple MDD guidelines list a variety of initial treatment options, to include bupropion; however, no one drug is preferred • Auvelity provides another treatment option for major depressive disorder in adults	• NF • Do not add to EMMI list

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

furosemide SC injection (Furoscix) **Diruretics**	• Soaanz (DR torsemide) • furosemide tab • bumetanide • furosemide IV	• Formulation: 80 mg/10 ml Injection Solution • Dosing: deliver 30 mg over the first hour then 12.5 mg per hour for the subsequent 4 hours	• Treatment of congestion due to fluid overload in adults with NYHA class II/III CHF	>20% • Infusion site bruising • Infusion site pain >10% • dizziness (12.5%)	• Single-use, on-body infusor that administers 80 mg SC furosemide over a period of 5 hours • pH of Furoscix is lower than IV furosemide which permits SC administration • Pharmacokinetic studies demonstrated similar bioavailability and total urine output to the IV furosemide formulation • Not for treatment of acute pulmonary edema • Although this is a novel device that allows self-administration of SC furosemide, there are no clinical studies available to show a reduction in hospitalization for heart failure	• Tier 4 (complete exclusion)
futibatinib (Lytgobi) **Oncological Agent: CML**	• Pemazyre • Truseltiq	• Formulation: 4 mg tablet • Dosing: 20 mg PO QD until disease progression or unacceptable toxicity occurs	• Treatment of previously treated, unresectable, locally advanced or metastatic intra-hepatic cholangio-carcinoma harboring FGFR2 gene fusions or re-arrangements in adults	• ≥20% • Nail toxicity • Musculoskeletal pain • Constipation • Diarrhea • Fatigue • Dry mouth • Alopecia • Stomatitis • Abdominal pain • Dry skin • Arthralgia • Dysgeusia • Dry eye • Nausea • Decreased appetite • UTI • Palmer-plantar erythron-dysesthesia syndrome • Vomiting	• Lytgobi is the third small molecule kinase inhibitor approved for adults with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene fusions or other rearrangements • A single phase 2 study demonstrated ORR of 42% and a duration of response of 10 months • Lytgobi has no direct comparisons to competitors, pemigatinib (Pemazyre) or infigratinib (Truseltiq) – all three approved via accelerated approval as single-arm phase 2 studies • FDA review of Lygtobi states it is reasonably likely to predict a clinically meaningful benefit over existing treatments, thus meeting the requirements for accelerated approval. • Lytgobi provides an additional treatment option for this fatal disease indication	• UF • Do not add to EMMI list

insulin glargine (Basaglar Tempo Pen) **Insulin: Basal**	• Inpen • Basaglar Kwikpen	• Formulation: SC Injection Pen • Dosing: patient specific dosing	• Improve glycemic control in adults and children with diabetes mellitus	• Injection site pain • Lipodystrophy • Pruritus • Pain • Weight gain • Hypoglycemia • Nasopharyngitis • Infectious disease	• Prefilled and disposable insulin pen that has the same active ingredient as Basaglar Kwikpen • When Tempo Smart Button is attached to Tempo Pen then it can transmit user data via Bluetooth to the smart phone application • Tempo Smart Button and App are not yet commercially available in United States • No new clinical studies • Provides no compelling advantage over existing agents	• NF • Add to EMMI list
insulin lispro (Humalog Tempo Pen) **Insulin: Rapid-Acting**	• Inpen • Humalog Kwikpen	• Formulation: SC Injection Pen • Dosing: patient specific dosing	• Improve glycemic control in adults and children with diabetes mellitus	• Injection site disorder • Lipodystrophy • Hypoglycemia • Hypokalemia • Nasopharyngitis • Upper respiratory infection	• Prefilled and disposable insulin pen that has the same active ingredient as Humalog Kwikpen • When Tempo Smart Button is attached to Tempo Pen then it can transmit user data via Bluetooth to the smart phone application • Tempo Smart Button and App are not yet commercially available in United States • No new clinical studies • Provides no compelling advantage over existing agents	• UF • Add to EMMI list
insulin lispro-aabc (Lyumjev Tempo Pen) **Insulin: Rapid-Acting**	• Inpen • Lyumjev Kwikpen	• Formulation: SC Injection Pen • Dosing: patient specific dosing	• Improve glycemic control in adults and children with diabetes mellitus	• Hypoglycemia • Nasopharyngitis • Upper respiratory infection	• Prefilled and disposable insulin pen that has the same active ingredient as Lyumjev Kwikpen • When Tempo Smart Button is attached to Tempo Pen then it can transmit user data via Bluetooth to the smart phone application • Tempo Smart Button and App are not yet commercially available in United States • No new clinical studies • Provides no compelling advantage over existing agents	• NF • Add to EMMI list

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

leuprolide acetate (Leuprolide Depot – unbranded) **LHRH Agents**	• Lupron Depot 22.5mg • Eligard 22.5mg	• Formulation: 22.5 mg IM Injection solution • Dosing: 22.5 mg IM Q 3 months	• Palliative treatment of advanced prostate cancer	≥10% • Hot flushes • Upper respiratory infection • Fatigue • Diarrhea • Pollakiuria • Arthralgia • Injection site pain	• Leuprolide Acetate Depot manufactured by Cipla is the third leuprolide acetate 22.5mg injection given at a 3-month frequency, all of which are indicated for treatment of end stage prostate cancer • No new clinical data • The active ingredient, route of administration, dosage form and strength are the exact same as the Lupron Depot 22.5mg product from Abbvie • No compelling clinical advantage compared to existing formulary agents	• UF • Do not add to EMMI list
levothyroxine sodium 150 mcg/5 mL oral solution (Ermeza) **Thyroid and Antithyroid agents**	• Tirosant-Sol • Thyquidity • Tirosant cap	• Formulation: 150mcg/5ml oral solution • Dosing: patient specific dosing	• Hypothyroidism in adult/pediatric patients.	• Palpitations, alopecia, sweating, weight loss, diarrhea, insomnia, anxiety, fatigue	• Ermeza is another levothyroxine sodium oral solution formulation • No new clinical studies conducted • This formulation provides little to no compelling clinical advantage over existing agents	• NF • Add to EMMI list

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

olutasidenib (Rezlidhia) **Oncological Agents: AML**	• Tibsovo	• Formulation: 150mg capsule • Dosing: 150 mg capsule given PO BID until disease progression or unacceptable toxicity	• For treatment of relapsed or refractory AML with IDH1 mutation	ADRs (≥ 20%): • AST increased • ALT increased • Potassium decreased • Sodium decreased • Alkaline phosphatase increased • Nausea • Creatinine increased • Fatigue/malaise • Arthralgia • Constipation • Lymphocytes increased • Bilirubin increased • Leukocytosis • Uric acid increased • Dyspnea • Pyrexia • Rash • Lipase increased • Mucositis • Diarrhea • Transaminitis	• Second isocitrate dehydrogenase-1 (IDH1) inhibitor approved for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with susceptible IDH1 mutation as detected by an FDA approved test • Phase 2 study demonstrated complete response rate (CR) + complete remission with partial hematological recovery rate (CRh) of 35% • Median response duration of CR plus CRh was 25.9 months • No direct comparisons with Tibsovo • However, when compared indirectly, Rezlidhia demonstrated less QT prolongation and more hepatotoxicity then Tibsovo • NCCN guidelines do not yet mention Rezlidhia • Offers a treatment option in a patient population with limited options and a poor prognosis	• UF • Do not add to EMMI list
pegfilgrastim-pbbk (Fylnetra) **WBC Stimulants: Pegfilgrastims**	• Udenyca • Nyvepria • Fulphila • Neulasta • Neulasta OnPro • Ziextenzo	• Formulation: 6 mg/0.6 mL solution in a single-dose prefilled syringe. 27-gauge, ½-inch needle • Dosing: 6 mg SC once per chemotherapy cycle; weight-based dosing for pediatrics	• To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	ADRs (≥ 5% difference in incidence compared to placebo): • Bone pain • Pain in extremity	• Fylnetra is the 5th biosimilar to Neulasta and 11th agent in the white blood cell stimulant class • No new clinical data • Latex-free product • Fylnetra provides little to no compelling clinical advantage over existing pegfilgrastim agents	• UF • Do not add to EMMI list

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

posaconazole DR oral suspension (Noxafil Powdermix Kit) **Antifungals**	• posaconazole oral sus • posaconazole ER tab • voriconazole	• Formulation: 30 mg/mL DR oral suspension • Dosing: weight-based dosing for pediatrics	• Prophylaxis of invasive *Aspergillus* and *Candida* infections in severely posaconazole • compromised patients that are **≥ 2 y/o and weigh ≤ 40 kg**	• Pyrexia • Febrile neutropenia • Vomiting • Mucosal inflammation • Pruritus • Hypertension • Hypokalemia • Stomatitis	• Another formulation of posaconazole in a delayed-release oral suspension • Comparing with posaconazole IV, Noxafil PowderMix has similar safety pharmacokinetic profile • Both formulations, IV and PowderMix, were well tolerated without dose-, exposure-, or age-related differences in the safety profiles • Unlike the delayed release tablets and oral solution, PowderMix can be used in patients ≥ 2 years AND ≤ 40 kg • PowderMix formulation contains sorbitol and contraindicated in hereditary fructose intolerance	• UF • Do not add to EMMI list
sodium phenyl-butyrate/ sodium taurursodiol (Relyvrio) **Neurological Agents Misc.**	• Tiglutik susp • Exservan film • Rilutek tab • Radicava soln	• Single dose pack, oral suspension: 3g sodium phenyl-butyrate and 1g taurursodiol • Dosing: Initial is 1 packet PO QD x3 weeks, then 1 packet PO BID	• Treatment of amyotrophic lateral sclerosis in adults	(≥15%) • diarrhea • abdominal pain, • nausea • upper respiratory tract infection	• Relyvrio is a specialty drug approved for adults with amyotrophic lateral sclerosis • Patients receiving Relyvrio were more likely than those who received PBO to discontinue secondary to adverse events (i.e. diarrhea) • A single, small phase 2 study demonstrated a benefit with slower functional decline, measured via ALSFRS-R compared to placebo; a follow-on open label extension study had a median survival benefit of 6.5 mo • FDA review did not find a statistically significant result for functional decline; however, the FDA states due to the life-threatening nature of ALS, the unmet medical need of the disease state, and lack of serious safety concerns with Relyvrio, its benefits outweigh the risk • FDA required follow up studies will include carcogenicity, drug interactions, hepatic and renal impairment • Relyvrio provides another treatment option for patients with ALS	• UF • Do not add to EMMI list

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

testosterone undecanoate (Kyzatrex) **Androgens-Anabolic Steroids: TRT**	• Jatenzo • Tlando	• Dose: 100 mg QD to 400 mg BID with food (adjusted to serum levels) Available as 100 mg, 150 mg or 200 mg capsules	• For testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone • Limitations of Use: safety and efficacy in males < 18 years old have not been established	ADRs (≥ 2%): • hypertension	• Kyzatrex is the 3rd oral capsule testosterone undecanoate and the 15th available testosterone • Unlike Tlando, Kyzatrex and Jatenzo do require dose adjustment based on serum testosterone levels • In an open-label, single-arm study, 88% of patients taking Kyzatrex met the primary outcome specified testosterone concentration • There are numerous alternative testosterone formulations available; Kyzatrex's place in therapy remains unclear, and there is no compelling clinical advantage over existing formulary agents	• NF • Add to EMMI list

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)
February 2023	**Drug Class Reviews** **Androgens-Anabolic Steroids: Testosterone Replacement Therapies** **Designated UF:** • testosterone patch Androderm • testosterone 2% gel Fortesta • testosterone 1% gel Testim • testosterone 1% gel (Vogelxo) • testosterone nasal gel (Natesto) **Designated NF:** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • testosterone undecanoate (Kyzatrex) • testosterone undecanoate (Jatenzo) • testosterone undecanoate (Tlando) • testosterone transdermal solution (Axiron) • testosterone transdermal gel (AndroGel 1% brand, Androgel 1.62% brand, 1.62% gel generic) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designate UF** • insulin lispro (Humalog Tempo Pen) **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar agents are already on list, and pending final cost:* • insulin glargine (Basaglar Tempo Pen) • inulin lispro-aabc (Lyumjev Tempo Pen) • levothyroxine sodium 150 mcg/5 mL oral solution (Ermezau	**Drug Class Reviews** **Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass** **Designated UF** • Belsomra • Dayvigo • Quviviq **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF:** *Acute use exception* • posaconazole DR oral suspension (Noxafil Powder mix kit) *Not yet clear if feasible to provide through Mail* • leuprolide acetate injection *Specialty Drug* • futibatinib (Lytgobl) • olutasidenib (Rezlidhia) • sodium phenylbutyrate/sodium taurursodiol (Relyvrio) *Consistent with others in the class* • pegfilgrastim-pbbk (Fylnetra) **Designated NF:** *Similar to other agents in the class* • Dextroamphetamine transdermal system (Xelstrym) *Comparable pricing at mail order vs MTFs or retail* • dextromethorphan hydrobromide/ bupropion hydrochloride (Auvelity)

* 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: May 1, 2023

Two weeks after signing: May 17, 2023

30 days after Signing: May 31, 2023

60 days after signing: July 12, 2023

90 days after signing: Aug 2, 2023

120 days after signing: Aug 30, 2023

180 days after signing Nov 1, 2023

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

Appendix H—Tier 4 Agents (completely excluded) and Therapeutic Alternatives*

P&T Committee Meeting Date	Drug Class	Tier 4 (complete exclusion) Products	Formulary Alternatives	Implementation
February 2023	Nephrology Agents Miscellaneous	• budesonide 4 mg DR capsules (Tarpeyo)	• methylprednisolone • prednisolone/prednisone • Entocort EC • Uceris • mycophenolate mofetil	• 180 days
February 2023	Diuretics	• furosemide SC injection (Fuoscix)	• furosemide • bumetanide • ethacrynic acid • torsemide	• 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 Tier 4 (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 Tier 4 (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 Tier 4(complete exclusion) agents at the Retail points of service.

The first Tier 4 (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 Tier 4 agents to date, refer to previous versions of the DoD P&T Committee quarterly meeting minutes, found on the heatlh.mil website.

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS

May 2023

I. CONVENING

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee convened at 0830 hours on May 3rd and 4th, 2023.

II. ATTENDANCE

The attendance roster is listed in Appendix A.

A. Approval of February 2023 Minutes—Dr. Brian Lein, Assistant Director, Healthcare Administration, DHA, approved the minutes from the February 2023 DoD P&T Committee meeting on May 1, 2023.

B. Clarification of previous meeting minutes

1. February 2023

- **Weight Loss Drugs PA updates: Prescribing weight loss drugs for Active-Duty Service Members (ADSM)—**Several updates were made to the prior authorization (PA) criteria for the weight loss drugs. A memo from Dr. Lein has clarified when prescribing weight loss medications for ADSM that providers must continue to follow Military Department-specific policies that set the requirements for participation in weight loss programs. The memo also clarifies that the service-specific policies have not been removed by these PA changes. See Appendix J.
- **Luteinizing Hormone Releasing-Hormone (LHRH) Agents—**The quantity limit (QL) for leuprolide acetate depot injection (unbranded) was clarified as 1 kit per fill, similar to the other LHRH agents.
- **Rapid Acting Insulin Agents—**A PA was included on the Humalog Tempo Pen requiring a trial of the Humalog Kwikpen.
- **Androgens-Anabolic Steroids: Testosterone Replacement Therapies—**It was clarified that the PA criteria for the renewal include both the patient who has had a positive response to therapy AND the risks of continued therapy do not outweigh the benefits. Previously it was listed as OR. Additionally, the implementation for the Testosterone Replacement Therapies was moved from July 5th to July 12th due to the holiday.

2. August 2022

- **Atopy Agents—dupilumab (Dupixent)—**The requirement for a trial of phototherapy or topical calcineurin inhibitors in children will be removed from the PA, because these treatments are not FDA-approved for this age range.

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 (Tier 4 (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. Antilipidemics-1—Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors

Background—The P&T Committee evaluated the relative clinical effectiveness of the PCSK9 inhibitors, which reduce low density lipoprotein cholesterol (LDL-C). The two drugs in the class include alirocumab (Praluent) and evolocumab (Repatha). The PCSK9 inhibitors were previously reviewed for formulary status in November 2016 based on trials demonstrating reduction in LDL-C. Since then, two large cardiovascular outcomes studies have been published.

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

Efficacy

- Both alirocumab (Praluent) and evolocumab (Repatha) are injectable nonstatin therapies that provide significant reductions in LDL-C, ranging from 45% to 65%.
- In addition to lowering LDL-C, both PCSK9 inhibitors reduce major adverse cardiovascular events when used as secondary prevention, based on data from the ODYSSEY OUTCOMES trial with alirocumab, and the FOURIER trial with evolocumab.
- The drugs are FDA-approved for patients with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction (MI), stroke and

coronary revascularization (for Repatha) or to reduce the risk of MI, stroke and unstable angina requiring hospitalization (for Praluent).

- There is conflicting data between the FOURIER and ODYSSEY OUTCOMES trials with regard to effects on risk of cardiovascular (CV) death and all-cause death.
- The full mortality benefits of PCSK9s inhibitors are unknown due to early study termination.

Guidelines

- Recent updated guidance for nonstatins from the 2022 American College of Cardiology Expert Consensus Decision Pathway continue to support use of high intensity statins first-line for adults with atherosclerotic cardiovascular disease (ASCVD). The high intensity statins include atorvastatin 40 mg and 80 mg, and rosuvastatin 20 mg and 40 mg.
- PCSK9 inhibitors either alone or with ezetimibe can be considered in patients receiving maximally tolerated statin therapy who require a greater than 50% reduction in LDL-C.
- PCSK9 inhibitors may be considered for patients with clinical ASCVD at very high risk for future ASCVD events and who require a greater than 25% additional LDL lowering. Patients at very high risk for future ASCVD events include those with a history of major ASCVD events (i.e., recent acute coronary syndrome within the past 12 months, prior MI, prior ischemic stroke or symptomatic peripheral arterial disease), or those with one major ASCVD event and who have multiple high-risk conditions (e.g., age older than 65 years, heterozygous familial hypercholesterolemia, prior coronary revascularization, diabetes mellitus, hypertension, chronic kidney disease, current smoking, LDL-C > 100 mg/dL despite maximal statin therapy and history of chronic heart failure).
- The decision pathway now recommends lower LDL-C thresholds for starting nonstatin therapy, based on clinical status.
    - For patients with ASCVD at very high risk of future ASCVD events, the threshold for starting a nonstatin is an LDL-C > 55 mg/dL.
    - For patients with ASCVD not at very high risk of future ASCVD events, the threshold for starting a nonstatin is an LDL-C of > 70 mg/dL.

Safety

- Overall, the PCSK9 inhibitors are well tolerated, with injection site reactions reported most commonly. Alirocumab is associated with significantly more injection site reactions than evolocumab, based on systematic review and network meta-analysis.

- No major differences are seen between the PCSK9 inhibitors with regard to discontinuations due to adverse effects.

Other Factors

- *Other nonstatins:* The results of a CV outcomes trial (CLEAR OUTCOMES) with bempedoic acid (Nexletol, Nexlizet) were recently published. CV outcomes trials are currently ongoing with inclisiran (Leqvio injection), which is available under the TRICARE medical benefit.
- Both PCSK9 inhibitors are indicated for treating homozygous familial hypercholesterolemia (HoFH) and heterozygous familiar hypercholesterolemia (HeFH), which are rare genetic conditions causing highly elevated LDL-C levels. Repatha is indicated for patients as young as 10 years of age with HoFH or HeFH, while Praluent is only labeled for use in adults.
- Repatha is available in a prefilled syringe, autoinjector, and an on-body infusor (Pushtronex), while Praluent is solely available in an autoinjector.

Overall Clinical Effectiveness Conclusion

- Although head-to-head trials are not available, the two PCSK9 inhibitors are highly therapeutically interchangeable, systematic reviews and network meta-analyses.
- At least one PCSK9 inhibitor is required on the formulary to meet the needs of MHS beneficiaries.

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 (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that evolocumab (Repatha) is more cost effective than alirocumab (Praluent).
- BIA was performed to evaluate the potential impact of designating the PCSK9 inhibitors as UF, NF, or completely excluded from the formulary. BIA results showed that designating evolocumab (Repatha) as UF and step-preferred and alirocumab (Praluent) as UF and non-step-preferred demonstrated significant cost avoidance to the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the current formulary status for the PCSK9 inhibitors.

- UF and step-preferred
  - evolocumab (Repatha)
- UF and non-step-preferred
  - alirocumab (Praluent)
  - Note that as part of the formulary recommendation for Praluent, a trial of Repatha is required first.
- NF
  - None
- Complete exclusion
  - None

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria have been in place for the PCSK9 inhibitors since market entrance in 2015. In general, the following are currently required: specialist prescribing by a cardiologist; a trial of both high intensity atorvastatin and rosuvastatin, or if the patient is not on a high-intensity statin, they must be on ezetimibe plus a lower intensity statin, unless statin intolerance is documented; and renewal criteria are required after one year. Additionally, a trial of Repatha is required before Praluent.

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following changes to the criteria for new users. Reducing the requirement to try both high intensity atorvastatin and rosuvastatin to a trial of one high intensity statin and removing the requirement for specialist prescribing. Updates to the threshold LDL-C for patients with ASCVD were made, based on the ACC Expert Consensus Decision Pathway. Lastly, the requirement for renewal criteria was removed, and the PA will not expire. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining the current QLs for the PCSK9 inhibitors. See Appendix D.

4. ***COMMITTEE ACTION: EXPANDED MILITARY TREATMENT FACILITY (MTF)/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) maintaining Repatha and Praluent on the EMMPI program.

5. ***COMMITTEE ACTION: UF, PA, QL, EMMPI and IMPLEMENTATION PERIOD—*** The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) an effective date of the first

Wednesday 30 days after signing of the minutes in all points of service. See Appendix G for the actual implementation date.

B. Ophthalmic—Dry Eye Agents

Background—The P&T Committee evaluated the relative clinical effectiveness of the Ophthalmic Dry Eye Agents, which are used to treat keratoconjunctivitis sicca (dry eye disease) and vernal keratoconjunctivitis (VKC). The class is comprised of 4 formulations containing differing concentrations of cyclosporine [0.05% ophthalmic emulsion unit dose and multidose (Restasis, Restasis Multidose), 0.09% ophthalmic solution (Cequa), and 0.1% ophthalmic emulsion (Verkazia)], lifitegrast 5% ophthalmic solution (Xiidra), loteprednol 0.25% ophthalmic suspension (Eysuvis), and varenicline nasal solution (Tyrvaya). Restasis and Xiidra were previously reviewed for formulary status in February 2018, while the remaining drugs were reviewed individually as new drugs.

All the drugs are indicated for dry eye disease, except for Verkazia, which is only indicated for VKC.

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

Clinical Practice Guidelines

Dry Eye Disease

- The 2018 American Academy of Ophthalmology Preferred Practice Pattern (AAO PPP), and the 2017 Tear Film and Ocular Surface Society International Dry Eye Workshop II (TFOS DEWS II) recommend a stepwise treatment approach based on disease severity, and do not favor one product over another.
    - Ocular lubricants (e.g., artificial tears) are recommended as first-line (Step 1) treatments for dry eye disease, along with education, environmental changes, and eyelid hygiene.
    - Second-line (Step 2) treatments include cyclosporine, lifitegrast, or short course low-dose ophthalmic steroids (e.g., prednisolone, loteprednol).
    - The guidelines have not yet been updated to include the newer agents Cequa, Tyrvaya, or Eysuvis.

Vernal Keratoconjunctivitis (VKC)

- VKC is a rare disease causing severe ocular inflammation which can lead to corneal scarring and vision loss. It most commonly occurs in pediatric males living in warm, dry subtropical climates.
- The 2018 AAO PPP guidelines for VKC recommend a stepwise treatment approach based on disease severity, along with cool compresses and ocular lubricants.
    - Mild disease can be treated with ocular mast cell stabilizers (e.g., azelastine, olopatadine) and antihistamines, followed by topical corticosteroids for moderate disease severity, with severe disease requiring

treatment with the immunomodulatory therapies (cyclosporine and tacrolimus).

Efficacy

- There are no direct comparative studies between Restasis, Xiidra, Cequa, Tyrvaya, and Eysuvis for treatment of dry eye disease.
- *Dry Eye Disease:* A 2022 abstract from the Association for the Research in Vision and Ophthalmology (ARVO) Annual Meeting indirectly compared Cequa, Restasis, and Xiidra. There were no significant differences between the products with regard to patient subjective improvement, objective tests (Schirmer's tear test and tear osmolarity) and side effects. Limitations to this analysis include the retrospective study design and small sample size.
- *VKC*: No direct comparative data is available between Verkazia and lower dose cyclosporine agents for VKC treatment; however, the 2018 AAO PPP guidelines state that cyclosporine 0.05% is an appropriate option for treatment and has been effective in preventing seasonal recurrences.

Safety

- Ocular stinging and burning are common adverse effects with all the products. Unique safety features include the following:
  - Xiidra can cause dysgeusia.
  - Eysuvis carries warnings of delayed healing, intraocular pressure increase, cataracts, and risk of bacterial, viral, and fungal infections
  - Tyrvaya as a nasal spray has unique nasal symptoms including nasal irritation, coughing, and sneezing.

Individual Product Characteristics

- **cyclosporine 0.05% (Restasis)** has a well-established efficacy and safety profile. Full clinical response may take 3 to 6 months to occur. The unit-dose formulation is now available as a generic product, while the multi-dose formulation is still branded. Ocular burning and stinging are the most commonly reported adverse effects. MHS providers agreed that generic Restasis can be trialed before other dry eye agents.
- **cyclosporine 0.09% (Cequa)** provides a higher strength of cyclosporine but does not show compelling clinical benefits over Restasis or Xiidra.
- **cyclosporine 0.1% (Verkazia)** is a higher strength cyclosporine formulation specifically indicated to treat VKC.
  - Clinical trial data and guidelines (2018 AAO PPP) support efficacy of lower-strength cyclosporine formulations for treatment of severe VKC.
  - MHS providers agreed that a trial with other cyclosporine strengths is appropriate, and Verkazia should be reserved for severe VKC cases.

- **lifitegrast (Xiidra)** offers a different mechanism of action and potentially a faster onset of action compared to Restasis (as early as 2 weeks, with peak effect at 12 weeks vs. 6 months with cyclosporine), but there are no significantly compelling clinical benefits of Xiidra over Restasis.
- **loteprednol 0.25% (Eysuvis)** is currently the only loteprednol formulation to carry the FDA indication for short-term treatment of dry eye disease. However, guidelines (2018 AAO PPP and 2017 TFOS DEWS II) and MHS providers support the use of alternative loteprednol formulations, as well as other low-dose steroids for effective treatment. Ophthalmic steroids should only be used for short-term periods due to the risk of corneal perforation and increased ocular pressure. Eysuvis provides little-to-no clinical benefit over other ophthalmic steroid products. Note that loteprednol 0.2% (Alrex) and loteprednol 0.5% (Lotemax) and several other ophthalmic steroids are on the UF.
- **varenicline nasal spray (Tyrvaya)** has a unique mechanism of action using the parasympathetic pathway to increase tear production and does not cause ocular burning. However, Tyrvaya does not correct the underlying ocular inflammation. Sneezing, coughing and throat irritation can occur. MHS providers recommend a trial OTC artificial tears and generic cyclosporine or Xiidra first, before Tyrvaya. Its place in therapy remains unclear, and long-term benefit has not been determined.

Overall Clinical Conclusion

- In order to meet the needs of MHS patients, at least one ophthalmic immunomodulatory agent is needed to treat the majority of patients with dry eye disease and VKC.

Relative Cost Effectiveness Analysis and Conclusion—The Committee reviewed the solicited bids from manufacturers and conducted a CMA, BIA, and sensitivity analysis. The P&T Committee concluded (17 for, 0 opposed, 0 abstained, 1 absent) the following:

- CMA results showed that cyclosporine 0.05% (Restasis and Restasis MultiDose), lifitegrast 5% (Xiidra), cyclosporine 0.09% (Cequa), varenicline nasal spray (Tyrvaya), and cyclosporine 0.1% (Verkazia) were cost effective, and that loteprednol 0.25% (Eysuvis) was not 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 cyclosporine 0.05% (Restasis and Restasis MultiDose), lifitegrast 5% (Xiidra), and cyclosporine 0.09% (Cequa) as UF, with varenicline nasal spray (Tyrvaya) and cyclosporine 0.1% (Verkazia) as NF, and loteprednol 0.25% (Eysuvis) as completely excluded, demonstrated the greatest cost avoidance for the MHS.

1. ***COMMITTEE ACTION: UF RECOMMENDATION—***The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following:

   - UF
     - cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generics)
       - Note that as part of the formulary recommendation the current Tier 1 copay for brand Restasis unit dose was removed; the Tier 2 copay will now apply to branded Restasis.
     - cyclosporine 0.05% ophthalmic emulsion multidose (Restasis Multidose)
     - cyclosporine 0.09% ophthalmic solution (Cequa) – *moves from NF to UF*
     - lifitegrast 5% ophthalmic solution (Xiidra)
   - NF
     - cyclosporine 0.1% ophthalmic emulsion (Verkazia)
     - varenicline nasal solution (Tyrvaya)
   - Complete exclusion
     - loteprednol etabonate 0.25% ophthalmic solution (Eysuvis) – *moves from NF to complete exclusion*

2. ***COMMITTEE ACTION: MANUAL PA CRITERIA***—PA criteria has applied to all the products in the class since they were first reviewed individually for formulary status. In general, the following are required: specialist prescribing, a trial of two OTC lubricants (including preservative-free products), objective testing to confirm the diagnosis of dry eye disease or VKC, and renewal criteria, as the PAs expire in one year. Off-label use of Restasis is allowed for several conditions, including VKC.

   The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) the following changes to the PAs for new patients. For generic Restasis unit dose, Restasis Multidose, Cequa and Xiidra, the current 18 year age restriction and renewal criteria will be removed. For Restasis Multidose, Cequa and Xiidra, a 3-month trial of generic Restasis unitdose will now be required for dry eye disease. Cequa will also be authorized for patients with VKC without requiring a trial of Restasis first. For Verkazia, a trial of Restasis or Cequa is required.

   There were no changes to the current PA criteria for Tyrvaya, which requires trial of Restasis or Xiidra first. See Appendix C for the full criteria.

3. ***COMMITTEE ACTION: MEDICAL NECESSITY (MN) CRITERIA***— The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining the MN criteria currently in place for Tyrvaya and

updating the MN criteria for Verkazia to require a trial of Cequa in addition to Restasis. See Appendix B for the full criteria.

4. ***COMMITTEE ACTION: EXPANDED MTF/MAIL PHARMACY INITIATIVE (EMMPI) PROGRAM REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) maintaining branded Restasis, Tyrvaya, and Verkazia on the EMMPI program and removing Xiidra and Cequa from the EMMPI program.

5. ***COMMITTEE ACTION: MAIL ORDER AUTO-REFILL REQUIREMENTS***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) excluding Restasis, Cequa, Xiidra, Verkazia and Tryvaya from the Auto-Refill program at the TRICARE Mail Order Pharmacy.

6. ***COMMITTEE ACTION: UF, MN, PA, EMMPI and AUTO-REFILL PROGRAM IMPLEMENTATION PERIOD***—The P&T Committee recommended (17 for, 0 opposed, 0 abstained, 1 absent) an effective date of the first Wednesday 60 days after signing of the minutes in all points of service for Restasis, Cequa, Xiidra, Verkazia, and Tryvaya, and an effective date of the first Wednesday 120 days after signing of the minutes in all points of service for Eysuvis. DHA will send letters to patients affected by the complete exclusion status of Eysuvis. See Appendix G for the actual implementation date.

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

The products were divided into two groups when presented at the P&T Committee meeting. The generic names are provided below. Group 1 included Krazati, Atorvaliq, Orserdu, Rezvoglar, Konvomep, Stimufend, and Jaypirca; Group 2 was comprised of Amjevita, Altuviiio, Filspari, Pradaxa, Daybue, and Tezspire.

Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions—The P&T Committee agreed (for both group 1 and group 2: 17 for, 0 opposed, 0 abstained, 1 absent) with the relative clinical and cost-effectiveness analyses presented for the newly approved drugs reviewed according to 32 CFR 199.21(g)(5). See Appendix E for the complete list of newly approved drugs reviewed at the May 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 (for group 1 and group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following:

    - UF

- adagrasib (Krazati) – Oncological agent for advanced or metastatic non-small cell lung cancer
- antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl vial (Altuviiio) – Antihemophilic Factors
- elacestrant (Orserdu) – Oncological agent for breast cancer
- omeprazole and sodium bicarbonate 2 mg/mL oral suspension (Konvomep) – Proton Pump Inhibitors
- pegfilgrastim-fpgk injection (Stimufend) – White Blood Cell Stimulants: pegfilgrastims
- pirtobrutinib (Jaypirca) – Oncological agent for relapsed or refractory mantle cell lymphoma
- sparsentan (Filspari) – Nephrology Miscellaneous Agent for immunoglobulin A nephropathy
- tezepelumab-ekko autoinjector (Tezspire) – Atopy Agent for add on maintenance severe asthma treatment
- trofinetide 200 mg/mL oral solution (Daybue) – Neurological Miscellaneous Agent for treatment of Rett syndrome

- NF
  - adalimumab-atto injection (Amjevita) – Targeted Immunomodulatory Biologics (TIBS); Humira biosimilar
  - atorvastatin 20 mg/5 mL oral suspension (Atorvaliq) – Antilipidemics-1 agents
  - dabigatran oral pellet packets (Pradaxa pellets) – Direct Acting Oral Anticoagulant for treatment of venous thromboembolism (VTE) in pediatric patients aged 3 months to less than 12 years
  - insulin glargine KwikPen (Rezvoglar) – Basal Insulins; Lantus biosimilar

- Tier 4 (complete exclusion) - None

2. ***COMMITTEE ACTION: MN CRITERIA***—The P&T Committee recommended (for group 1 and group 2: 17 for, 0 opposed, 0 abstained, 1 absent) MN criteria for Amjevita, Atorvaliq, Pradaxa and Rezvoglar. See Appendix B for the full criteria.

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended (for both group 1 and group 2: 17 for, 0 opposed, 0 abstained, 1 absent) the following PA criteria (see Appendix C for the full criteria):

- Applying manual PA criteria to new users of the Amjevita (the biosimilar to Humira), similar to what is required for all non-step-preferred TIBs. A trial of brand Humira is required first before the biosimilar in new users.
- Oncologic drugs: Applying manual PA criteria to new users of Krazati, Jaypirca, and Orserdu.
- Applying manual PA criteria to new users of Atorvaliq oral suspension, Pradaxa oral pellets, Filspari, Rezvoglar, Konvomep oral suspension, Daybue oral solution, and Tezspire injection.
- Applying manual PA criteria to Stimufend, similar to what is in place for the other non-step-preferred pegfilgrastims. New patients receiving Stimufend or one of the other non-step-preferred pegfilgrastims (Neulasta, Neulasta Onpro, and Ziextenzo) will be required to have a trial of Nyvepria, Udenyca or Fulphila first.

4. ***COMMITTEE ACTION: QUANTITY LIMITS (QLs)***—The P&T Committee recommended (for group 1: 16 for, 1 opposed, 0 abstained, 1 absent; and for group 2: 17 for, 0 opposed, 0 abstained, 1 absent) QLs for Krazati, Orserdu, Jaypirca, Amjevita, Altuviiio, Daybue, and Tezspire. See Appendix D for the QLs.

5. ***COMMITTEE ACTION: EMMPI PROGRAM***—The P&T Committee recommended (for group 1 and group 2: 17 for, 0 opposed, 0 abstain, 1 absent)) adding or exempting the drugs listed in Appendix F to/from the Select Maintenance List (EMMPI List) for the reasons outlined in the table. Note that the Add/Do Not Add recommendations listed in Appendix F pertain to the combined list of drugs under the EMMPI program and the NF to mail requirement.

6. ***COMMITTEE ACTION: UF, MN, PA, QL, and EMMPI IMPLEMENTATION PERIOD***—The P&T Committee recommended (for group 1 and group 2: 17 for, 0 opposed, 0 abstain, 1 absent) an effective date of the following:
   - **New Drugs Recommended for UF or NF Status**: An effective date of the first Wednesday two weeks after signing of the minutes in all points of service; see Appendix G.

VI. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. New Manual PA Criteria

a) **Gastrointestinal-2 Agents—sacrosidase oral solution (Sucraid)—**Sucraid is approved to treat patients with Congenital Sucrase-Isomaltase Deficiency (CSID).

Sucraid was identified as a high-cost, specialty medication with increasing utilization. Many commercial health plans require PA for Sucraid, and MTF providers support the addition of a prior authorization restricting it to its FDA-approved indication.

COMMITTEE ACTION: SACROSIDASE ORAL SOLUTION (SUCRAID)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria in new and current users of Sucraid, limiting use to patients who have a CSID diagnosis and symptoms. The new PA will become effective the first Wednesday 60 days after the signing of the minutes, and DHA will send letters to affected patients. See Appendix C for the full criteria.

b) Thyroid Agents—levothyroxine sodium capsule (Tirosint)—Tirosint is a formulation that does not contain some common excipients (e.g., dyes, gluten, etc.) found in other levothyroxine formulations. However, Tirosint is not cost-effective relative to generic levothyroxine tablets or Synthroid. MTF providers support the addition of a prior authorization, to encourage use of more cost-effective levothyroxine formulations.

COMMITTEE ACTION: LEVOTHYROXINE SODIUM CAPSULES (TIROSINT)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) manual PA criteria in new users of Tirosint capsules requiring a trial or contraindication to generic levothyroxine tablets or Synthroid first. The new PA will become effective the first Wednesday 60 days after the signing of the minutes. See Appendix C for the full criteria.

2. Updated PA Criteria for New FDA-Approved Indications

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

a) Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)—abrocitinib (Cibinqo)— The manual PA criteria were updated to include the new expanded age indication for adolescents with refractory, moderate-to-severe atopic dermatitis. Cibinqo is now approved for patients 12 years of age and older. In addition, the new PA criteria were edited to allow for pediatric patients to try and fail, have a contraindication to, or intolerability to any topical corticosteroid (as opposed to a high potency topical corticosteroid).

b) **Breast Cancer Agents: Cyclin-Dependent Kinase (CDK) Inhibitors—** abemaciclib (Verzenio)—The manual PA criteria were updated to remove the requirement for patients to have a high Ki-67 score.

c) **Corticosteroid-Immune Modulators for Hereditary Angioedema (HAE) Prophylaxis—lanadelumab (Takhzyro)—**Expands the HAE prophylaxis indication to include patients 2 years of age and older.

d) **Immunological Agents Miscellaneous: Oral Agents—**house dust mite allergen extract (Odactra)—Manual PA criteria were updated to reflect the expanded pediatric age indication. Odactra is now approved for patients ranging from 12 to 65 years of age.

e) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors—zanubrutinib (Brukinsa)—**A new indication was added for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adults.

f) **Oncological Agents—tucatinib (Tukysa)—**The manual PA criteria were updated for Tukysa to allow for use in combination with trastuzumab for the treatment of RAS wild-type, HER2-positive, unresectable, or metastatic colorectal cancer in adults that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

g) **Therapeutic Continuous Glucose Monitoring Systems (CGMS)—Freestyle Libre 2 and 3**—The Freestyle Libre 2 and 3 systems are now approved for use in pregnant patients. The manual PA criteria were updated to change the requirement that patient had a diagnosis of "type 1 or type 2 diabetes" to a requirement that patients just have a diagnosis of "diabetes". Patients will still need to meet all additional PA requirements as last specified at the November 2022 meeting.

COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria for Brukinsa, Odactra, Takhzyro, Tukysa, Cibinqo, Verzenio and Freestyle Libre 2 and 3 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) **Antipsychotic Agents: Atypical—olanzapine/samidorphan (Lybalvi)—**Lybalvi was reviewed as an innovator at the November 2021 meeting and designated non-formulary with a PA. Although Lybalvi was associated with approximately 5 pounds less weight gain than olanzapine alone, several other options are available to mitigate antipsychotic-induced weight gain, including choosing a different antipsychotic (e.g., aripiprazole and ziprasidone) or adding on metformin. The

P&T Committee recommended clarifying the PA criteria to include these other options. In addition, the medical necessity criteria were changed to require a trial of four formulary agents including one olanzapine containing product (i.e., olanzapine or olanzapine/fluoxetine) and aripiprazole, ziprasidone, and lurasidone.

b) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)—liraglutide (Victoza) and exenatide once weekly (Bydureon BCise)—**Dulaglutide (Trulicity) is the DoD's preferred GLP1RA, and it was previously only indicated for adults. Victoza and Bydureon BCise are indicated for patients as young as 10 years of age. The Victoza and Bydureon BCise PAs currently bypass the requirement to try Trulicity first in pediatric patients. The Trulicity package label was recently updated to allow for use in children 10 years of age and older, based on the results of a clinical trial. The P&T Committee recommended removing both the PA and MN criteria that allow the bypass of a trial of Trulicity first for pediatric patients with prescriptions for Victoza and Bydureon BCise.

c) **Oncological Agents: Lung Cancer—sotorasib (Lumakras)—**Previously, Lumakras had only been available as a 120 mg tablet. In order to get the recommended dose of 960 mg, a patient needed to take eight tablets. A new 320 mg tablet is now available which only requires a patient to take three tablets, but it is significantly less cost-effective than the 120 mg formulation. Both the 120 mg and 320 mg tablets can be dispersed in 4 ounces of water for patients who have swallowing difficulties. MTF provider feedback supports the addition of prior authorization criteria preferring the Lumakras 120 mg tablets over the 320 mg tablets.

> ***COMMITTEE ACTION: UPDATED MANUAL PA CRITERIA, MEDICAL NECESSITY CRITERIA, AND IMPLEMENTATION PERIOD—***The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) updates to the manual PA criteria and medical necessity criteria for olanzapine/samidorphan (Lybalvi), liraglutide (Victoza), and exenatide (Bydureon BCISE) in new users, and updates to the manual PA criteria for new users of sotorasib (Lumakras) 320 mg tablets. Implementation will be effective the first Wednesday 60 days after signing of the minutes. See Appendix B and Appendix C for the full criteria.

d) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors Agents—adalimumab (Humira)—**The PA criteria for Humira were updated to allow for approval if the prescriber specialty is Rheumatology. Humira is a high value medication, and the inclusion of this new PA criteria enables rheumatologists, who possess advanced training and certification, to prescribe Humira without having to complete a PA. This change will also encourage appropriate use of this preferred product.

> ***COMMITTEE ACTION: ADALIMUMAB (HUMIRA)—NEW PA CRITERIA AND IMPLEMENTATION PERIOD—***The P&T Committee

recommended (16 for, 0 opposed, 0 abstained, 2 absent) updated manual PA criteria in new users of Humira allowing for PA approval if the prescriber is a rheumatologist. The new PA will become effective the first Wednesday 30 days after the signing of the minutes. See Appendix C for the full criteria.

5. **Removal of PA**

   a) **Diabetes Non-Insulin: Thiazolidinediones (TZDs) and Dipeptidyl Peptidase-4 inhibitors (DPP-4s)—** Several diabetes drug classes are available on the formulary, and new products are now recommended first-line in addition to metformin, including the GLP1RAs (e.g., Trulicity) and SGLT-2 inhibitors (e.g., Jardiance). However, older classes still play a role in lowering glucose levels. The American Diabetes Association 2023 guidelines includes guidance for using the TZDs and DPP-4 inhibitors before metformin.

   The UF preferred TZD pioglitazone and UF preferred DPP-4 inhibitor sitagliptin and their combination products are cost-effective, with high PA approval rates. Additionally, the TZDs and DPP-4 inhibitors have a low likelihood for off-label use (in contrast to the GLP1RAs.) The P&T Committee recommended removing the PA requirements for the UF TZD and DDP-4 inhibitors. PA will still remain for the NF, non-step-preferred TZD (e.g., rosiglitazone) and DPP-4 inhibitors (e.g., linagliptin, saxagliptin).

   COMMITTEE ACTION: REMOVAL OF PA CRITERIA AND IMPLEMENTATION PLAN—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) removing the PA criteria for pioglitazone (Actos), pioglitazone/metformin (Actoplus Met), pioglitazone/glimepiride (Duetact), sitagliptin (Januvia), and sitagliptin/metformin (Janumet, Janumet XR). Implementation will be effective the first Wednesday 2 weeks after signing of the minutes.

B. Line Extensions

The P&T Committee clarified the formulary status for seven 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) **Atopy Agents—**designating mepolizumab (Nucala) 40 mg prefilled syringe with the same formulary status (UF), PA, QL, Specialty program, and EMMPI status as the parent Nucala 100 mg syringe.

b) **Hematological Agents: Sickle Cell Anemia Agents—**designating voxelotor (Oxbryta) 300 mg tablets with the same formulary status (UF), PA and Specialty status as the parent Oxbryta 300 mg tablets for oral suspension.

c) **Laxatives-Cathartics-Stool Softeners: Bowel Preparations—**designating Na picosulfate, MgO, anhydrous citric acid (Clenpiq) 10 mg-3.5 g-12 g/175 mL with the same formulary status (UF) as the parent Clenpiq 10 mg-3.5 g-12 g/160 mL.

d) **Leukemia and Lymphoma: Bruton Tyrosine Kinase (BTK) Inhibitors—** designating ibrutinib (Imbruvica) oral suspension with the same formulary status (UF), PA, QL, and Specialty status as the parent Imbruvica capsules.

e) **Oncological Agents**—designating pexidartinib (Turalio) 125 mg capsule with the same formulary status (UF), PA, QL, and Specialty program status as the parent Turalio 200 mg capsules.

f) **Oncological Agents: Second-Generation Antiandrogens—**designating apalutamide (Erleada) 240 mg tablet with the same formulary status (UF, non-step preferred), PA, QL, and Specialty program status as the parent Erleada 60 mg tablets.

g) **Pulmonary Arterial Hypertension (PAH) Agents: Prostacyclins—**designating treprostinil extended-release (Orenitram ER) 1, 2, and 3 month titration packs with the same formulary status (UF), PA and Specialty program status as the parent Orenitram ER tablets.

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD— The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, Specialty program, and EMMPI status of the line extension products, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes.

VII. BRAND OVER GENERIC AUTHORIZATION AND TIER 1 COPAY FOR FLUTICASONE/SALMETEROL (ADVAIR HFA), LENALIDOMIDE (REVLIMID) AND TOPIRAMATE ER (TROKENDI XR)

The Committee evaluated drugs from 3 classes that are currently UF:

- Pulmonary Is: Inhaled Corticosteroid/Long-Acting Beta Agonist Inhalers—fluticasone/salmeterol HFA inhaler (Advair HFA)
- Oncological Agents: Multiple Myeloma—lenalidomide (Revlimid)
- Anticonvulsant-Anti Mania Agents—topiramate ER (Trokendi XR)

AB-rated generic versions of all three drugs have entered the market; however, the generic products are less cost-effective compared to the branded agents. Therefore, the branded Advair HFA, Revlimid, and Trokendi XR 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 Advair HFA, Revlimid, and Trokendi XR dose is recommended.

The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) requiring brand Advair HFA, Revlimid and Trokendi XR over their respective generic formulations in all new and current users at all points of service, based on cost effectiveness. The

prescriber will provide patient-specific justifications as to why the branded product cannot be used. The Tier 1 (generic) copay will apply to the brand Advair HFA, Revlimid and Trokendi XR. Advair HFA will also remain on the EMMI list. The effective date will be the first Wednesday 60-days after signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to AB-rated generics.

COMMITTEE ACTION: BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (17 for, 0 opposed, 1 abstained, 0 absent) requiring brand Advair HFA, Revlimid, and Trokendi XR over their respective generic formulations 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 Advair HFA, Revlimid, and Trokendi XR. The effective date will be 60 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics.

VIII. OVER-THE-COUNTER (OTC) DRUG BENEFIT—NALOXONE NASAL SPRAY (OTC NARCAN NASAL)

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

OTC Naloxone Nasal: The P&T Committee evaluated the clinical and cost-effectiveness for the addition of OTC nasal naloxone 4 mg/0.1mL (OTC Narcan Nasal Spray) to the UF. Other prescription naloxone formulations are available on the UF (Kloxxado, Zimhi), with prescription Narcan nasal designated with BCF status. The OTC naloxone nasal spray is the same as the prescription product.

Multiple references, including guidance from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, and the 2022 DoD/VA Guideline for the Use of Opioids in Management of Chronic Pain, as well as input from DoD pain management specialists, support the use of intranasal naloxone for the emergency treatment of known or suspected opioid overdose. Based on clinical effectiveness and ease of access, OTC naloxone nasal (4 mg/0.1mL) was recommended for addition to the UF, when the product is launched

commercially (expected in summer 2023). QLs currently exist for the class and were recommended for the OTC product.

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

- adding OTC naloxone 4 mg/0.1 mL nasal spray to the UF
- waiving the copay requirement
- waiving the prescription requirement
- applying the current quantity limit of 2 cartons per fill at all POS (Retail/MTF/Mail) (note each carton contains 2 devices)
- implementation plan of two weeks after signing of the minutes and market launch of OTC Narcan nasal in all points of service

The P&T Committee voted to waive the prescription and copay requirements. While the P&T Committee voted to waive the requirement for a prescription at all points of service, there may be state or operational limitations that require some provider input for processing. As an example, some states allow pharmacists who have National Provider Identifier (NPI) numbers to prescribe but the pharmacy claims adjudication systems may require a valid prescription. According to National Council for Prescription Drug Programs (NCPDP) rules, a provider NPI is required for claims to process.

Regarding copay, 32 CFR 199.21(i)(2)(xii) states as a general rule, OTC drugs placed on the UF will have copayments equal to those for generic drugs on the UF. However, upon the recommendation of the P&T Committee and approval of the Director, DHA, the copayment may be established at $0.00 for any particular OTC drug in the retail pharmacy network. The P&T Committee recommended the copay for OTC naloxone be zero at retail and the Tier 1 generic copay at mail.

Note that additional considerations of dispensing OTC naloxone (e.g., distribution to first responders) fall outside the scope of P&T Committee.

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

NF medications are generally restricted to the Mail Order program 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.

- Atopy agents
- LHRH agonists-antagonists
- Multiple sclerosis agents
- Oncological Agents: 2nd Generation Antiandrogens (oral)
- Oncological Agents: Melanoma agents (oral)
- Targeted Immunomodulatory Biologics (TIBs)

COMMITTEE ACTION: EXPANDED MAINTENANCE MEDICATION PROGRAM DRUG LIST—The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 0 absent) addition of appropriate agents in these six 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. 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.

X. ITEMS FOR INFORMATION

A. Commercial Trends

The DoD P&T Committee was updated on MHS prescribing patterns, including overall trends and spends, utilization by point of service, comparative costs across points of service, and comparison of DoD to commercial trends, including percent spend on specialty medications, drug classes experiencing the greatest growth, and the top 20 individual medications by total cost. Other information included the near-term forecast for biosimilar and generic introduction and a comparison of DoD and average commercial copays.

B. DoD/VA Continuity of Care List Annual Review

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

C. Ruxolitinib (Opzelura) and coverage for Nonsegmental Vitiligo

The P&T Committee reviewed use of ruxolitinib (Opzelura) to treat nonsegmental vitiligo. Although Opzelura treats the depigmentation caused by vitiligo, it has no other known

functional impacts. Medication intended to treat depigmentation is excluded by federal regulation [32 CFR 199.4(e)(8)] and Tricare Policy Manual [Chapter 4, Section 2.1], therefore, no update to coverage for this indication was recommended. Opzelura remains covered for treatment of atopic dermatitis.

D. Specialty Medications

The P&T Committee was updated on potential changes regarding procurement and dispensing of specialty pharmaceuticals through the TRICARE Mail Order Program under the 5th Generation TRICARE Pharmacy Service (TPharm5) contract.

XI. ADJOURNMENT

The meeting adjourned at 1630 hours on May 4th. The next meeting will be in August 2023.

Appendix A—Attendance: May 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 February 2023 DoD P&T Committee Meeting
Appendix G—Implementation Dates
Appendix H—Completely Excluded Agents (Tier 4) and Therapeutic Alternatives
Appendix I—Table of Administrative Authorities
Appendix J—Prescribing Weight Loss Medications to Active-Duty Service Members memo

DECISION ON RECOMMENDATIONS

SUBMITTED BY:

//sign

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:

//sign

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

26 Jul 2023
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, COL (Ret.), MC, USA	DoD P&T Committee Chair
COL Paul Carby, MSC for Mr. Edward Norton	Chief, DHA Pharmacy Operations Division (POD)
Ed VonBerg, PharmD	Chief, Formulary Management Branch (Recorder)
LTC Rosco Gore, MC	Army, Internal Medicine Physician
Ruben Salinas, 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 Bridgette Faber, MSC	Navy, Pharmacy Consultant
Col Larissa Weir, MC	Air Force, OB/GYN Physician
Capt Courtney Clutter, MC	Air Force, Internal Medicine Physician
Col Soo Sohn, BSC, for Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	Physician at Large, DHA
Maj Blair Destefano, MC	Oncology Physician, Air Force
Beth Days, RPh, BCOP	Oncology Pharmacist
CDR Chris Janik, USCG	Coast Guard, Pharmacy Consultant
COL Yang Xia, MC	TRICARE Latin America and Canada

Appendix A—Attendance

Nonvoting Chartered Members	
Ms. Megan Gemunder	Attorney Advisor, Contract Law
Eric Parsons, RPh	TPharm5 Clinical COR, Purchased Care Branch
Eugene Moore, PharmD	TPharm4 Clinical COR, Purchased Care Branch
Dean Valibhai, PharmD	TPharm5 Clinical COR, Purchased Care Branch
CAPT Bill Kelly, MSC	DLA
Richard Ruck, MD	TRICARE Health Plan Chief Medical Officer
Pete Glassman, MD	Department of Veteran's Affairs
Ms. Marsha Peterson	DHA Contracting Officer
Guests	
CDR Phung Thien Nguyen, USPHS	Senior Executive Officer, DHA Pharmacy Operations Division
Major Greg Palmrose, BSC	DHA Direct Care Branch
Ms. Tracy Banks	DHA Contracting
Ms. Stephanie Erpelding	DHA Contracting
Ms. Sheila Mirrieles	DHA Contracting
Others Present	
CDR Scott Raisor, BCACP, 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
LCDR Elizabeth Hall, BCPS, USPHS	DHA Formulary Management Branch
Maj Angelina Escano, MC	DHA Formulary Management Branch
LCDR Giao Phung, MSC	DHA Formulary Management Branch
LT Stephanie Klimes, MC	DHA Formulary Management Branch
Julia Trang, PharmD	DHA Formulary Management Branch
Ellen Roska, PharmD, PhD	DHA Formulary Management Branch,
Mr. David Folmar	DHA Formulary Management Branch Contractor
Mr. Kirk Stocker	DHA Formulary Management Branch Contractor

Appendix A—Attendance

Mr. Michael Lee	DHA Formulary Management Branch Contractor
Ms. Martha Hutchinson	DHA Formulary Management Branch Contractor

Appendix B—Table of Medical Necessity Criteria

Drug / Drug Class	Medical Necessity Criteria
Drug Class Reviews MN Criteria	
• cyclosporine 0.1% ophthalmic emulsion (Verkazia) **Ophthalmic: Dry Eye**	**Changes from May 2023 meeting are in BOLD** • Formulary agents result or are likely to result in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis) **AND** cyclosporine 0.09% (Cequa)
• varenicline nasal solution (Tyrvaya) **Ophthalmic: Dry Eye**	**Changes from May 2023 meeting are in BOLD** • Formulary agents have resulted in therapeutic failure **Formulary alternatives:** cyclosporine 0.05% (Restasis/Multidose), lifitegrast 5% (Xiidra), **cyclosporine 0.09% (Cequa)**
New Drugs MN Criteria	
• atorvastatin oral suspension (Atorvaliq) **Antilipidemics-1**	• No alternative formulary agent: Patient requires simvastatin, atorvastatin, or rosuvastatin and cannot swallow all formulary alternatives **Formulary alternatives:** rosuvastatin tablets and sprinkles, simvastatin tablets, atorvastatin tablets
• insulin glargine KwikPen (Rezvoglar) **Insulins: Basal**	• Patient has experienced significant adverse effects from formulary agents **Formulary alternatives:** insulin glargine (Lantus), insulin glargine U-300 (Toujeo)
• adalimumab-atto injection (Amjevita) **TIBs: Tumor Necrosis Factor Inhibitors**	• Patient has experienced significant adverse effects from all formulary agents **Formulary alternatives:** adalimumab (Humira), certolizumab (Cimzia), ustekinumab (Stelara)
• dabigatran oral pellets (Pradaxa) **Anticoagulants: Oral anticoagulants**	• Use of all formulary agents is contraindicated • Patient has experienced significant adverse effects from all formulary agents • All formulary agents resulted in therapeutic failure • Patient previously responded to all non-formulary agents and changing to a formulary agent would incur unacceptable risk **Formulary alternatives:** enoxaparin (Lovenox), rivaroxaban (Xarelto), dabigatran capsules (Pradaxa)

Appendix B—Table of Medical Necessity Criteria

Utilization Management Updated MN Criteria	
• olanzapine/samidorphan (Lybalvi) **Atypical Antipsychotic Agents**	**Updates from the May 2023 meeting are in bold and strikethrough** • Patient has experienced significant adverse effects from ~~**two**~~ **four** formulary agents **including one olanzapine containing product (olanzapine or olanzapine/fluoxetine) AND aripiprazole, ziprasidone, and lurasidone** **Formulary alternatives:** olanzapine/fluoxetine, olanzapine, aripiprazole, ziprasidone, and lurasidone
• liraglutide (Victoza) • exenatide once weekly (Bydureon BCise) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	**Updates from the May 2023 meeting are in bold and strikethrough** • Patient has experienced significant adverse effects from dulaglutide (Trulicity) and semaglutide (Ozempic) which is not expected with the non-preferred products. • ~~**No alternative formulary agent - for Victoza and Bydureon BCise only: patient is between the ages of 10 to less than 18 years**~~ Formulary and non-formulary alternatives: dulaglutide (Trulicity) semaglutide (Ozempic), and **tirzepatide (Mounjaro)**

Appendix C—Table of Prior Authorization (PA) Criteria

Drug / Drug Class	Prior Authorization Criteria
Drug Class Review PAs	

• evolocumab (Repatha)
 	
PCSK9 Inhibitor
	Changes from May 2023 meeting are in BOLD and strikethrough
	
	PA applies to new patients
	
	Manual PA Criteria: evolocumab (Repatha) is approved if all criteria are met
	
	• ~~The initial prescription is written by a cardiologist, lipidologist, or endocrinologist.~~
	
	For HoFH and HeFH
	
	• For heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH), the patient is 10 years of age or older.
	
	• The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol.
	
	• The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses.
	
	For ASCVD
	
	• The patient is at least 18 years of age for clinical atherosclerotic cardiovascular disease (ASCVD).
	
	• ~~The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >70 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below:~~
	
	• **The patient has established ASCVD with the following LDLs, despite maximally tolerated statin doses:**
	
	  • **Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high risk conditions. *Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information*) OR**
	
	  • **Not at very high risk of events: LDL > 70 mg/dL**
	
	  AND
	
	  • The patient must have tried **either** ~~both~~ atorvastatin 40-80 mg **or** ~~and~~ rosuvastatin 20-40 mg, OR
	
	  • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR
	
	  • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy ~~with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants)~~, AND
	
	  • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy.
	
	• For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below:
	
	  • Intolerance
	
	  ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND
	
	  ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR

Appendix C—Table of Prior Authorization (PA) Criteria

	▪ The patient has had a creatine kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. • Contraindication to statin ▪ The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) *For all FDA-approved indications* • Repatha is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • Repatha is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: • 140 mg every 2 weeks, or • 420 mg every 4 weeks. Note that only patients with HoFH will be allowed to use 3 of the 140 mg syringes to make the 420 mg dose. **PA does not expire** ~~PA expires in one year.~~ ~~• PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, and lipidologist. Continued use of Repatha will be approved for the following:~~ ~~• The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND~~ ~~The patient has documented adherence~~
• alirocumab (Praluent) **PCSK9 Inhibitor**	**Changes from May 2023 meeting are in BOLD and strikethrough** Manual PA criteria apply to all new users of alirocumab (Praluent). ~~All new users of alirocumab (Praluent) are required to try evolocumab (Repatha) first~~. <u>Manual PA criteria:</u> Praluent is approved if: *For HoFH and HeFH* ~~• The initial prescription is written by a cardiologist, lipidologist, or endocrinologist.~~ • For HeFH and HoFH, patient is at least 18 years of age and older. • The patient has homozygous familial hypercholesterolemia (HoFH) and is receiving other LDL-lowering therapies (e.g., statin, ezetimibe, LDL apheresis), and requires additional lowering of LDL cholesterol. • The patient has heterozygous familial hypercholesterolemia (HeFH) and is on concurrent statin therapy at maximal tolerated doses. *For ASCVD* • The patient is at least 18 years of age for clinical ASCVD. ~~• The patient has established atherosclerotic cardiovascular disease (ASCVD) with an LDL >100 mg/dL despite statin therapy at maximally-tolerated doses, according to the criteria below:~~ • **The patient has established atherosclerotic cardiovascular disease (ASCVD) with the following LDLs, despite maximally tolerated statin doses:** • **Very high risk of events: LDL > 55 mg/dL (very high risk of events includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high risk conditions. *Refer to the 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of ASCVD for more information*) OR**

	• **Not at very high risk of events: LDL > 70 mg/dL** **AND** • The patient must have tried **either** ~~both~~ atorvastatin 40-80 mg **or** ~~and~~ rosuvastatin 20-40 mg, OR • The patient must have tried any maximally-tolerated statin in combination with ezetimibe, OR • If the patient is statin-intolerant, they must have tried at least ezetimibe monotherapy ~~with or without other lipid-lowering therapy (e.g., fenofibrate, niacin, bile acid sequestrants)~~, AND • The patient must have had a trial of at least 4-6 weeks of maximally-tolerated therapy. • For both HeFH and ASCVD: If the patient is not on concurrent statin therapy, the patient is either intolerant of statins or has a contraindication to statins as defined below: • Intolerance ▪ The patient has experienced intolerable and persistent (for longer than 2 weeks) muscle symptoms (muscle pain, weakness, cramps), AND ▪ The patient has undergone at least 2 trials of statin re-challenges with reappearance of muscle symptoms, OR ▪ The patient has had a creatin kinase (CK) level >10x ULN and/or rhabdomyolysis with CK > 10,000 IU/L that is unrelated to statin use. • Contraindication to statin ▪ The contraindication must be defined (active liver disease, hypersensitivity, pregnancy, breastfeeding) *For all FDA-approved indications* • Praluent is not approved for any indication other than HoFH, HeFH, or clinical ASCVD. • **The patient has tried and failed therapy with evolocumab (Repatha) OR** • **The patient has experienced a significant adverse reaction to evolocumab (Repatha) that is not expected to occur with alirocumab (Praluent)** • Praluent is not approved for patients who are pregnant or lactating. • The dosage must be documented on the PA Form as either: • 75 mg every 2 weeks, or • 150 mg every 2 weeks. **PA does not expire** ~~PA expires in one year.~~ ~~• PA criteria for renewal: After one year, PA must be resubmitted. The renewal request may be submitted by a primary care provider in consultation with the initial prescribing cardiologist, endocrinologist, and lipidologist. Continued use of Repatha will be approved for the following:~~ ~~• The patient has a documented positive response to therapy with LDL < 70 mg/dL (or LDL ↓ >30% from baseline), AND~~ ~~The patient has documented adherence~~

Appendix C—Table of Prior Authorization (PA) Criteria

• cyclosporine 0.05% ophthalmic emulsion unit dose (Restasis, generic unit dose) **Ophthalmic Dry Eye**	**Updates from the May 2023 meeting are in Bold and strikethrough** ~~**Patients younger than 18 years of age do not require a PA**~~ **Manual PA criteria apply to all new users of cyclosporine 0.05% ophthalmic emulsion unit-dose (Restasis unit-dose, generic)** ~~Automated PA: If there is no Restasis, Cequa, or Xiidra prescription in the past 120 days, a manual PA is required.~~ Manual PA criteria: Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • ~~The patient is 18 years of age or older~~ • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: ▪ Positive symptomology screening for moderate to severe dry eye disease from an appropriate measure ▪ At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systame, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) • Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. • Restasis unit-dose is also approved for the following conditions: graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC) / vernal keratoconjunctivitis (VKC), and LASIK associated dry eye (limited to 3 months of therapy) **Other** Non-FDA-approved uses are not approved. ~~PA expires in one year.~~ **PA does not expire** ~~Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely if all criteria are met:~~ ~~• The drug is prescribed by an ophthalmologist or optometrist.~~ ~~• The patient must have documented improvement in ocular discomfort.~~ ~~The patient must have documented improvement in signs of dry eye disease.~~

Appendix C—Table of Prior Authorization (PA) Criteria

• cyclosporine 0.05% ophthalmic multi dose (Restasis Multidose) • cyclosporine 0.09% ophthalmic (Cequa) • lifitegrast 5% ophthalmic solution (Xiidra) **Ophthalmic Dry Eye**	**Updates from May 2023 are in BOLD and strikethrough** **Manual PA criteria apply to all new users of Restasis Multidose, Cequa and Xiidra** ~~PA criteria apply to all new and current users~~. ~~A new user is defined as a patient who has not filled a prescription for Cequa in the past 120 days.~~ • ~~If there is no Restasis, Cequa, or Xiidra prescription in the past 120 days, a manual PA is required.~~ Manual PA Criteria: Coverage is approved if all the criteria are met: • The drug is prescribed by an ophthalmologist or optometrist • ~~For Cequa: the patient is 18 years of age or older~~ • A diagnosis of moderate to severe dry eye disease is supported by both of the criteria below: ▪ Positive symptomatology screening for moderate to severe dry eye disease from an appropriate measure ▪ At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test) • Patient must try and fail the following: ▪ At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube]) ▪ Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol) ▪ **3-month trial of cyclosporine 0.05% unit dose** • Concomitant use of Restasis, Cequa, or Xiidra is NOT allowed. • **Cequa is approved if the patient has a diagnosis of Vernal Keratoconjunctivitis (VKC)** **Other** Non-FDA-approved uses are NOT approved. ~~PA expires in one year.~~ **PA does not expire** ~~Renewal Criteria: Coverage will be approved indefinitely if all criteria are met:~~ • ~~The drug is prescribed by an ophthalmologist or optometrist.~~ • ~~The patient must have documented improvement in ocular discomfort.~~ ~~The patient must have documented improvement in signs of dry eye disease~~
• cyclosporine 0.1% ophthalmic emulsion (Verkazia) **Ophthalmic Dry Eye**	**Updates from May 2023 are in BOLD and strikethrough** Note that an age edit and automated look back apply. • Patients who are younger than 21 years of age who have a history of Restasis **or Cequa** do not require a PA; Verkazia is approved • Patients who are younger than 21 years of age who do not have a history of Restasis **or Cequa** require manual PA • Manual PA is required in all new patients 21 years of age and older Automated PA criteria: The patient is younger than age 21 years AND has filled a prescription for cyclosporine 0.05% ophthalmic solution (Restasis) **or cyclosporine 0.09% (Cequa)** at any MHS pharmacy point of service (MTFs, retail network pharmacies, or mail order) during the previous 720 days.

Appendix C—Table of Prior Authorization (PA) Criteria

	Manual PA Criteria: If automated criteria are not met, coverage is approved for Verkazia if all criteria are met: • Verkazia is prescribed by or in consultation with an optometrist or ophthalmologist • Patient has a diagnosis of moderate to severe vernal keratoconjunctivitis (VKC) • Patient has tried and failed an adequate course of at least one mast cell stabilizer/antihistamine (i.e., olopatadine, azelastine, epinastine, lodoxamide, cromolyn) • Patient has tried and failed, or has a contraindication to an adequate course of cyclosporine 0.05% ophthalmic emulsion (Restasis) **or the patient has tried and failed, or has a contraindication to an adequate course of cyclosporine 0.09% (Cequa)** Non-FDA-approved uses are NOT approved including dry eye disease, graft rejection/graft versus host disease (GvHD), corneal transplant, atopic keratoconjunctivitis (AKC), and LASIK associated dry eye PA does not expire

• varenicline nasal solution (Tyrvaya)
 	
Ophthalmic Dry Eye
	Note – there were no changes to the current PA criteria
	
	Manual PA criteria apply to all new users of Tyrvaya.
	
	Manual PA criteria: Tyrvaya is approved if all criteria are met:
	• The patient is 18 years of age or older
	• Tyrvaya is prescribed by an ophthalmologist or optometrist
	• Patient has a diagnosis of dry eye disease as supported by both of the criteria below:
	  • Positive symptomology screening for dry eye disease from an appropriate measure
	  • At least one positive diagnostic test (e.g., Tear Film Breakup Time, Osmolarity, Ocular Surface Staining, Schirmer Tear Test)
	• Patient must try and fail the following:
	  • At least 1 month of one ocular lubricant used at optimal dosing and frequency (e.g., carboxymethylcellulose [Refresh, Celluvisc, Thera Tears, Genteal, etc.], polyvinyl alcohol [Liquitears, Refresh Classic, etc.], or wetting agents [Systane, Lacrilube])
	  • Followed by at least 1 month of a different ocular lubricant that is non-preserved at optimal dosing and frequency (e.g., carboxymethylcellulose, polyvinyl alcohol)
	• If the patient has moderate to severe dry eye dissease:
	  • Patient has tried and failed an adequate course (at least 6 weeks) of treatment of lifitegrast or cyclosporine treatment
	
	Non-FDA-approved uses are not approved.
	Prior Authorization expires after 1 year
	
	Renewal Criteria: (Initial TRICARE PA approval is required for renewal) Coverage will be approved indefinitely if all criteria are met:
	• The drug is prescribed by an ophthalmologist or optometrist.
	• The patient must have documented improvement in ocular discomfort.
	• The patient must have documented improvement in signs of dry eye disease.

Appendix C—Table of Prior Authorization (PA) Criteria

Newly Approved Drug PAs	
• adagrasib (Krazati) **Oncological Agents: Lung Cancer**	Manual PA criteria apply to all new users of adagrasib (Krazati) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a hematologist or oncologist The patient has a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test • The patient will be monitored for QTC prolongation, gastrointestinal adverse reactions, hepatotoxicity, and interstitial lung disease • If patient is a female, the patient will avoid breastfeeding during treatment and for at least 1 week after cessation of treatment • The diagnosis is NOT listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation Other non-FDA approved uses are NOT approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• adalimumab-atto injection (Amjevita)
 	
TIBS: Tumor Necrosis Factor Inhibitors
	Manual PA criteria apply to all new and current users of adalimumab-atto (Amjevita)
	
	Manual PA criteria: Coverage is approved if all criteria are met:
	• Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations
	• Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient
	  ○ Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Amjevita biosimilar.
	• If patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease
	  ○ If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older
	  ○ If indication is moderate to severe Crohn's disease patient must be 6 years of age or older AND must have had an inadequate response to non-biologic systemic therapy (For example: methotrexate, aminosalicylates [such as, sulfasalazine, mesalamine], corticosteroids, immunosuppressants [such as, azathioprine], etc. unless they have fistulizing Crohn's disease
	• If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, and hidradenitis suppurativa
	  ○ If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease
	  ○ If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months
	• Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira
	• Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed)
	• Patient is not receiving other targeted immunomodulatory biologics with Humira, including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER)
	
	Non-FDA approved uses are NOT approved
	PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• atorvastatin oral suspension (Atorvaliq) **Antilipidemics-1**	Manual PA criteria apply to all new users of atorvastatin oral suspension (Atorvaliq) Age edit: PA does not apply to patients younger than 12 years of age (Age edit) PA criteria apply to all new users of Atorvaliq 12 years of age and older Manual PA criteria: Coverage is approved if all criteria are met: • Provider must explain why patient requires atorvastatin oral suspension and cannot take simvastatin, atorvastatin or rosuvastatin tablets or sprinkles ○ Acceptable responses include that the patient requires a high intensity statin and cannot swallow the statin tablets due to some documented medical condition (e.g., dysphagia, oral candidiasis, systemic sclerosis), and not due to convenience, and cannot take Ezallor sprinkles Non-FDA approved uses are NOT approved PA does not expire
• dabigatran oral pellet (Pradaxa) **Anticoagulant: Oral Anticoagulant**	Manual PA criteria apply to all new users of dabigatran oral pellets (Pradaxa) Age edit: PA does not apply to patients less than 8 years of age (age edit) AND who have tried Xarelto Suspension OR Lovenox Injection within the past 180 days Manual PA criteria: Coverage is approved if all criteria are met: • Patient is between the ages of 3 months to 12 years • The drug is prescribed by or in consultation with a pediatric hematologist/oncologist or pediatric cardiologist • Patient is being treated for venous thromboembolic events AND has been treated with parenteral anticoagulant for at least 5 days • Patient has tried and failed or has a contraindication to Xarelto Suspension AND Lovenox Injection • Patient is between the ages of 8 and 12 years and cannot take the Pradaxa capsule Non-FDA approved uses are NOT approved PA does not expire
• elacestrant (Orserdu) **Oncological Agents: Breast Cancer**	Manual PA criteria apply to all new users of elacestrant (Orserdu) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • Patient is a male or a postmenopausal female • The medication is prescribed by or in consultation with a hematologist or oncologist • The patient has a diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer • Patient had disease progression following at least one line of endocrine therapy, which must include a CDK4/6 inhibitor • Patient does not have severe hepatic impairment (Child-Pugh C) • 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 Other non-FDA approved uses are NOT approved except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• insulin glargine KwikPen (Rezvoglar) **Basal Insulin**	Manual PA criteria apply to all new and current users of Rezvoglar Kwikpen Manual PA criteria: Coverage is approved if all criteria are met: • Patient must have tried and failed insulin glargine (Lantus) first. Non-FDA approved uses are NOT approved PA does not expire
• omeprazole and sodium bicarbonate 2 mg/mL oral suspension (Konvomep) **Proton Pump Inhibitors**	Manual PA criteria apply to all new users of omeprazole and sodium bicarbonate oral suspension (Konvomep) Age edit: PA does not apply to patients younger than 12 years of age (Age edit) PA criteria apply to all new users of Konvomep 12 years of age and older Manual PA criteria: Coverage is approved if all criteria are met: Manual PA criteria: Coverage is approved if all criteria are met: • The provider must provide patient-specific clinical rationale as to why the patient cannot take omeprazole capsules, pantoprazole tablets, or esomeprazole capsules • Acceptable response: Patient has a G-tube or patient cannot swallow other PPI capsules or tablets due to some documented medical condition – dysphagia, oral candidiasis, systemic sclerosis, etc. and not due to convenience Non-FDA approved uses are NOT approved PA does not expire
• pegfilgrastim-fpgk injection (Stimufend) **White Blood Cell Stimulants: Pegfilgrastims**	Manual PA criteria apply to all new users of pegfilgrastim (Neulasta), pegfilgrastim (Neulasta OnPro), pegfilgrastim-bmez (Ziextenzo) **and pegfilgrastim-fpgk (Stimufend)** Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) and pegfilgrastim-apgf (Nyvepria) are the preferred pegfilgrastims and are available without a PA • Drug is prescribed by or in consultation with a hematologist/oncologist • For Neulasta OnPro only: 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-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) or pegfilgrastim-apgf (Nyvepria) and is expected to respond to pegfilgrastim (Neulasta), pegfilgrastim-bmez (Ziextenzo), or **pegfilgrastim-fpgk (Stimufend)** Non-FDA approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• pirtobrutinib (Jaypirca) **Oncological Agents**	Manual PA criteria apply to all new users of pirtobrutinib (Jaypirca) Manual PA criteria: Coverage is approved if all criteria are met: • Patient is 18 years of age or older • The medication is prescribed by or in consultation with a hematologist or oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment • The diagnosis Is not listed above but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____ Other non-FDA approved uses are not approved, except as noted above PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• sparsentan (Filspari) **Nephrology Agents Miscellaneous**	Manual PA criteria apply to all new users of sparsentan (Filspari) Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that Filspari is only available through a Risk Evaluation and Mitigation Strategies (REMS) program due to the risk of hepatotoxicity and embryo-fetal toxicity, and will follow the monitoring requirements • Patient is 18 years of age or older • Filspari is prescribed by a nephrologist • The patient has a diagnosis of biopsy-verified primary immunoglobulin A nephropathy (IgAN) without cellular crescents in more than 25% of sampled glomeruli • Patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/gram • Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73 m^2 • Patient is not currently receiving dialysis or has not undergone kidney transplant • Patient has not received immunosuppressants, including corticosteroids, in the past 2 weeks and is not expected to need immunosuppressants in the next 6 months • Patient has continued to have proteinuria despite maximal ACE-inhibitor or ARB therapy and is at high risk for disease progression • The patient is not receiving concomitant renin-angiotensin-aldosterone system inhibitors (for example ACE-inhibitors or ARBs such as irbesartan, telmisartan, losartan; or spironolactone), endothelin receptors antagonists (for example ambrisentan or bosentan) or aliskiren). • The patient's baseline liver aminotransferase (AST and ALT) levels are not elevated to greater than 3 times the upper limit of normal • If patient is a female of child-bearing age, the patient must be tested for pregnancy before, during and 1 month after treatment discontinuation • If patient can become pregnant, they will use effective contraception before starting treatment, during and for 1 month after treatment discontinuation Non-FDA approved uses are NOT approved, including IgAN due to systemic lupus erythematosus, liver cirrhosis, Henoch-Schonlein purpura, or pulmonary arterial hypertension, or focal segmental glomerulosclerosis (FSGS) PA expires in 9 months Renewal criteria: coverage will be approved indefinitely if all the following apply • Patient has had a response to Filspari defined by: o reduction in urine protein-to-creatinine ratio (UPCR) from baseline OR o reduction in proteinuria from baseline • Patient's eGFR rate ≥ 30 mL/min/1.73 m2 • Filspari is not being used in combination with any RAAS blocker (e.g., ACE-Is, ARB), endothelin receptor antagonists, or aliskiren

Appendix C—Table of Prior Authorization (PA) Criteria

• tezepelumab-ekko autoinjector (Tezspire) **Atopy**	Manual PA is required for all new users of tezepelumab (Tezspire) <u>Manual PA Criteria</u>: Tezspire coverage will be approved if all criteria are met: • The patient is 12 years of age and older • The patient has a diagnosis of severe persistent asthma • The drug is prescribed by an allergist, immunologist, or pulmonologist • Provider acknowledges the FDA warnings and precautions associated with Tezspire • The patient's asthma must be uncontrolled, despite adherence to optimized medication therapy regimen, defined as requiring ONE of the following: o Hospitalization for asthma in past year OR o Two courses of corticosteroids for asthma exacerbation in past year OR o Daily high-dose inhaled corticosteroids with inability to taper off the inhaled corticosteroids • The patient has tried and failed an adequate course (3 months) of TWO of the following while using a high-dose inhaled corticosteroid: o Long-acting beta agonist (LABA e.g., Serevent, Striverdi), OR o Long-acting muscarinic antagonist (LAMA e.g., Spiriva, Incruse), OR o Leukotriene receptor antagonist (e.g., Singulair, Accolate, Zyflo) Non-FDA-approved uses are not approved Prior authorization expires after 12 months <u>Renewal Criteria</u>: Note initial Tricare PA approval is required for renewal. Renewal PA criteria will be approved indefinitely if all the following apply • The patient has had a positive response to therapy, as defined by one of the following: o a decrease in asthma exacerbations o improvements in forced expiratory volume in one second (FEV1) o decrease in oral corticosteroid use
• trofinetide oral solution (Daybue) **Neurological Agents Miscellaneous**	Manual PA criteria apply to all new users of trofinetide (Daybue) <u>Manual PA criteria:</u> Coverage is approved if all criteria are met: • Patient is 2 years of age and older • The medication is prescribed by a geneticist, neurologist, or a developmental pediatrician • The patient has a diagnosis of Rett Syndrome with documented MECP2 gene mutation. Non-FDA approved uses are NOT approved PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

Utilization Management New PAs	
• levothyroxine sodium capsule (Tirosint) **Thyroid Agents**	Manual PA criteria apply to all new users of levothyroxine capsules (Tirosint) Manual PA criteria: Tirosint is approved if all criteria are met: • Tirosint is prescribed by or in consultation with an endocrinologist • Patient is 6 years of age or older • Patient must have tried and failed or have a contraindication to levothyroxine tablets that is not expected to occur with levothyroxine capsules Non-FDA approved uses are NOT approved PA does not expire
• sacrosidase oral solution (Sucraid) **Gastrointestinal-2 Agents**	Manual PA criteria apply to all new and current users of sacrosidase (Sucraid) Manual PA criteria: Coverage is approved if all criteria are met: • Sucraid is prescribed by or in consultation with a gastroenterologist or geneticist • Patient has a diagnosis of congenital sucrase-isomaltase deficiency (CSID) • Prior to starting therapy with Sucraid, patient had symptomatic CSID (e.g., diarrhea, bloating, abdominal cramping) Non-FDA approved uses are NOT approved PA does not expire
Utilization Management Updated PAs	
• adalimumab (Humira) **Targeted Immunomodulatory Biologics (TIBs): Tumor Necrosis Factor (TNF) Inhibitors**	**Updates from the May 2023 meeting are in bold.** **Automated PA Criteria: If the provider is a Rheumatologist (Internal Medicine or Pediatric). PA is approved.** Manual PA Criteria: **If automated criteria are not met for Rheumatologist prescribing,** Humira is approved if all criteria are met: Coverage is approved for patients 18 years of age or older with one of the following diagnoses/indications: • Moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), or active ankylosing spondylitis (AS) • Moderate to severe chronic plaque psoriasis (Ps) who are candidates for systemic therapy or phototherapy • Moderate to severely active Crohn's disease (CD) • Moderate to severely active ulcerative colitis (UC) • Moderate to severe hidradenitis suppurativa (HS) • Non-infectious intermediate, posterior, and panuveitis • Active non-radiographic axial spondyloarthritis (nr-ax SpA) with objective signs of inflammation • Moderately to severely active pyoderma gangrenosum (PG) that is refractory to high-potency corticosteroids OR • Coverage approved for pediatric patients 12-17 years of age with diagnosis of: • Moderate to severe hidradenitis suppurativa (HS) Coverage approved for pediatric patients 6-17 years of age with diagnosis of: • Moderate to severely active Crohn's disease (CD) Coverage approved for pediatric patients 5-17 years of age with diagnosis of:

	• Moderately to severely active ulcerative colitis (UC) Coverage approved for pediatric patients 4-17 years of age with diagnosis of: • Severe chronic plaque psoriasis who are candidates for systemic or phototherapy and when other systemic therapies are medically less appropriate OR Coverage approved for pediatric patients 2-17 years of age with one of the following diagnosis/indication: • Moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) • Non-infectious intermediate, posterior, and panuveitis Below criteria applies to AS indication only: • Patient has had an inadequate response to at least two NSAIDs over a period of at least two months Below criteria applies to adult patients for all indications except for fistulizing Crohn's disease, ankylosing spondylitis (AS), and pyoderma gangrenosum (PG), psoriatic arthritis (PsA) and applies to pediatric patients with plaque psoriasis or Crohn's disease: • Patient has had an inadequate response to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine]) Below criteria applies to all patients (regardless of age): • Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Humira. Is the prescriber aware of this? • Patient has evidence of a negative TB test result in past 12 months (or TB is adequately managed) Coverage for non-FDA-approved uses not listed above: Please provide the diagnosis and rationale for treatment. Supportive evidence will be considered. Prior authorization does not expire. Coverage is NOT provided for concomitant use with other TIBs including, but not limited to, the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER).

Appendix C—Table of Prior Authorization (PA) Criteria

• abrocitinib (Cibinqo) **Atopy Agents: Oral Janus Kinase Inhibitor (JAK-1)**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of abrocitinib (Cibinqo). Manual PA criteria: abrocitinib (Cibinqo) is approved if all criteria are met: • Patient is **12 ~~18~~** years of age or older • Medication is prescribed by an allergist, dermatologist, or immunologist • Drug is used to treat moderate to severe atopic dermatitis • Provider acknowledges that the requested medication is to be used for disease that is not adequately controlled with other systemic drug products including biologic, or when use of those therapies is inadvisable. • Patient failed, has a contraindication, or intolerability to one medication in each of the following four categories: 1. Topical Corticosteroids: ▪ **For patients 18 years of age or older:** high potency/class 1 topical corticosteroids (e.g., clobetasol propionate 0.05% ointment/cream, fluocinonide 0.05% ointment/cream). ▪ **For patients 12 to 17 years of age: any topical corticosteroid.** 2. Topical calcineurin inhibitor (e.g.,pimecrolimus, tacrolimus). 3. Injectable interleukin antagonist: dupilumab (Dupixent). 4. Oral JAK: upadacitinib (Rinvoq). • Provider is aware of the boxed FDA warnings. • Patient is unable to access, has a contraindication to, or intolerability to UVB phototherapy. • Patient has had a negative TB test in the last 12 months (or is adequately managed). • Patient has no history of venous thromboembolism (VTE). • Patient does not have neutropenia (ANC < 1000). • Patient does not have lymphocytopenia (ALC < 500). • Patient does not have anemia (Hgb < 8 mg/dL). • Patient is not taking a concomitant JAK inhibitors, immunosuppressants, or biologic immunomodulatory agents. Non-FDA-approved uses are not approved. PA expires in 1 year. Renewal PA criteria will be approved indefinitely. Renewal criteria: (initial TRICARE PA approval is required for renewal) The patient's disease severity has improved and stabilized to warrant continued therapy.

Appendix C—Table of Prior Authorization (PA) Criteria

• abemaciclib (Verzenio)
 	
Breast Cancer Agents: CDK Inhibitors
	Updates from the May 2023 meeting are in bold and strikethrough.
	
	Manual PA criteria apply to all new users of Verzenio.
	
	Manual PA Criteria: Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack is approved if all of the following criteria are met:
	
	• Drug is prescribed by or in consultation with an oncologist
	• The patient is not currently taking another cyclin-dependent kinase inhibitor
	• For Verzenio only: The patient has hormone receptor HR(+)/HER2(-), node(+) early breast cancer at high risk of recurrence **~~and a Ki67 score ≥ 20%~~** as determined by an FDA approved test.
	• The patient has advanced or metastatic hormone receptor (HR(+))/HER2(-) breast cancer
	• If the patient is female, the patient meets one of the following criteria:
	  • Ibrance, Verzenio, Kisqali, or Kisqali Femara Co-Pack will be used as first-line endocrine therapy in combination with anastrozole, exemestane, or letrozole; OR
	  • Ibrance, Verzenio, Kisqali or Kisqali Femara Co-Pack will be as first-line or later-line endocrine therapy in combination with fulvestrant; OR
	  • For Verzenio only: Will be used as monotherapy following metastatic progression on chemotherapy
	• If the patient is a premenopausal or perimenopausal woman, she is receiving ovarian suppression/ablation with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex [goserelin]), surgical bilateral oophorectomy, or ovarian irradiation.
	• Provider is aware and has informed the patient of the risks of neutropenia and interstitial lung disease
	• For Ibrance only: provider is aware and has informed the patient of the risk of pulmonary embolism
	• For Verzenio only: provider is aware and has informed the patient of the risk of venous thromboembolism, diarrhea, and hepatotoxicity
	• For Kisqali and Kisqali Femara Co-Pack only: provider is aware and has informed the patient of the risk of QT prolongation and hepatobiliary toxicity
	• Female patients of childbearing age are not pregnant confirmed by (-) HCG
	• Female patients will not breastfeed during treatment and for at least 3 weeks after the cessation of treatment
	• Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 3 weeks after cessation of therapy if female; and for 3 months if male if using Ibrance only
	• Male patients have been informed of the risk of infertility
	• For Kisqali Femara Co-Pack only, female patients have been informed of the risk of infertility from letrozole
	• 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:_____.
	
	Non-FDA approved uses are not approved, except as noted above
	
	Prior authorization does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

• Freestyle Libre 2 and 3 **CGM: Therapeutic ontinuous Glucose Monitoring Systems**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Abbott FreeStyle Libre 3 Manual PA criteria: Coverage is approved if all criteria are met: • *Patients who have previously received a CGM under the medical benefit must still fill out prior authorization criteria* • Patient has a diagnosis of ~~**type 1 or type 2**~~ 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 ~~**a Type 2 diabetes mellitus**~~ 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 (≥ 2 years if Dexcom G6, ≥ 4 years if FreeStyle Libre 2, 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

Appendix C—Table of Prior Authorization (PA) Criteria

• house dust mite allergen extract (Odactra) **Immunological Agents Miscellaneous: Oral Agents**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Odactra. Manual PA criteria: Coverage will be approved if all criteria are met: • Odactra is prescribed by an allergist/immunologist AND • The patient is between the ages of ~~18~~ **12** and 65 years AND • The patient has a diagnosis of house dust mite (HDM) allergic rhinitis confirmed with either a positive skin test or an in vitro test for pollen-specific for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites AND • The patient's symptoms of allergic rhinitis have not been controlled with a nasal corticosteroid (e.g., fluticasone) AND at least one of the following: oral antihistamine, nasal antihistamines, or a leukotriene receptor antagonist (montelukast) OR • The patient has a diagnosis of HDM-related allergic rhinitis and allergic asthma that has not responded to an adequate trial of inhaled steroids, and the patient's FEV1 >70% AND • The patient has received the first dose in the office setting and was observed for 30 minutes with no allergic reactions noted AND • The patient has a prescription for self-administered SC epinephrine AND • The patient does not have a history of severe local allergic reaction to sublingual immunotherapy AND • Patient is not receiving co-administered SC immunotherapy AND • Patient does not have severe, uncontrolled, unstable asthma Other off-label uses other than allergic asthma are not approved. PA expires in 6 months. Renewal Criteria: Coverage will be continued indefinitely if the patient has responded positively to treatment and is not receiving co-administered SC immunotherapy and does not have sever, uncontrolled unstable asthma.
• lanadelumab (Takhzyro) **Corticosteroid-Immune Modulators for Hereditary Angioedema Prophylaxis (HAE)**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Orladeyo, Takhzyro, Cinryze, and Haegarda. Manual PA criteria: Orladeyo, Takhzyro, Cinryze, or Haegarda is approved if all apply: • Patient Age ▪ For Orladeyo, the patient is 12 years of age or older ▪ For Takhzyro, the patient is ~~12~~ **2** years of age or older ▪ For Cinryze, the patient is 13 years of age or older • The patient has a diagnosis of hereditary angioedema (HAE) • Orladeyo, Takhzyro, Cinryze or Haegarda is prescribed by an allergist, immunologist, or rheumatologist, or in consultation with an HAE specialist • The patient must have monthly HAE attacks or a history of severe attacks that require prophylaxis treatment (i.e., ≥2 HAE attacks/month, laryngeal attacks, etc.) • The patient is not currently receiving another drug for HAE prophylaxis (e.g., Orladeyo, Takhzyro, Cinryze or Haegarda will not be used concomitantly) Non-FDA-approved uses NOT approved. Prior Authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• liraglutide (Victoza) • exenatide (Bydureon BCISE) **Non-Insulin Diabetes Drugs: Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs)**	**Changes from the May 2023 meeting are in bold and strikethrough.** All new users of a GLP1RA are required to try metformin before receiving a GLP1RA. Patients currently taking a GLP1RA must have had a trial of metformin first. New users of Bydureon BCise, Byetta, Victoza, or Adlyxin, must try Trulicity and Ozempic first. Manual PA criteria—Bydureon BCise, Byetta, Victoza, or Adlyxin is approved (i.e., a trial of metformin is NOT required) if: • The patient has a confirmed diagnosis of Type 2 diabetes mellitus. • The patient has experienced any of the following issues on metformin: ▪ impaired renal function precluding treatment with metformin ▪ history of lactic acidosis • The patient has had inadequate response to metformin • The patient has a contraindication to metformin AND In addition to the above criteria regarding metformin the following PA criteria would apply specifically to new users of Bydureon BCise, Byetta, Victoza, and Adlyxin: • The patient has had an inadequate response to Trulicity and Bydureon BCise Ozempic • ~~**For Victoza and Bydureon BCise, patient is age 10 years to < 18 years.**~~ Non-FDA-approved uses are not approved. Prior Authorization does not expire
• olanzapine/samidorphan (Lybalvi) **Antipsychotic Agents: Atypical**	**Updates from the May 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Lybalvi. Manual PA criteria: Lybalvi is approved if all criteria are met: • Patient is 18 years of age or older • Patient has a documented diagnosis of schizophrenia or bipolar 1 disorder • **Patient has tried either olanzapine alone or olanzapine/fluoxetine combination (Symbyax generic) and experienced significant weight gain or other metabolic complications (i.e., worsening diabetes, new sleep apnea, development of NASH or obesity hypoventilation syndrome)** • **Patient has tried and failed either aripiprazole or ziprasidone** • ~~**Patient has tried and had an adverse event to at least 2 antipsychotic agents**~~ • ~~**Provider must indicate the drug, date of initiation, duration of therapy, and whether the patient had an adverse reaction or failure to therapy of other therapies tried**~~ ▪ ~~**Drug: Date_____ Duration of therapy _____Adverse Reaction _____ Therapeutic Failure _____**~~ ▪ ~~**Drug: Date_____ Duration of therapy _____Adverse Reaction _____ Therapeutic Failure _____**~~ Non-FDA-approved uses are not approved including major depressive disorder, fibromyalgia, or other mood disorders. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• sotorasib (Lumakras) **Oncological Agents: Lung Cancer**	**Updates from the May 2023 meeting are in bold.** Manual PA criteria apply to all new users of Lumakras. Manual PA criteria: Lumakras is approved if all criteria are met: • Patient is 18 years of age or older • Patient has laboratory evidence of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test • **The provider acknowledges that sotorasib 120 mg tablets are significantly more cost effective than sotorasib 320 mg tablets** • **If the prescription is for sotorasib 320 mg, the patient cannot tolerate sotorasib (Lumakras) 120 mg tablets dispersed in water per manufacturer instructions and has documented swallowing dysfunction.** • The patient will be monitored for interstitial lung disease and hepatotoxicity • The drug is prescribed by or in consultation with a hematologist/oncologist • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior authorization does not expire.
• tucatinib (Tukysa) **Oncological Agents**	**Updates from the May 2023 meeting are in bold.** Manual PA is required for all new users of Tukysa. Manual PA Criteria: Tukysa is approved if all criteria are met: • Patient is 18 years of age or older • Medication is prescribed by or consultation with a hematologist or oncologist • The patient has a confirmed diagnosis of unresectable or metastatic HER2-positive breast cancer (including patients with brain metastases) and has received at least one prior anti-HER2-based regimen in the metastatic setting AND Tucatinib will be used in combination with trastuzumab (Herceptin) and capecitabine (Xeloda) **OR** • **The patient has a confirmed diagnosis of RAS wild-type, HER2-positive, unresectable, or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy AND tucatinib will be used in combination with trastuzumab** • Provider agrees to monitor for hepatotoxicity • Patient has been counseled on risk of diarrhea • Female patients of childbearing age are not pregnant confirmed by (-) HCG • Female patients will not breastfeed during treatment and for at least 1 week after the cessation of treatment • Both male and female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of therapy • Patient has a diagnosis for another indication that is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. Prescriber must provide specific diagnosis for documentation. Non-FDA approved uses are not approved except as noted above. Prior authorization does not expire.

Appendix C—Table of Prior Authorization (PA) Criteria

• zanubrutinib (Brukinsa) **Leukemia and Lymphoma Agents: Bruton Tyrosine Kinase (BTK) Inhibitors**	**Updates from the May 2023 meeting are in bold.** Manual PA apply to all new users of Brukinsa. Manual PA Criteria: Brukinsa is approved if all criteria are met: • Patient is 18 years of age or older • Prescribed by or in consultation with a hematologist/oncologist • Patient has pathologically confirmed relapsed or refractory mantle cell lymphoma (MCL) OR • Patient has Waldenström's macroglobulinemia (WM), a rare non-Hodgkin lymphoma OR • Patient has relapsed or refractory marginal zone lymphoma (MZL) who have received at least 1 anti-CD20-based regimen OR • **Patient has chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)** • Monitor for bleeding, infection (including opportunistic infection), cardiac arrhythmias, secondary primary malignancies, and cytopenias • Patient will use sun protection in sun-exposed areas • Female patients of childbearing age and are not pregnant confirmed by (-) HCG. • Female patients will not breastfeed during treatment and for at least 2 weeks after the cessation of treatment • Female patients of childbearing potential agree to use effective contraception during treatment and for at least 1 week after the cessation of treatment • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Other non-FDA-approved uses are not approved. Prior Authorization does not expire.

Appendix D—Table of Quantity Limits (QL)

Drug / Drug Class	Quantity Limits
• alirocumab (Praluent) **PCSK9 Inhibitors**	▪ Retail: 2 syringes/30 days ▪ MTF and Mail Order: 6 syringes/90 days
• evolocumab (Repatha) **PCSK9 Inhibitors**	▪ Retail: 2 x 140 mg syringes/30 days (prefilled syringe or autoinjector) ▪ MTF and Mail Order: 6 x 140 mg syringes/90 days (prefilled syringe or autoinjector) ▪ Repatha Pushtronex o Retail: 1 infusor device o MTF and Mail Order: 3 infusor devices
• adagrasib (Krazati) **Oncological Agents: Lung Cancer**	▪ Retail/MTF/Mail: 60-day supply
• elacestrant (Orserdu) **Oncological Agents**	▪ Retail/MTF/Mail: 60-day supply
• pirtobrutinib (Jaypirca) **Oncological Agents**	▪ Retail/MTF/Mail: 60-day supply
• adalimumab-atto (Amjevita) **Oncological Agents**	▪ Retail/MTF/Mail: 60-day supply
• antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl (Altuviiio) **Antihemophilic Factors**	▪ Retail/MTF/Mail: 30-day supply
• trofinetide (Daybue) **Neurological Agents, Miscellaneous.**	▪ Retail/MTF/Mail: 30-day supply
• tezepelumab-ekko (Tezspire) **Atopy**	▪ Retail: 1 device ▪ MTF/Mail: 2 devices
• OTC naloxone 4mg/0.1 mL nasal spray	▪ Retail/MTF/Mail: 2 cartons per fill; note each carton contains 2 devices

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
adagrasib (Krazati) **Oncological Agents: Lung Cancer**	• sotorasib (Lumakras)	Formulation: • 200 mg film-coated tablets Dosing: • 600 mg PO BID until disease progression or unacceptable toxicity • Dose reduction/ interruption for adverse events	• For adults with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer, as determined by FDA approved test, who have received at least one prior systemic therapy	ADRs (≥25%) • nausea, diarrhea, vomiting • fatigue • musculoskeletal pain • hepatotoxicity • renal impairment • edema • dyspnea • ↓ appetite (≥2%) Grade 3/4 lab abnormalities: • ↓lymphocytes • ↓hemoglobin • ↑AST/ALT • ↑alkaline phosphatase • ↓ K; ↓ NA • ↑lipase • ↓leukocytes • ↓neutrophils	• Second oral inhibitor of KRAS G12C (Lumakras was first) • Phase 2 study demonstrated an overall response rate (ORR) of 42.9% • Approved under accelerated approval based objective response rate and duration of response; continued approval may be contingent upon confirmatory trials • High incidence of GI side effects; can cause QTc prolongation, hepatotoxicity or worsening of interstitial lung disease • No direct comparisons to Lumakras which was also approved via accelerated approval with a single-arm phase 2 study • NCCN guidelines make the same recommendation for Krazati and Lumakras as subsequent therapy options after at least one prior systemic treatment • Patients who progressed on one of the agents should not attempt to switch to the other • Provides no compelling clinical advantage over existing agents	• UF • Do not add to EMMI List

adalimumab-atto injection (Amjevita) **TIBS**	• adalimumab (Humira)	Formulations: • 40 mg/0.8 mL single-use prefilled autoinjector, and prefilled syringe 20 mg/0.4 mL single-use prefilled glass syringe; citrate free • Dosing: Varies based on indication	• Rheumatoid Arthritis • Juvenile Idiopathic Arthritis • Psoriatic Arthritis • Ankylosing Spondylitis • Adult Crohn's Disease • Ulcerative Colitis • Plaque Psoriasis • Hidradenitis Suppurativa	ADRs (> 10%): • infections (e.g., upper respiratory, sinusitis) • injection site reactions • headache • rash	• First Humira biosimilar to launch out of eight FDA approved Humira biosimilar products • Label does not have all the FDA-indications found in the Humira label • Two phase 3 studies demonstrated similar clinical efficacy, safety, and immunogenicity to the reference product • One of the phase 3 studies demonstrated similar clinical efficacy, safety, and immunogenicity after a single transition from reference product to Amjevita • Provides no compelling clinical advantage over existing agents	• NF non-step-preferred • Add to EMMI List
Antihemophilic factor recombinant, (Altuviiio) **Antihemophilic Factors**	• emicizumab-KXWH (Hemlibra) • Anti-hemophilic Factor - Recombinant, Fc Fusion Protein (Eloctate)	Formulation: • In kits with single-dose vials containing 250, 500, 750, 1000, 2000, 3000, or 4000 IU of Factor VIII potency, Dosing: • <u>Routine prophylaxis</u>: 50 IU/kg IV injection every week • <u>Treatment/ Control</u>: 30 or 50 IU/kg IV PRN bleeding every 2 to 3 days • <u>Perioperative dose</u>: 50 IU/kg once then 30-50 IU/kg IV PRN q2-3 days	• Indicated for use in adults and children with hemophilia A for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment & control of bleeding episodes • Perioperative management of bleeding	ADRs (>10%) • headache • arthralgia	• New once weekly antihemophilic factor VIII injection indicated for hemophilia A • Provides near-normal factor activity (>40%) for most of the week • Altuviiio was evaluated in two studies: XTEND-1 and XTEND-Kids – Results were significant for week-long efficacy (no comparators) – XTEND-Kids has not been published yet – While not reported, FVIII antibody development may still occur with use • May provide some clinical benefit relative to existing formulary agents • Altuviiio offers an additional option for the treatment of hemophilia A, although alternative formulary agents are available and there is no comparative efficacy data	• UF • Do not add to EMMI List

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

atorvastatin oral suspension (Atorvaliq) **LIP-1s**	• atorvastatin tabs • simvastatin suspension (FloLipid) • rosuvastatin sprinkles (Ezallor)	Formulation: • 150 mL bottles of 20 mg/5 mL • Orange flavoring Dosing: • Adults: 10 to 80 mg QD. • Pediatrics HeF): 10 to 20 mg QD. • Pediatrics with HoFH: 10 to 80 mg QD.	• same as Lipitor • ↓ risk of MI, stroke, RV procedures, angina with multiple risk factors for CHD • ↓LDL in adults with primary hyperlipidemia and • ≥ 10 y.o. with HeFH • ≥ 10 y.o. with HoFH • primary dys-betalipoproteinemia or ↑TG	Incidence ≥ 5%): • nasopharyngitis • arthralgia • diarrhea • pain in extremity • UTI • Same warnings as Lipitor re: hepatotoxicity and rhabdomyolysis	• 3rd statin approved in an alternate dosage form (simvastatin oral susp – FloLipid; rosuvastatin sprinkles – Ezallor) • Approved via 505b2 pathway using data from Lipitor; no clinical trials; only pharmacokinetic data available • FDA review mentioned some issues with the bioavailability data and significant deficiencies were identified in the manufacturing process and facility inspection • Other than a convenience formulation, provides no compelling clinical advantages over other statins	• NF • Add to EMMI List
dabigatran oral pellets (Pradaxa) **Anticoagulants**	• dalteparin inj. (Fragmin) • enoxaparin inj. • rivaroxaban oral suspension (Xarelto)	Formulation: • 20, 30, 40, 50, 110 and 150 mg packets Dosing: Varies based on weight	• patients from 3 months to < 12 years of age for VTE treatment • to reduce the risk of recurrent VTE	Incidence >15% • GI adverse events • bleeding	• Alternative Pradaxa formulation for pediatrics. • Not substitutable on a milligram-to-milligram basis with other dabigatran dosage forms • Phase 2/3 study demonstrated that Pradaxa pellets were non-inferior to standard of care • Phase 3 safety study demonstrated 99% overall probability of freedom from recurrence of VTE • Provides an oral option for patients 3 months to < 12 years old	• NF • Add to EMMI List
elacestrant (Orserdu) **Oncological Agents: Breast Cancer**	• fulvestrant • anastrozole • letrozole • exemestane	Formulation: • 86 mg oral tab • 345mg oral tab Dosing: • 345mg QD	• ER+/HER2- ESR1 mutated advanced or metastatic breast cancer after at least one line of endocrine therapy	• nausea • vomiting • increased AST • fatigue • decreased appetite • arthralgia • diarrhea • back pain	• First oral selective estrogen receptor degrader (SERD) for treatment of ER+/HER2- ESR1 mutation advanced or metastatic breast cancer • Phase 3 study demonstrated increased mean progression-free survival (PFS) compared with standard of care in patients with ESR1 mutation • Provides alternative and oral option after disease progression on established therapies	• UF • Do not add to EMMI List

insulin glargine injection (Rezvoglar Kwikpen) Insulins: Basal	• Lantus Solostar • Basaglar Kwikpen • Semglee Pen	Formulation: • 3ml single-patient-use prefilled pen Dosing: • Individualize dose	• T1DM and T2DM	Same as Lantus	• Second biosimilar of insulin glargine (Lantus) that is interchangeable with Lantus and unbranded Lantus • No new clinical studies; approved via 351(k) • Provides no compelling clinical advantage over existing agents	• NF NSP • Add to EMMI List
omeprazole and sodium bicarbonate oral suspension (Konvomep) **Proton Pump Inhibitors**	• Zegerid Cap/Susp • Protonix Susp	Formulation: • Suspension: 2mg/ml Dosing: • 40 mg QD	• Active benign ulcer • Decrease GI bleed risk	Same as Zegerid	• Another formulation of omeprazole and sodium bicarbonate oral suspension for the treatment of active benign gastric ulcer and for the reduction of risk of upper GI bleeding in critically ill patients • No new clinical studies; approved via 505(b)(2) • Zegerid packets for oral suspension is available OTC and in generics – Rx formulation is designated NF • Provides no compelling clinical advantage over existing agents	• UF • Do not add to EMMI List
pegfilgrastim-fpgk injection (Stimufend) **White Blood Cell Stimulants: Peg-filgrastims**	• pegfilgrastim (Neulasta) • pegfilgrastim-jmdb (Fulphila) • pegfilgrastim-cbqv (Udenyca) • pegfilgrastim-bmez (Ziextenzo) • pegfilgrastim-apgf (Nyvepria) • pegfilgrastim-pbbk (Fylnetra)	• Formulation: 6 mg/0.6 mL solution in a single-dose prefilled syringe. 27-gauge, ½-inch needle (needle cap is made with natural rubber latex) • Dosing: 6 mg SC once per chemotherapy cycle. Weight based dosing for pediatrics.	• Decrease incidence of infection, as manifested by febrile neutropenia in patients with non-myeloid malignancies receiving myelo-suppressive anti-cancer drugs	ADRs (≥ 5% difference in incidence compared to placebo) • Bone pain • Pain in extremity	• Stimufend is the 6th biosimilar to Neulasta and 13th agent in the white blood cell stimulant class • No new clinical data • Stimufend provides little to no compelling clinical advantage over existing pegfilgrastim agents	• UF NSP • Do not add to EMMI List

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

pirtobrutinib tablet (Jaypirca) **Oncological Agents**	• acalabrutinib (Calquence) • zanubrutinib (Brukinsa) • ibrutinib (Imbruvica)	Formulation: • 50 mg, 100 mg tablet Dosing: • 200 mg PO QD	• Treatment of adults with relapsed or refractory mantle cell lymphoma after >2 lines of systemic therapy, including a Bruton Tyrosine Kinase inhibitor	ADR (≥15%) • fatigue • musculoskeletal pain • diarrhea • edema • dyspnea • pneumonia • bruising	• Non-covalent BTK inhibitor approved for the treatment of adults with relapsed or refractory mantle cell lymphoma • NCCN guidelines recommends the use of Jaypirca after 2nd line therapy with a covalent BTKi • Received FDA accelerated approval based on an overall response rate and a favorable benefit/risk profile • No direct comparisons to Brukinsa, Calquence or Imbruvica • Provides an alternative treatment option for this generally incurable disease state	• UF • Do not add to EMMI List
sparsentan tablet (Filspari) **Nephrology Agents Miscellaneous**	• budesonide delayed-release caps (Tarpeyo) • ARBs (irbesartan) • prednisone • methylprednisolone	Formulation: • 200mg and 400mg tablet Dosing: • 200 mg daily for 2 weeks, then 400 mg daily thereafter	• To reduce proteinuria in adults with primary immune-globulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g	• Same teratogenicity concerns as with other endothelin receptor agonists used for PAH (ambrisentan, etc.) • increased LFTs • hepatotoxicity • hypotension • acute kidney injury • fluid retention	• 2nd drug formally approved for IgA (after Tarpeyo) • New mechanism of action - dual-acting angiotensin II and endothelin type A receptor antagonist; (not a steroid like Tarpeyo, prednisone; not an immunosuppressant) • Unpublished Phase 3 PROTECT study in 400 pts vs. irbesartan 300 mg showed ↓ proteinuria (UPCR) from baseline at 36 weeks: 49.8% sparsentan vs. 15.1% irbesartan; p <0.001 • REMS program for teratogenicity and hepatotoxicity concerns • Approved using a surrogate endpoint; confirmatory studies are underway using eGFR • Indirect comparison vs Tarpeyo showed greater reduction in proteinuria with sparsentan • Initial results remain to be confirmed	• UF • Do not add to EMMI List
tezepelumab-ekko injection (Tezspire) **Atopy**	• mepolizumab (Nucala) • benralizumab (Fasenra) • dupilumab (Dupixent) • reslizumab (Cinqair)	Formulation: • 210 mg/1.91 mL in a single-dose prefilled pen Dosing: • 210 mg subcutaneously once every 4 weeks	• Add-on maintenance treatment of severe asthma, aged 12 years and older	(≥3%) • pharyngitis • arthralgia • back pain	• Adjunct treatment with a new mechanism of action for severe asthma • Clinical trials showed statistically significant relative reduction in asthma exacerbation vs. placebo • Adverse events are generally mild and include pharyngitis, arthralgia, back pain • Provides another treatment option in the management of severe asthma	• UF • Add to EMMI list

trofinetide oral solution (Daybue) **Neurological Agents, Miscellaneous**	• none	Formulation: • Solution, 450 mL (200 mg/mL) in a multi-dose, child-resistant bottle Dosing: • Orally or g-tube BID with or without food; weight based	• Treatment of Rett syndrome in patients 2 years of age and older	(≥10%) • Diarrhea • Vomiting	• Specialty orphan drug approved for the treatment of Rett Syndrome • Single phase 3 study demonstrated statistically significant improvement vs. placebo on Rett Behavior Questionnaire and Clinical Global Impression-Improvement Scale • GI adverse events are most common, diarrhea and vomiting • Daybue provides a pharmacologic treatment option outside of supportive care for this rare condition	• UF • Do not add to EMMI list

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)
May 2023	**Drug Class Reviews** **Dry Eye Disease** **Designated UF:** *Remain on EMMPI program* • cyclosporine 0.05% (Restasis) – brand only **Designated NF:** *No reason to exempt from NF-2-Mail requirement (remain on list):* • varenicline nasal solution (Tryvaya) • cyclosporine 0.1% ophthalmic solution (Verkazia) **PCSK9 inhibitors** **Designated UF** *Remain on EMMPI program* • evolocumab (Repatha) • alirocumab (Praluent) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF** *Add to EMMPI program (implementation date is the first Wednesday 2 weeks after signing of the minutes)* • atorvastatin oral suspension (Atorvaliq) • dabigatran oral pellet (Pradaxa) *Add to EMMPI program (implementation date contingent on cost effectiveness and operational considerations)* • tezepelumab-ekko (Tezspire) *Note that after the meeting it was discovered that Tezspire could not operationally be added to the EMMPI program.* **Designated NF** *No reason to exempt from NF-2-Mail requirement (implementation date is the first Wednesday 2 weeks after signing of the minutes)* • insulin glargine (Rezvoglar) • adalimumab-atto (Amjevita)	**Drug Class Reviews** **Dry Eye Disease** **Designated UF** *Remove from EMMPI program (implementation date is the first Wednesday 2 weeks after signing of the minutes)* • cyclosporine 0.09% ophthalmic solution (Cequa) • lifitegrast 5% ophthalmic solution (Xiidra) **Newly Approved Pharmaceutical Agents per 32 CFR 199.21(g)(5)** **Designated UF:** *Limited duration of use* • pegfilgrastim-fpgk (Stimufend) *Not yet clear if feasible to provide through Mail* • adagrasib (Krazati) • elacestrant (Orserdu) • pirtobrutinib (Jaypirca) • sparsentan (Filspari) • trofinetide (Daybue) *Comparable pricing across points of service* • omeprazole/sodium bicarbonate oral suspension (Konvomep) *Consistent with others in the class* • antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl (Altuviiio)

Appendix F—Mail Order Status of Medications Designated Formulary or Nonformulary during the November 2021 DoD P&T Committee Meeting

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)
	Products in Classes Designated by the P&T Committee as Generally Suitable for Inclusion *(implementation date contingent on cost effectiveness and operational considerations)* **Designated UF** • degarelix acetate (Firmagon) - Luteinizing Hormone-Releasing Hormone Agonists-Antagonists for Prostate Cancer • ozanimod HCl (Zeposia) - MS • siponimod (Mayzent) - MS • apalutamide (Erleada – Oncological Agents: 2nd-Generation Antiandrogens • darolutamide (Nubeqa) – Oncological Agents: 2nd-Generation Antiandrogens • enzalutamide (Xtandi) – Oncological Agents: 2nd-Generation Antiandrogens • binimetinib (Mektovi) – Oncological Agents: Melanoma • cobimetinib (Cotellic) – Oncological Agents: Melanoma • encorafenib (Braftovi) – Oncological Agents: Melanoma • vemurafenib (Zelboraf) – Oncological Agents: Melanoma • TIBs – The Committee agreed that the TIBS are generally suitable for inclusion on the EMMPI program **Designated NF** *No reason to exempt from NF-2-Mail requirement, similar agents already on list:* • tralokinumab-ldrm (Adbry) – Atopy • TIBs – The Committee agreed that the TIBS are generally suitable for inclusion on the EMMPI program	

* 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.

Implementation Dates for UF Recommendations/Decisions*

Upon signing: July 26, 2023

Two weeks after signing: August 9, 2023

30 days after Signing: August 30, 2023

60 days after signing: September 27, 2023

90 days after signing: October 25, 2023

120 days after signing: November 22, 2023

*** 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 (Tier 4) and Therapeutic Alternatives

P&T Committee Meeting Date	Drug Class	Tier 4 (complete exclusion) Products	Formulary Alternatives	Implementation
May 2023	Ophthalmic Dry Eye Agents	• loteprednol etabonate 0.25% ophthalmic suspension (Eysuvis)	• cyclosporine 0.05% ophthalmic emulsion unit-dose (generic Restasis) • cyclosporine 0.05% ophthalmic emulsion multi-dose (Restasis Multidose) • cyclosporine 0.09% ophthalmic solution (Cequa) • lifitegrast 5% ophthalmic solution (Xiidra) • loteprednol 0.2% ophthalmic suspension (Alrex, generic) • loteprednol 0.5% ophthalmic suspension (Lotemax, generic)	• 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 Tier 4 (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 Tier 4 (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 Tier 4(complete exclusion) agents at the Retail points of service.

The first Tier 4 (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 Tier 4 agents to date, refer to previous versions of the DoD P&T Committee quarterly meeting minutes, found on the heatlh.mil website.

DoD P&T Committee Updates to Approval Authorities

Note that updates are in **bold** font.

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

Process	Function
Administrative (not part of DoD P&T Committee process; Beneficiary Advisory Panel (BAP) comments not required; Director, DHA, approval not required) Responsible parties include: TPharm4 (Mail Order Pharmacy and Retail Pharmacy Network) Contracting Officer Representative (CORs), DHA Pharmacy Program, DHA Office of General Counsel, and Pharmacy Operations Division Formulary Management Branch (FMB) staff; **P&T Committee Chair and others as needed**	▪ Identification of new FDA-approved medications, formulations, strengths, package sizes, fixed dose combinations, etc. ▪ If situation unclear, determination as to whether a new FDA-approved medication is covered by TRICARE. ▪ If situation unclear, determination as to whether a new FDA-approved medication is part of the pharmacy benefit (e.g., IV infusions). ▪ If situation unclear, determination as to whether a new FDA-approved medication is suitable for dispensing through the TRICARE Mail Order Pharmacy (e.g., Accutane with proof of negative pregnancy testing requirements). ▪ Calculating and implementing quantity limits. The QLs will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making changes to quantity limits as needed based on non-clinical factors such as changes to packaging (e.g., medication previously available in boxes of 5 now only available packaged in boxes of 8). ▪ Establishing and making changes to days supply and quantity limits for specialty medications as needed, consistent with days supply or quantity limits for similar agents, expert opinion from providers and specialty pharmacists, dosing, package sizes, and other considerations, to be reviewed by the DoD P&T Committee at the next meeting. ▪ Establishing adjudication edits (Pharmacy Data Transaction Service [PDTS] limitations which are set well above the clinical maximum and are intended to prevent entry errors [e.g., entering a quantity of 17 for a 17-gram inhaler for which the actual unit of measure is 1 inhaler] or are intended to limit diversion. ▪ Implementing prior authorization (PA) requirements if already established through the DoD P&T Committee process for a given medication or class of medications. ▪ Implementing step therapy (automated PA criteria) for a new entrant to a medication class if already established through the DoD P&T Committee process. The entrant will be designated as “non step preferred” (i.e., behind the step). The step therapy criteria for the new entrant will be reviewed by the DoD P&T Committee at the next meeting. ▪ Making minor changes to prior authorization forms or Medical Necessity (MN) forms NOT involving changes to underlying criteria, such as correcting contact information or rewording clinical questions. ▪ Making changes to PA criteria, MN criteria, quantity limits and any associated documents to accommodate new FDA-approved indications or to respond to changes in FDA-recommended safety limitations (changes will be reviewed by DoD P&T Committee at next meeting). ▪ **Implementing temporary prior authorization (PA) requirement changes for existing PAs, or medical necessity criteria based on new reliable evidence from new randomized controlled trials or new national guidelines (changes will be reviewed by the DoD P&T Committee at the next meeting).**

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

	of parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee meeting minutes. ▪ Removing medications withdrawn from the U.S. market from Basic Core Formulary (BCF) or Extended Core Formulary (ECF) listings and other documents. ▪ Providing clarifications to existing BCF/ECF listings in the event of market entrant of new dosage strengths, new formulations, new delivery devices (e.g., HandiHaler vs. Respimat inhaler) or manufacturer removal/replacement of products (e.g., mesalamine Asacol changed to Delzicol). BCF clarifications of this type will be reviewed by the DoD P&T Committee at the next meeting. ▪ Providing clarifications to existing listings on the BCF or ECF to designate specific brands/manufacturers when a national contract (e.g., joint DoD/VA, Defense Logistics Agency) is awarded for a given product. ▪ Other functions as necessary to accomplish the functions listed above; for example, making changes to PDTS coding for TPharm4, communicating status of medications as part of the pharmacy or medical benefit to Managed Care Support Contractors (MCSCs), and making changes to the DHA "health.mil" website. ▪ Adding or removing products from the Specialty Agent Reporting List that have previously been designated by the DoD P&T Committee. The Specialty Agent Reporting List is maintained for purposes of monitoring specialty drug utilization trends and spends, and is based on the definition of a specialty drug previously agreed upon by the DoD P&T Committee at the August 2014 meeting. ▪ Adding or deleting drugs or drug classes from the Clinical Services Drug List, based on approved P&T Committee criteria, which identifies drugs for which specialty care pharmacy services are provided at the Mail Order Pharmacy under the TRICARE pharmacy contract. The list also designates which drugs must be filled through the Specialty Drug Home Delivery Program or at specified Retail Network pharmacies. Addition or deletion of drugs or drug classes from the Clinical Services Drug List will be formally reviewed by the DoD P&T Committee at the next meeting. ▪ In order to avert or respond to drug shortages due to widespread (national or worldwide) emergency situations (e.g., pandemics) and after consultation with the Chair of the DoD P&T Committee and other parties as needed (e.g., Deputy Assistant Director – Health Affairs), applying manual PA criteria or Quantity Limits to certain drugs, to ensure adequate supply and or appropriate usage in the MHS. Any actions taken will be presented to the P&T Committee at the next meeting. PAs and/or QLs implemented in these situations will removed when the situation has resolved. ▪ FDA approval of a device or supply does not require consideration by the DoD P&T Committee. If deemed appropriate, identification of new FDA approved devices or supplies and determination as to whether a new FDA approved device or supply should be considered for coverage by TRICARE Pharmacy Benefit. This includes new versions or models. If determination made to consider for coverage, timeline for review by DoD P&T Committee. The DoD P&T Committee must evaluate cost and clinical effectiveness for inclusion on the benefit and resulting formulary status recommendation. Additionally, devices or supplies may be reviewed periodically and may be designated UF, NF or excluded/removed from the pharmacy benefit.

Appendix I—Table of Administrative Authorities

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

Appendix I—Table of Administrative Authorities

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

Appendix J—Prescribing Weight Loss Medications to Active-Duty Service Members memo

DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

Healthcare Administration

MEMORANDUM FOR: ALL DEFENSE HEALTH AGENCY (DHA) MARKETS AND MILITARY MEDICAL TREATMENT FACILITIES

Subject: Prescribing Weight Loss Medications to Active-Duty Service Members

This memorandum is meant to clarify a recent action made by the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee members at the February 2023 DoD P&T Committee meeting. While a Prior Authorization (PA) continues to be required when prescribing weight loss medications, during the February 2023 meeting P&T Committee members made a recommendation, which DHA leadership approved, to remove two questions from the required PA process when military Medical Treatment Facility (MTF) providers prescribe weight loss medications. The following questions will be removed from the PA form in early August 2023:

- Is the patient an Active-Duty Service Member?
- Does the individual continue to be enrolled in a Service-specific Health/Wellness Program AND adhere to Service policy AND will remain engaged throughout the course of therapy?

For clarification, providers must continue to follow Military Department-specific policies that set the requirements for participation in weight loss programs for Active-Duty Service Members.

The PA form still requires answers to the following questions:

- Patient has a Body Mass Index (BMI) ≥ 30, or a BMI ≥ 27 for those with risk factors in addition to obesity (diabetes, impaired glucose tolerance, dyslipidemia, hypertension, sleep apnea) OR patient is a pediatric patient 12 years of age or older with BMI ≥ 95th percentile standardized for age and sex, AND
- Patient has engaged in behavioral modification and dietary restriction for at least 6 months and has failed to achieve the desired weight loss and will remain engaged throughout course of therapy.

While there may be a need for the Military Departments to update their policies to incorporate recent additions to, or modifications of, weight loss medications available on the uniform formulary, **the Military Departments (not DHA) will continue to determine and direct the appropriate use of these medications in their health/weight loss and fitness programs for Active-Duty Service Members.**

My point of contact for this memorandum is Dr. Paul R. Cordts at //email or 703-681-8003. Please ensure widest dissemination in your Markets and MTFs.

//sign
Brian C. Lein, MD
Assistant Director
Health Care Administration

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. Manual PA Criteria: 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. Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that pegfilgrastim-jmdb (Fulphila), pegfilgrastim-pbbk (Fylnetra), pegfilgrastim-apgf (Nyvepria), pegfilgrastim-fpgk (Stimufend), pegfilgrastim-cbqv (Udenyca), and pegfilgrastim-bmez (Ziextenzo) are the 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 Manual PA Criteria: Coverage is approved for initial therapy for one year if all criteria are met: • Patient does not have congenital or acquired long QT syndrome or arrhythmias associated with QT prolongation • Patient does not have severe hepatic impairment • Patient is not taking any of the following: monoamine oxidase inhibitors (MAOIs) within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine) Huntington's Disease Chorea • Prescribed by or in consultation with a neurologist • Patient has a diagnosis of chorea associated with Huntington's disease • Patient does not have suicidal ideation • Patient does not have depression or is being adequately treated for depression • Patient has had an adequate trial of tetrabenazine for 12 weeks and has experienced treatment failure or experienced an adverse event that is not expected to occur with Austedo 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

	▪ 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) <u>Manual PA criteria</u>: 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.

DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE

MINUTES AND RECOMMENDATIONS
November 2023

I. CONVENING

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

II. ATTENDANCE AND PREVIOUS MEETING CLARIFICATION

The attendance roster is listed in Appendix A.

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

B. Clarification of previous meeting minutes

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

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

III. REQUIREMENTS

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

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

IV. UF DRUG CLASS REVIEWS

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

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

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

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

CGRP antagonists vs. oral preventive therapies

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

CGRP antagonist vs. CGRP antagonist

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

Safety

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

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

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

Individual Product Characteristics

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

Overall Clinical Conclusion

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

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

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

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

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

   Chronic and Episodic Migraine

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

   Cluster Headache

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

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

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

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

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

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

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

B. Neurological Agents Miscellaneous – Movement Disorders Subclass

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

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

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

Guidelines

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

Efficacy

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

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

Safety

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

Individual Product Characteristics

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

Clinical Coverage

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. ***COMMITTEE ACTION: PA CRITERIA—***The P&T Committee recommended Group 1: 20 for, 0 opposed, 0 abstained, 0 absent; and Group 2: 18 for, 0 opposed, 0 abstained, 2 absent) the following PA criteria (see Appendix C for the full criteria):
    - Applying manual PA criteria to new users of Akeega, Iyuzeh, Sohonos, and Vanflyta.
    - Applying manual PA criteria to new and current users of Xdemvy.
    - Applying manual PA criteria to new users of the Humira biosimilars, similar to what is in place for the first Humira biosimilar, Amjevita. A trial of the Humira branded product is required first as per the February 2023 P&T Committee meeting minutes.
    - Applying manual PA criteria to Brenzavvy, similar to what is in place for the other non-step-preferred SGLT2 Inhibitors. New patients receiving Brenzavvy or one of the other non-step-preferred SGLT2 Inhibitors (Farxiga, Invokana, Steglatro, or Inpefa) will require a trial of Jardiance first.
    - Applying manual PA criteria to Ngenla, similar to what is in place for the other non-step-preferred growth stimulating agents. A trial of Norditropin, the step-preferred product is required first.
    - Applying interim manual PA criteria for colchicine 0.5 mg tabs (LODOCO) prior to implementation of complete exclusion status, in order to minimize the impact on beneficiaries. See Appendix C for full criteria.

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

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

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

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

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

Addendum to the UF recommendation – COVID Therapeutics

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

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

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

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

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

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

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

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

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

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

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

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

B. Contraceptives

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

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

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

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

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

VII. UTILIZATION MANAGEMENT: PULMONARY-1 AGENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VIII. UTILIZATION MANAGEMENT

A. PA and MN Criteria

1. Updated PA Criteria for New FDA-Approved Indications

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

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

b) Metabolic Agents-Miscellaneous

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

c) Oncological Agents—dabrafenib (Tafinlar) and trametinib (Mekinist)— The manual PA criteria were updated to allow for use in pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF

V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

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

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

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

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

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

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

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

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

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

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

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

B. Line Extensions

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

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

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

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

COMMITTEE ACTION: LINE EXTENSION, FORMULARY STATUS CLARIFICATION, AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) the formulary, QL, PA, Specialty program, and EMMPI program status of the line extension products, as outlined above. Implementation will occur the first Wednesday two weeks after signing of the minutes, with the exception that the Breo Ellipta new formulation will be updated at 30 days with the other pulmonary UM drugs.

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

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

COMMITTEE ACTION: TIOTROPIUM DRY POWDER INHALER (HANDIHALER) BRAND OVER GENERIC REQUIREMENT, PA CRITERIA, TIER 1 COPAY AND IMPLEMENTATION PERIOD—The P&T Committee recommended (20 for, 0 opposed, 0 abstained, 0 absent) requiring brand Spiriva HandiHaler over the generic in all new users at all POS, based on cost effectiveness. The prescriber will provide patient specific justification as to why the brand cannot be

used. The Tier 1 (generic) copayment will apply to brand Spiriva HandiHaler. The effective date will be no later than 30 days after the signing of the minutes. The "brand over generic" requirement will be removed administratively when it is no longer cost-effective compared to the AB-rated generics. Additionally, Spiriva HandiHaler will be added to the rapid response ("safety net") program, which is included in the new TRICARE Pharmacy 5th Generation (TPharm5) contract. See Appendix C for full criteria.

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

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

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

Progestin-Only Contraceptive—OTC Opill:

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

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

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

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

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

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

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

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

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

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

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

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

- vosoritide (Voxzogo)
- belimumab (Benlysta)

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

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

Background: In accordance with 10 U.S.C. 1074g(a)(10), as implemented in 32 CFR 199.21(e)(3)(i), the P&T Committee may recommend and the Director may, after considering the comments and recommendations of the Beneficiary Advisory Panel, approve special uniform formulary actions to encourage use of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries and DoD, including consideration of better care, healthier people, and smarter spending.

Contraceptives:

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

Menopausal Hormone Therapy:

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

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

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

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

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

XIII. MHS GENESIS OTC LIST

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

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

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

XIV. CLARIFYING LANGUAGE APPLICABLE TO ALL PAs REGARDING CONTRAINDICATIONS

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

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

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

XV. P&T COMMITTEE ADMINISTRATIVE AUTHORITY

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

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

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

XVI. ITEMS FOR INFORMATION

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

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

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

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

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

XVII. ADJOURNMENT

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

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

DECISION ON RECOMMENDATIONS

SUBMITTED BY: [redacted]

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

The Director, DHA:

☒ concurs with all recommendations.

☐ concurs with the recommendations, with the following modifications:

1.
2.
3.

☐ concurs with the recommendations, except for the following:

[redacted]

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

29Jan24
Date

Appendix A—Attendance

Voting Members Present	
John Kugler, MD, COL (Ret.), MC, USA	DoD P&T Committee Chair
CAPT P. Thien Nguyen for COL Paul Carby, MSC	DHA Pharmacy Operations Division (POD); Beneficiary Advisory Panel DFO Alternate
Ed VonBerg, PharmD , CAPT (Ret.) MSC, USN	Chief, Formulary Management Branch (Recorder)
LTC Charles Lin, MC	Army, Internal Medicine Physician
Ruben Salinas, MD, COL (Ret.) MC, USA	Army, Family Medicine Physician
MAJ Megan Donahue, MC	Army, Physician at Large
COL Aatif Sheikh, MSC	Army, Pharmacy Consultant
CAPT Austin Parker, MC	Navy, Internal Medicine Physician
CDR Danielle Barnes, MC	Navy, Pediatrics Representative
CAPT Peter Cole, MC	Navy, Physician at Large
CAPT Bridgette Faber, MSC	Navy, Pharmacy Consultant
Col Larissa Weir, MC	Air Force, OB/GYN Physician
MAJ Courtney Clutter, MC	Air Force, Internal Medicine Physician
Capt Andrew Gaillardetz, MC	Air Force, Physician at Large
Col Corey Munro, BSC	Air Force, Pharmacy Consultant
Walter Downs, MD, CAPT (Ret.) MC, USN	Physician at Large, DHA
COL Jason Burris, MC	Oncology Physician
Laura Au, RPh, BCOP	Oncology Pharmacist
CAPT Chris Janik, USCG	Coast Guard, Pharmacy Consultant
Richard Ruck, MD, COL (Ret.), MC, USA (Day #2)	TRICARE Health Plan Chief Medical Officer
COL Yang Xia, MC (Day #1)	TRICARE Latin America and Canada

Appendix A—Attendance

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

Appendix A—Attendance

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

Appendix B—Table of Medical Necessity Criteria

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

Appendix B—Table of Medical Necessity Criteria

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

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

Appendix B—Table of Medical Necessity Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

• galcanezumab-gnlm 100 mg injection (Emgality) **Migraine Agents: CGRP Cluster Headache**	**Changes from the November 2023 meeting are in BOLD and strikethrough.** Note that this PA applies to the Emgality 100 mg cluster headache formulation. **The Emgality 120 mg migraine prophylaxis formulation is available without a PA**. ~~**The Emgality 120 mg migraine prophylaxis indication PA criteria is on a separate form.**~~ Manual PA criteria apply to all new users of Emgality for episodic cluster headaches. Manual PA Criteria: Emgality 100 mg at a dosage of 300 mg/month is approved if all criteria are met: • Patient is 18 years of age or older • Patient is not pregnant • The drug must be prescribed by or in consultation with a neurologist • Patient has a diagnosis of episodic cluster headaches • Patient has a contraindication to, intolerability to, or has failed an adequate trial of verapamil, topiramate, or lithium • Concurrent use with other CGRP inhibitors (e.g., Aimovig, Emgality 120 mg, Ajovy) is not allowed Non-FDA-approved uses, including for migraine prophylaxis, chronic cluster headache, medication overuse headache, etc., are not approved PA expires after 6 months Renewal Criteria: Note that initial TRICARE PA approval is required for renewal. Coverage will be approved indefinitely for continuation of therapy if there is a clinically appropriate reduction in weekly attacks (≥ 50% reduction in weekly cluster headache attack frequency) during an episode as reported by the patient.
• deutetrabenazine immediate release (Austedo) • deutetrabenazine extended-release (Austedo XR) • valbenazine (Ingrezza) **Neurological Agents Miscellaneous: Movement Disorders**	**Changes from the November 2023 meeting are in bold and strikethrough** Manual PA criteria apply to all new users of Austedo IR, Austedo XR **and Ingrezza** Manual PA Criteria: Coverage is approved for initial therapy for one year if all criteria are met: • ~~**Patient does not have congenital or acquired long QT syndrome or arrhythmias associated with QT prolongation**~~ • ~~**Patient does not have severe hepatic impairment**~~ • ~~**Patient is not taking any of the following: MAOI within the past 14 days, reserpine, CYP3A4 inducers, or another VMAT2 inhibitor (e.g., tetrabenazine, deutetrabenazine [Austedo, Austedo XR], valbenazine [Ingrezza])**~~ • **Patient is 18 years of age or older** • **Provider acknowledges the FDA safety alerts, boxed warnings, precautions, and drug interactions** Huntington's Disease Chorea • Prescribed by or in consultation with a neurologist • Patient has a diagnosis of chorea associated with Huntington's Disease • Patient does not have suicidal ideation • Patient does not have depression or is being adequately treated for depression

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

Appendix C—Table of Prior Authorization (PA) Criteria

• adalimumab-adbm injection (Cyltezo) • adalimumab-fkip injection (Hulio) • adalimumab-fkip injection unbranded biologic • adalimumab-aacf injection (Idacio) • adalimumab-bwwd injection (Hadlima) • adalimumab-aqvh injection (Yusimry) • adalimumab-aaty injection (Yuflyma) • adalimumab-adaz injection (Hyrimoz) • adalimumab-adaz injection unbranded biologic • **adalimumab-atto (Amjevita) (included from the UM section)** Targeted Immunomodulatory Biologics (TIBs)	**Updates from November 2023 are in bold** Manual PA criteria apply to all new and current users of the Humira biosimilar Manual PA criteria: Coverage is approved if all criteria are met: • Provider acknowledges that the originator adalimumab (Humira) is the preferred product over biosimilar adalimumab formulations • Provider must provide patient specific justification as to why the originator Humira product cannot be used in this patient ▪ Acceptable responses include that the patient has an allergy to an inactive ingredient found in the originator Humira that is not in the Humira biosimilar • If patient is younger than 18 years of age, coverage is provided for moderate to severe polyarticular juvenile idiopathic arthritis or moderate to severe Crohn's disease ▪ If indication is moderate to severe polyarticular juvenile idiopathic arthritis, patient must 2 years of age or older ▪ If indication is moderate to severe Crohn's disease patient must be 6 years of age or older • If patient is 18 years of age or older coverage is provided for moderately to severely active rheumatoid arthritis, moderate to severe Crohn's disease, moderate to severe chronic plaque psoriasis where patient is candidate for systemic or phototherapy or when other systemic therapies are medically less appropriate, psoriatic arthritis, ankylosing spondylitis, moderate to severe ulcerative colitis, **non-infectious uveitis, intermediate uveitis, posterior uveitis and panuveitis**, and hidradenitis suppurativa ▪ If indication is moderate to severe chronic plaque psoriasis OR moderate to severe Crohn's disease OR moderate to severe ulcerative colitis then patient must have had an inadequate response, intolerance, or contraindication to non-biologic systemic therapy. (For example: methotrexate, aminosalicylates [e.g., sulfasalazine, mesalamine], corticosteroids, immunosuppressants [e.g., azathioprine, cyclosporine], acitretin, or phototherapy), etc. unless they have fistulizing Crohn's disease ▪ If indication is ankylosing spondylitis has patient must have had inadequate response to at least two NSAIDs over a period of at least 2 months • Patient has not had case of worsening congestive heart failure (CHF) and new onset CHF has not been reported with TNF blockers, including Humira • Patient had evidence of negative TB test in the past 12 months (or TB is adequately managed) • Patient is not receiving other targeted immunomodulatory biologics with Humira, including but not limited to the following: certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), apremilast (Otezla), ustekinumab (Stelara), abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), tofacitinib (Xeljanz/Xeljanz XR), rituximab (Rituxan), secukinumab (Cosentyx), ixekizumab (Taltz), brodalumab (Siliq), sarilumab (Kevzara), guselkumab (Tremfya), baricitinib (Olumiant), tildrakizumab (Ilumya), risankizumab (Skyrizi), or upadacitinib (Rinvoq ER) Non-FDA-approved uses are NOT approved, with the exception **that if an indication is approved for Humira, it is approved for a biosimilar** PA does not expire

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

	Non-FDA-approved uses are NOT approved PA does not expire
Utilization Management Updated PAs	
• adalimumab-atto (Amjevita) **TIBs: Tumor Necrosis Factor Inhibitors Agents**	See PA section above for the new drugs
• odevixibat (Bylvay) **Metabolic Agents-Miscellaneous**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of (Bylvay). Manual PA criteria: Coverage is approved if all criteria are met: • Patient **~~is ≥ 3 months and ≥ 5 kg and~~ has** diagnosed progressive familial intrahepatic cholestasis (PFIC) with sever refractory pruritis OR • **Patient has diagnosed Alagille Syndrome with severe refractory pruritus (ALGS) AND** • The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist • Has been evaluated for possible orthotopic liver transplant (OLT) • Has previously tried and failed all of the following: ▪ Ursodiol ▪ Cholestyramine ▪ Rifampin ▪ Naltrexone ▪ At least 1 antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as **~~Alagille syndrome,~~** non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD), progressive familial intrahepatic cholestasis (PFIC), biliary atresia, and other cholestatic diseases are not approved PA expires every 6 months Coverage will be approved for an additional 6 months if the following apply: Renewal Criteria TRICARE PA approval required ▪ Patient must demonstrate significant improvement in pruritis symptoms
• maralixibat (Livmarli) **Metabolic Agents-Miscellaneous**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria apply to all new users of Livmarli. Manual PA criteria: Coverage is approved if all criteria are met: • Patient is **~~1 year~~ 3 months** of age or older • The patient has diagnosed Alagille syndrome with severe refractory pruritus • The prescription is written by a pediatric gastroenterologist or pediatric hepatology transplant specialist • The patient has been evaluated for possible orthotopic liver transplant (OLT) • The patient has previously tried and failed all of the following:

	▪ Ursodiol, cholestyramine, rifampin, naltrexone, and at least one antihistamine (e.g., Atarax, Benadryl, etc.) Non-FDA-approved uses such as non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD), progressive familial intrahepatic cholestasis (PFIC), biliary atresia, and other cholestatic diseases are not approved PA expires every 6 months Coverage will be approved for an additional six months if the following apply: Renewal criteria: ▪ TRICARE PA approval required ▪ Patient must demonstrate significant improvement in pruritus symptoms.
• trametinib (Mekinist) **Oncological Agents**	**Updates from the November 2023 meeting are in bold and strikethrough.** Manual PA criteria applies to all new users of Tafinlar. Manual PA criteria**:** Coverage will be approved if: • Treatment (alone or in combination with dabrafenib [Tafinlar]) of unresectable or metastatic melanoma with BRAF-V600E or BRAF-V600K mutation; OR • In combination with dabrafenib (Tafinlar), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation • For the treatment of adult and pediatric patients **~~6 years~~ 1 year** of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options • In combination with dabrafenib (Tafinlar), For the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy • Coverage not approved as a single agent in patients who have received prior BRAF inhibitor therapy • Combination with dabrafenib (Tafinlar) for locally advanced or metastatic anaplastic thyroid cancer with BRAF V600E mutation with no satisfactory locoregional treatment options • Patient is not on concurrent encorafenib (Braftovi), binimetinib (Mektovi), vemurafenib (Zelboraf), nor cobimetinib (Cotellic) • The diagnosis IS NOT listed above but IS cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation. If so, please list the diagnosis: _____. Non-FDA-approved uses are not approved PA does not expire
• dabrafenib (Tafinlar) **Oncological Agents**	**Updates from the November 2023 meeting are in bold.** Manual PA criteria applies to all new users of Tafinlar. Manual PA criteria**:** Coverage will be approved if: • Utilized as a single agent for treatment of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutation • Combination use with trametinib (Mekinist) in the treatment of unresectable or metastatic melanoma with BRAF V600E or BRAF V600K mutations OR • In combination with trametinib (Mekinist), for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

Appendix C—Table of Prior Authorization (PA) Criteria

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

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

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

Appendix D—Table of Quantity Limits (QL)

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

Appendix D—Table of Quantity Limits (QL)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix G—Implementation Dates for UF Recommendations/Decisions

Implementation Dates for UF Recommendations/Decisions*

Upon signing: January 29, 2024

Two weeks after signing: February 14, 2024

30 days after Signing: February 28, 2024

60 days after signing: April 3, 2024

90 days after signing: May 1, 2024

120 days after signing: June 12, 2024

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

Appendix H—Completely Excluded Agents and Therapeutic Alternatives*

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

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

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

The first complete exclusion products were designated at the February 2019 P&T Committee meeting, with implementation occurring on August 28, 2019. For a cumulative listing of all completely excluded agents to date, refer to previous versions of the P&T Committee quarterly meeting minutes, found on the heatlh.mil website.

Appendix I—Table of Administrative Authorities

DoD P&T Committee Updates to Approval Authorities

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

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

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

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

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

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

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