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:

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:

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.