DEPARTMENT OF DEFENSE
PHARMACY AND THERAPEUTICS COMMITTEE RECOMMENDATIONS FROM THE FEBRUARY 2023 MEETING

INFORMATION FOR THE UNIFORM FORMULARY BENEFICIARY ADVISORY PANEL MEETING APRIL 4, 2023

I. UNIFORM FORMULARY REVIEW PROCESS

Under 10 United States Code § 1074g, as implemented by 32 Code of Federal Regulations 199.21, the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee is responsible for developing the Uniform Formulary (UF). Recommendations to the Director, Defense Health Agency (DHA) or their designee, on formulary or Tier 4 (complete exclusion) status, prior authorizations (PAs), pre-authorizations, and the effective date for a drug's change from formulary to non-formulary (NF) or Tier 4/complete exclusion status are received from the Beneficiary Advisory Panel (BAP), which must be reviewed by the Director or their designee before making a final decision.

II. UF DRUG CLASS REVIEWS—SLEEP DISORDERS—INSOMNIA AGENTS: DUAL OREXIN RECEPTOR ANTAGONISTS SUBCLASS

P&T Comments

A. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass—Relative Clinical Effectiveness Conclusion

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.

B. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass—Relative Cost Effectiveness Analysis and Conclusion

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.

C. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass—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.
- NF
  - None
- Tier 4 (complete exclusion)
  - None

D. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists—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.

The Manual PA criteria is as follows:

daridorexant (Quviviq), suvorexant (Belsomra), and lemborexant (Dayvigo)

Note there were no changes to the PA criteria from the May 2021 and August 2022 P&T meetings.

Manual PA Criteria: Quviviq, Belsomra, and 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

E. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists—UF, PA, 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.

III. UF DRUG CLASS REVIEWS—SLEEP DISORDERS—INSOMNIA AGENTS: DUAL OREXIN RECEPTOR ANTAGONISTS SUBCLASS

BAP Comments

A. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass—UF Recommendation

The P&T Committee recommended the formulary status for the Insomnia Agents as discussed above.

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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass—Manual PA Criteria

The P&T Committee recommended manual PA criteria as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Sleep Disorders—Insomnia Agents: Dual Orexin Receptor Antagonists Subclass—UF, PA, and Implementation Plan

The P&T Committee recommended an effective date of the first Wednesday 30 days after signing of the minutes in all points of service.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

IV. UF DRUG CLASS REVIEWS—ANDROGENS-ANABOLIC STEROIDS—TESTOSTERONE REPLACEMENT THERAPIES SUBCLASS

P&T Comments

A. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—Relative Clinical Effectiveness Analysis and Conclusion

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 was 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.

B. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—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.

C. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—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.

D. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—Manual Prior Authorization 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. The criteria for uses other than for gender-dysphoric patients are outlined below.

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.

The Manual PA criteria is as follows:

1. **transdermal patch (Androderm), transdermal gel and gel pump 1%, 1.62% (AndroGel), transdermal 2% gel pump (Fortesta), nasal gel (Natesto), transdermal 1% gel tubes (Testim), transdermal 1% gel (Vogelxo), and transdermal solution (Axiron)**

   Updates from the February 2023 meeting are in bold and strikethrough.

   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

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?**~~

~~o **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 one of the following apply:

- **The patient has had a positive response to therapy**
- **The risks of continued therapy do not outweigh the benefits**

2. **testosterone cypionate IM injection, testosterone enanthate IM injections, and testosterone enanthate SC injection (Xyosted)**

   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 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 one of the following apply**
  - The patient has had a positive response to therapy
  - The risks of continued therapy do not outweigh the benefits

3. **testosterone undecenoate oral capsules (Jatenzo, Tlando, and Kyzatrex)**

Updates from the February 2023 meeting are in bold and strikethrough.

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

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 injection**
    2. **testosterone 2% gel (Fortesta) OR testosterone 1% gel (Androgel generic)**

~~OR~~

~~• The patient requires a 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 one of the following apply:

- **The patient has had a positive response to therapy**
- **The risks of continued therapy do not outweigh the benefits**

4. methyltestosterone oral tablet or capsule

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 one of the following apply:

- The patient has had a positive response to therapy
- The risks of continued therapy do not outweigh the benefits

E. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—Manual Prior Authorization 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.

In addition to the PA criteria outlined above, the transgender use criteria will be included for the topical and nasal gel formulations, the IM injectable products, the SC injectable products, and the oral testosterone undecanoate products (the transgender criteria will not apply to the oral methyltestosterone products.) Product preference for IM testosterones and testosterone 2% gel (Fortesta) or generic testosterone 1% gel (Androgel) applies to Transgender Use criteria.

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 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**c,** 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)

F. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—UF, PA, 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.

V. UF DRUG CLASS REVIEWS—Testosterone Replacement Therapies Subclass

BAP Comments

A. Testosterone Replacement Therapies Subclass—UF Recommendation

The P&T Committee recommended maintaining the formulary status for the testosterone replacement agents as discussed above:

- 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.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Testosterone Replacement Therapies Subclass—Manual Prior Authorization Criteria for indications other than Transgender use

The P&T Committee recommended Manual PA criteria for testosterone replacement agents as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Androgens-Anabolic Steroids—Testosterone Replacement Therapies Subclass—Manual Prior Authorization Criteria for Transgender Use

The P&T Committee recommended Manual PA criteria for testosterone replacement agents in transgender patients as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

D. Testosterone Replacement Therapies Subclass—UF, PA, and Implementation Period

The P&T Committee recommended an effective date of the first Wednesday 60 days after signing of the minutes in all points of service.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

VI. UF DRUG CLASS REVIEWS—NEPHROLOGY AGENTS MISCELLANEOUS

P&T Comments

A. Nephrology Agents Miscellaneous—Relative Clinical Effectiveness Analysis and Conclusion

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.

B. Nephrology Agents Miscellaneous—Relative Cost Effectiveness Analysis and Conclusion

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.

C. Nephrology Agents Miscellaneous—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.

D. Nephrology Agents Miscellaneous—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.

Manual PA Criteria: Manual PA criteria apply to all new users of Tarpeyo and 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 35ml/min
- 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

E. Nephrology Agents Miscellaneous—UF, Interim PA, and Implementation

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.

VII. UF DRUG CLASS REVIEWS—Nephrology Agents Miscellaneous

BAP Comments

A. Nephrology Agents Miscellaneous—UF Recommendation

The P&T Committee recommended the formulary status for the nephrology agents miscellaneous as discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Nephrology Agents Miscellaneous—Interim Manual PA Criteria

The P&T Committee recommended interim manual PA criteria for Tarpeyo as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Nephrology Agents Miscellaneous —UF, Interim PA, and Implementation Period

The P&T Committee recommended 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

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—Relative Clinical Effectiveness and Relative Cost-Effectiveness Conclusions

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).

B. Newly Approved Drugs per 32 CFR 199.21(g)(5)—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. Note that as part of this recommendation the Humalog Tempo pen will be step-preferred.
- 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)
  - furosemide SC injection (Furoscix) – Diuretic
    - Furoscix was recommended for Tier 4 (complete exclusion) placement 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.

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—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:

- 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, 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.

The Manual PA criteria is as follows:

1. dextroamphetamine transdermal system (Xelstrym)

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.

2. dextromethorphan hydrobromide and bupropion hydrochloride (Auvelity)

Manual PA criteria apply to all new users of Auvelity.

Manual PA criteria: 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.

3. futibatinib (Lytgobi)

Manual PA criteria apply to all new users of futibatinib (Lytgobi)

Manual PA criteria: 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/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.

4. insulin glargine (Basaglar Tempo Pen)

Manual PA criteria apply to all new users of insulin glargine (Basaglar Tempo Pen)

Manual PA criteria: 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.

5. insulin lispro-aabc (Lyumjev Tempo Pen)

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.

6. levothyroxine sodium 150 mcg/5 mL oral solution (Ermeza)

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

7. olutasidenib (Rezlidhia)

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.

8. pegfilgrastim-pbbk (Fylnetra)

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:

- Provider acknowledges that pegfilgrastim-cbqv (Udenyca), pegfilgrastim-jmdb (Fulphila) and pegfilgrastim-apgf (Nyvepria) are the preferred pegfilgrastims and are available without a PA
- Fylnetra 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

9. sodium phenylbutyrate and taurursodiol (Relyvrio)

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 (AML)

Non-FDA approved uses are NOT approved.
PA does not expire.

D. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF 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.
- **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.

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

BAP Comments

A. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF Recommendation

The P&T Committee recommended the formulary status for the newly approved drugs as discussed above.

- UF
  - futibatinib (Lytgobi)
  - insulin lispro (Humalog Tempo Pen)
  - leuprolide acetate depot injection (no brand name)
  - olutasidenib (Rezlidhia)
  - pegfilgrastim-pbbk (Fylnetra)
  - posaconazole DR oral suspension (Noxafil Powdermix Kit)
  - sodium phenylbutyrate/sodium taurursodiol powder for oral suspension (Relyvrio)
- NF
  - dextroamphetamine transdermal system (Xelstrym)
  - dextromethorphan hydrobromide/bupropion hydrochloride (Auvelity)
  - insulin glargine (Basaglar Tempo Pen)
  - insulin lispro-aabc (Lyumjev Tempo Pen)
  - levothyroxine sodium 150 mcg/5 mL oral solution (Ermeza) – Thyroid agent

- Tier 4 (complete exclusion)
  - furosemide SC injection (Furoscix) – Diuretic

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Newly Approved Drugs per 32 CFR 199.21(g)(5) PA Criteria

The P&T Committee recommended the PA criteria for new drugs as stated previously.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

C. Newly Approved Drugs per 32 CFR 199.21(g)(5)—UF, PA, and Implementation Period

The P&T Committee recommended the implementation plans as described above.

BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

X. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA AND FORMULARY STATUS MIFEPRISTONE

P&T Comments

A. 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.

The Manual PA criteria is as follows:

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 is 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

B. Prior Authorization Criteria—mifepristone 200 mg tablet (Mifeprex)—TRICARE pharmacy benefit addition, UF 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.

C. Prior Authorization Criteria—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.

XI. UTILIZATION MANAGEMENT— NEW MANUAL PA CRITERIA AND FORMULARY STATUS FOR MIFEPRISTONE

BAP Comments

A. Prior Authorization Criteria—mifepristone 200 mg tablet (Mifeprex)—TRICARE pharmacy benefit addition, UF status and PA Criteria for pregnancy loss and Implementation Period

The P&T Committee recommended addition to the TRICARE pharmacy benefit, UF status, and new manual PA criteria for mifepristone 200 mg tablet (Mifeprex) for pregnancy loss and an implementation period of 30 days, as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Prior Authorization Criteria—mifepristone 200 mg tablet (Mifeprex)—PA criteria for pregnancy termination in accordance with 10 U.S. Code 1093

The P&T Committee recommended new manual PA criteria for mifepristone 200 mg tablet (Mifeprex), for pregnancy termination in accordance with 10 U.S. Code 1093.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA FOR NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

P&T Comments

A. 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.

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.

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.

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.

B. New Manual PA Criteria for Newly Approved Drugs Not Subject to 32 CFR 199.21(g)(5) 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 60 days after the signing of the minutes, and DHA will send letters to affected patients.

XIII. UTILIZATION MANAGEMENT—NEW MANUAL PA CRITERIA for NEWLY APPROVED DRUGS NOT SUBJECT TO 32 CFR 199.21(g)(5)

BAP Comments

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

The P&T Committee recommended manual PA criteria for allopurinol 200 mg tablet and methocarbamol 1000 mg tablet as stated above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

The P&T Committee recommended the new PAs will become effective the first Wednesday 60 days after the signing of the minutes.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XIV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS

P&T Comments

A. 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.

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.

B. Updated Manual PA Criteria and Implementation Plan

The P&T Committee recommended (18 for, 0 opposed, 0 abstained, 2 absent) updates to the manual PA criteria for Firdapse, Cotellic, Retevmo, Tymlos, Tascenso ODT, Rinvoq, and Dupixent in new users. Implementation will be effective the first Wednesday 60 days after signing of the minutes.

XV. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR NEW FDA-APPROVED INDICATIONS

BAP Comments

A. Updated PA Criteria for New FDA-Approved Indications

The P&T Committee evaluated updates to the PA criteria for several drugs, due to new FDA as outlined above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Updated Manual PA Criteria for New FDA-Approved Indications Implementation Plan

The P&T Committee recommended an effective date of 60 days after signing of the minutes for the drugs discussed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XVI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR SAFETY INFORMATION

P&T Comments

A. Updated PA Criteria for Safety Information—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.

B. Updated PA Criteria for Safety Information—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 60 days after signing of the minutes.

XVII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR SAFETY INFORMATION

BAP Comments

A. Updated PA Criteria for Updated PA Criteria for Safety Information—Oral Oncologic Agents: Ovarian Cancer—niraparib (Zejula)

The P&T Committee recommended PA revisions as listed above.

BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

B. Updated PA Criteria for Updated PA Criteria Safety Information Implementation Plan

The P&T Committee recommended the implementation plan as stated above.

BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***

XVIII. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS

P&T Comments

A. 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 Humira if a patient has an intolerance or contraindication to non-biologic systemic therapy.

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**.**

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.

B. Updated PA Criteria for Reasons other than New Indications—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 60 days after signing of the minutes.

XIX. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR REASONS OTHER THAN NEW INDICATIONS

BAP Comments

A. Updated PA Criteria for Reasons other than New Indications

The P&T Committee recommended PA revisions as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

B. Updated PA Criteria for Reasons other than New Indications Implementation Period

The P&T Committee recommended PA Implementation Period as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

XX. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR WEIGHT LOSS DRUGS

P&T Comments

A. Updated PA Criteria for Weight Loss Drugs and Implementation Period

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 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 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 60 days after signing of the minutes.

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.

XXI. UTILIZATION MANAGEMENT—UPDATED PA CRITERIA FOR WEIGHT LOSS DRUGS AND IMPLEMENTATION PERIOD

BAP Comments

Updated PA Criteria for Weight Loss Drugs and implementation period

The P&T Committee recommended PA revisions and an implementation of 60 days after signing of the minutes as listed above.

BAP Comments

Concur: Non-Concur: Abstain: Absent:

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

P&T Comments

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.

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 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 60-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

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

BAP Comments

The P&T Committee recommended authorized generic PA criteria for Xyrem, and Implementation Period as outlined above.

BAP Comments

Concur: ***Non-Concur:*** ***Abstain:*** ***Absent:***