Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Testosterone Products**

Effective: June 9, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Kyzatrex (testosterone undecanoate) capsule is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter Syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Methyltestosterone tablet (Methitest) and capsules are indicated for**:**

1. Males

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenita or acquired) — Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.
- Hypogonadotropic hypogonadism (congenital or acquired) — Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance.) If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of methyltestosterone in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

- Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every 6 months to assess the effect of treatment on the epiphyseal centers.

2. Females

Androgens may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in

premenopausal women with breast cancer who have benefitted from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Clinical Guideline Coverage Criteria

Request for Kyzatrex (testosterone undecanoate) Oral Capsule

The plan may authorize coverage of **Kyzatrex (testosterone undecanoate) capsules** when the following criteria are met:

1. The patient is 18 years of age or older

AND

2. Documented diagnosis of one of the following:
    A. Primary hypogonadism or hypogonadotropic hypogonadism
    B. Gender affirmation or status-post gender-affirming surgery
    C. Metastatic breast cancer
    D. Delayed Puberty
    E. AIDS wasting syndrome

AND

3. Documentation of inadequate response, intolerance, or contraindication to ALL of the following alternative generic testosterone formulations:
    a. A generic testosterone intramuscular injection (e.g., testosterone cypionate)
    b. A generic testosterone topical gel or solution (e.g., testosterone 1% gel, testosterone 30 mg/actuation solution)

Request for Methyltestosterone Oral Formulations

The plan may authorize coverage of **generic methyltestosterone capsules or Methitest (methyltestosterone) tablets** when the following criteria are met:

1A. Diagnosis of hereditary angioedema (HAE)

OR

2A. The patient has a diagnosis of one of the following:
    A. Primary hypogonadism or hypogonadotropic hypogonadism
    B. Gender Dysphoria, Female-to-Male Transition
    C. metastatic breast cancer

AND

2B. The patient is 18 years of age or older

AND

2C. Documentation of inadequate response, intolerance, or contraindication to use ALL of the following alternative generic testosterone formulations
    a. A generic testosterone intramuscular injection (e.g. testosterone cypionate)
    b. A generic testosterone topical gel or solution (e.g. testosterone 1% gel, testosterone 30 mg/actuation solution)

AND

2D. If the request is for methyltestosterone tablets, the patient has had an inadequate response, intolerance, or contraindication to methyltestosterone capsule

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
2. Documentation of a Patient having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.
3. Exposure to topical testosterone gel or solution to other family members does not qualify as a medically acceptable contraindication to topical testosterone gel or solution.

Codes

None

References

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18. Testim [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc. August 2021.
19. Vogelxo [prescribing information]. Maple Grove, MN: Upsher-Smith Laboratories, Inc. December 2022.
20. Xyosted (testosterone) [prescribing information]. Ewing, NJ: Antares Pharma, Inc; March 2025.
21. Kyzatrex (testosterone undecanoate) oral [prescribing information]. Raleigh, NC: Marius Pharmaceuticals; July 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 2022 e-vote: Effective January 1, 2023, removed the requirement for trial of generic testosterone alternatives for Androderm patch.
- December 13, 2022: Effective January 1, 2023, added Kyzatrex (testosterone undecanoate capsules) to the MNG. Added the Limitation that exposure to topical testosterone gel or solution does not qualify as a medically acceptable contraindication to topical testosterone gel or solution.
- June 13, 2023: Effective August 1, 2023, for diagnosis of hereditary angioedema (HAE) removed requirement for methyltestosterone tablet that requires inadequate response, intolerance, or contraindication to methyltestosterone capsule.
- June 11, 2024: No changes
- June 10, 2025: Removed Androderm (testosterone) transdermal patch as product has been discontinued (eff 6/10/25).
- June 9, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.