Reference number(s)
3059-A

Initial Prior Authorization Testosterone – Oral Testosterone Undecanoate

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Jatenzo	testosterone undecanoate	oral
Kyzatrex	testosterone undecanoate	oral
Tlando	testosterone undecanoate	oral
Undecatrex	testosterone undecanoate	oral

Indications

FDA-approved Indications

Jatenzo, Kyzatrex, Tlando, Undecatrex

Testosterone undecanoate is indicated for testosterone 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 (follicle stimulating hormone (FSH), luteinizing hormone (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.

Limitations of Use:

- Safety and efficacy of testosterone undecanoate in males less than 18 years old have not been established.

Coverage Criteria

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 3059-A: DOA: 12 months

Reference number(s)
3059-A

References

1. Jatenzo [package insert]. Fort Collins, CO: Tolmar, Inc.; August 2023.
2. Kyzatrex [package insert]. Raleigh, NC: Marius Pharmaceuticals LLC; September 2022.
3. Tlando [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; February 2024.
4. Undecatrex [package insert]. San Antonio, TX: Trifluent Pharma, LLC; September 2022.
5. Testopel (testosterone pellets) [package insert]. Malvern, PA: Endo USA; March 2024.
6. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 4, 2025.
7. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/04/2025).
8. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.