blue california

testosterone undecanoate (Aveed)

Commercial Medical Benefit Drug Policy

Place of Service
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (SEX HORMONES/MODIFIERS)
Mechanism of Action: Testosterone replacement
HCPCS:
J3145:Injection, testosterone undecanoate, 1 mg
How Supplied:
750 mg/3 mL (250 mg/mL) injectable solution in single-use vials

Condition(s) listed in policy *(see coverage criteria for details)*

- Testosterone Replacement

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Testosterone Replacement
Meets medical necessity if all the following are met:

1. Being used for male hypogonadism or testosterone replacement therapy for transgender patient
2. Inadequate response or intolerance to a generic long-acting testosterone injection (e.g. IM testosterone cypionate, IM testosterone enanthate)
3. Inadequate response or intolerance to a topical testosterone (e.g. testosterone 1% gel)

Covered Doses:
750 mg given IM at Week 0 and Week 4, then every 10 weeks thereafter

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Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
E29.1, F64.0, F64.1, F64.8, F64.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. Aveed (testosterone undecanoate) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; July 2025.
3. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1): S1-S259.
4. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
5. Shalender Bhasin, Juan P Brito, Glenn R Cunningham et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 103, Issue 5, May 2018, 1715-1744
6. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. J Urol. 2018;200(2):423-432.

Review History

Date of Last Annual Review: 1Q2026
Changes from previous policy version:

- No clinical changes following routine annual review

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee