

Testosterone undecanoate (Aveed®)

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

HCPCS: J3145 per 1 mg

Condition listed in policy (see criteria for details)

- [Testosterone replacement:](#)
 - Hypogonadism in adult males
 - Testosterone replacement therapy for transgender patient

AHFS therapeutic class: Androgen

Mechanism of action: Testosterone replacement

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for testosterone undecanoate (Aveed®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Testosterone replacement

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

Covered dose

750 mg IM at Weeks 0 and Week 4, then every 10 weeks thereafter

Coverage period

Yearly based on continued response to therapy

ICD-10:

E29.1, F64.0, F64.1, F64.8, F64.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for testosterone undecanoate (Aveed®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

PHP Medi-Cal

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Effective: 01/03/2024

(5) Additional Information

How supplied:

750 mg/3 mL (250 mg/mL) injectable solution in single-use vials

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- Aved® (testosterone undecanoate) [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Inc.; 8/2021.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 7). 2012.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*