Testosterone undecanoate (Aveed™)

<u>Place of Service</u> Office Administration Outpatient Facility Infusion Administration Infusion Center Administration

Use HCPC: J3145 per 1mg

NDC: 67979-0511-43

Condition listed in policy (see criteria for details)

• Hypogonadism in adult males

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 (AveedTM) must be <u>sent for clinical review</u> and receive authorization <u>prior to drug administration or claim payment</u>.

Hypogonadism in adult males

- Documentation of low testosterone confirmed by laboratory testing performed on at least two separate days (please submit lab), AND
- Patient is a male age 18 or older, AND
- Inadequate response or intolerance to a generic long-acting testosterone injection [testosterone cypionate or enanthate] AND
- Inadequate response or intolerance to a topical testosterone

Covered dose:

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

Coverage period:

Yearly based on continued response to therapy

ICD-9: 257.2

ICD-10: E29.1

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for testosterone undecanoate (Aveed[™]) must be <u>sent for clinical review</u> and receive authorization <u>prior to drug administration or claim payment</u>.

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

The following conditions and other indications not listed in this policy do not meet the coverage criteria established by the Blue Shield of CA P&T Committee and are NOT-COVERED. Please refer to the user guide for more information.

(5) Additional Information

How supplied: 750 mg/3 mL (250 mg/mL) injectable solution in single use vials

(6) References

- AveedTM Prescribing Information. Endo Pharmaceuticals 2017.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- 1. American Association of Clinical Endocrinologists Position Statement on the Association of Testosterone and Cardiovascular Risk. Endocr Pract 2015;21:1066-1073. Available at: https://www.aace.com/files/position-statements/ep14434ps.pdf

(7) Policy Update

Date of previous review: 3Q2017 Date of next review: 3Q2018 Changes from previous policy version:

• No change to policy following routine review

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