Aveed® (testosterone undecanoate)

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Definition
Aveed 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 cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter’s 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.

Length of Authorization
Coverage will be provided for 12 months and may be renewed.

I. INITIAL APPROVAL CRITERIA
Aveed may be considered medically necessary if the below conditions are met AND use is consistent with the medical necessity criteria that follows:

1. Primary Hypogonadism
   a. Member is at least 18 years of age; AND
   b. Members have at least 2 confirmed low morning serum total testosterone concentrations based on the reference laboratory range.
Limitations/Exclusions
Aveed is not considered medically necessary for when any of the following selection criteria is met:

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate
- Safety and efficacy of Aveed in men with “age-related hypogonadism”
- Safety and efficacy of Aveed in males less than 18 years old have not been established
- Women who are or may become pregnant, or who are breastfeeding. Testosterone can cause fetal harm when administered to a pregnant woman. Aveed may cause serious adverse reactions in nursing infants. Exposure of a female fetus or nursing infant to androgens may result in varying degrees of virilization

II. RENEWAL CRITERIA

- Patient continues to meet INITIAL APPROVAL CRITERIA.
- Patient achieved and/or maintained a positive clinical response to therapy.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Primary hypogonadism, Male</td>
<td>Aveed is for intramuscular use only. Dosage titration is not necessary. The recommended dose of Aveed is 3 mL (750 mg) injected intramuscularly, followed by 3 mL (750 mg) injected after 4 weeks, then 3 mL (750 mg) injected every 10 weeks thereafter.</td>
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</tbody>
</table>

Applicable Procedure Codes

- J3145 Injection, testosterone undecanoate, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

- 67979-0511-43 Aveed single use vial; 250 mg/ml solution

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>E23.6</td>
<td>Other disorders of pituitary gland [covered for hypothalamic hypogonadism; not covered for idiopathic hypogonadism (not due to disorders of the testicles, pituitary gland or brain)]</td>
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<tr>
<td>E29.1</td>
<td>Testicular hypofunction</td>
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</tbody>
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Revision History

04/07/2020 Added under Limitations:
- Men with carcinoma of the breast or known or suspected carcinoma of the prostate
- Safety and efficacy of Aveed in men with “age-related hypogonadism”
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- Women who are or may become pregnant, or who are breastfeeding. Testosterone can cause fetal harm when administered to a pregnant woman. Aveed may cause serious adverse reactions in nursing infants. Exposure of a female fetus or nursing infant to androgens may result in varying degrees of virilization
- Updated Dosing per FDA label
References