Aveed® (testosterone undecanoate)

Last Review Date: June 1, 2020
Number: MG.MM.PH.134

Medical Guideline Disclaimer
Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, (“EmblemHealth”) has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated, GHI HMO Select, ConnectiCare, Inc., ConnectiCare Insurance Company, Inc. ConnectiCare Benefits, Inc., and ConnectiCare of Massachusetts, Inc. related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 and Hypogonadotropic 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>
</tr>
</thead>
<tbody>
<tr>
<td>Primary and Hypogonadotropic 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>
</tr>
</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>
</tr>
</thead>
<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>
</tr>
<tr>
<td>E29.1</td>
<td>Testicular hypofunction</td>
</tr>
</tbody>
</table>

Revision History

- 06/01/2020 Annual Review: Highlighted covered indications for Primary and Hypogonadotropic Hypogonadism
- 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”
  - 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

-Updated Dosing per FDA label

References