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:

II. RENEWAL CRITERIA

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

Dosage/Administration

<table>
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<tr>
<th>Indication</th>
<th>Dose</th>
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| Primary hypogonadism, Male  | – Initial, 237 mg orally twice daily in the morning and evening with food; adjust dose based on serum testosterone measurement (minimum dosage, 158 mg twice daily; MAX 396 mg twice daily) to a range of 425 to 970 nanograms/dL; measure testosterone level 6 hours after the morning dose and wait 7 days after starting treatment or adjusting the dose  
  – Then, 750 mg IM, and then 750 mg IM 4 weeks later, and then 750 mg IM every 10 weeks thereafter.  |

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

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<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<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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References