SPECIALTY GUIDELINE MANAGEMENT

AVEED (testosterone undecanoate injection)

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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.

Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis.

Limitations of use:

- Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

- Safety and efficacy of Aveed in males less than 18 years old have not been established.

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- Pretreatment morning serum total testosterone concentrations

C. EXCLUSIONS

- Use for age-related hypogonadism or late-onset hypogonadism

D. CRITERIA FOR APPROVAL

1. Primary Hypogonadism or Hypogonadotropic Hypogonadism

Authorization of 12 months may be granted to male members who are at least 18 years of age and have at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines

E. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
1. Dosing Limits
   The following dosing limits apply:
   • All indications: 750 mg to start therapy, 750 mg four weeks after the start of therapy, then 750mg every 10 weeks thereafter

REFERENCES