Reference number(s)
3918-A, 6042-A

SPECIALTY GUIDELINE MANAGEMENT

AVEED (testosterone undecanoate injection)

POLICY

I. INDICATION

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.

A. FDA-Approved Indications
Aveed is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

1. 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.
2. 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 (POME) 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.

B. Compendial Uses
Gender dysphoria (also known as transgender and gender diverse [TGD] persons)

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: For primary hypogonadism or hypogonadotropic hypogonadism, pretreatment morning serum total testosterone concentrations

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions: Use for age-related hypogonadism or late-onset hypogonadism

IV. PRESCRIBER SPECIALITIES

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

V. CRITERIA FOR INITIAL APPROVAL

A. Primary hypogonadism or hypogonadotropic hypogonadism

Authorization of 12 months may be granted for treatment of primary hypogonadism or hypogonadotropic hypogonadism when all of the following criteria are met:

1. Member is a biological male or a person that self identifies as male.
2. Member is at least 18 years of age.
3. Member has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines.

B. Gender dysphoria

1. Authorization of 12 months may be granted for gender dysphoria when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in hormone therapy.
   iii. The member's comorbid conditions are reasonably controlled.
   iv. The member has been educated on any contraindications and side effects to therapy.
   v. The member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for gender dysphoria in an adolescent member when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in hormone therapy.
   iii. The member has reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.

VI. CONTINUATION OF THERAPY

A. Primary hypogonadism or hypogonadotropic hypogonadism

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for primary hypogonadism or hypogonadotropic hypogonadism when all of the following criteria are met:

1. Member is a biological male or a person that self identifies as male.
2. Member is at least 18 years of age.
3. Before the start of therapy, the member had at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines.

B. Gender dysphoria

1. Authorization of 12 months may be granted for continued treatment for gender dysphoria in members requesting reauthorization when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in hormone therapy.
   iii. The member's comorbid conditions are reasonably controlled.
   iv. The member has been educated on any contraindications and side effects to therapy.
   v. Before the start of therapy, the member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for continued treatment for gender dysphoria in adolescent members requesting reauthorization when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in hormone therapy.
   iii. The member has previously reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.

VII. OTHER

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

VIII. REFERENCES

1. Aveed [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2021.
2. Bhasin S, Brito JP, Cunninghan GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2018;103(5):1715-1744.
3. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
4. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
5. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
6. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: February 7, 2024).
7. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.