Reference number(s)
6296-A

Standard Medicare Part B Management Aveed

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aveed	testosterone undecanoate

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[1]

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 (POME) and anaphylaxis.

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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.

Compendial Uses[3-6]

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions: For primary hypogonadism or hypogonadotropic hypogonadism, pretreatment morning serum total testosterone concentrations (initial requests).

Exclusions

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

Coverage Criteria

Primary Hypogonadism or Hypogonadotropic Hypogonadism[1,2]

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

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

Gender Dysphoria[3-6]

Authorization of 12 months may be granted for members with a diagnosis of gender dysphoria.

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Authorization of 12 months may be granted for an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member has reached Tanner stage 2 of puberty or greater.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Primary Hypogonadism or Hypogonadotropic Hypogonadism

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat primary hypogonadism or hypogonadotropic hypogonadism.
- The member is receiving benefit from therapy.

Gender Dysphoria

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat gender dysphoria.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Aveed.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline
- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline

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- Gender Identity Research and Education Society: Guidance for GPs and other clinicians on the treatment of gender variant people
- Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Aveed are covered in addition to gender dysphoria.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Aveed for gender dysphoria can be found in the Endocrine Society Clinical Practice Guideline for Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons. The guideline supports the use of hormonal therapy to replace endogenous sex hormone levels consistent with the individual's gender identity by using the principles of hormone replacement treatment of hypogonadal patients. For transgender males, clinicians can use either parenteral or transdermal androgen preparations to achieve testosterone values in the normal male range.

Support for using Aveed for gender dysphoria can also be found in the World Professional Association for Transgender Health (WPATH). According to the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, transgender and gender diverse (TGD) persons may require medically necessary gender-affirming hormone therapy (GAHT) to achieve changes consistent with their embodiment goals, gender identity, or both. In eligible youth who have reached the early stages of puberty, the focus is usually to delay further pubertal progression with gonadotropin releasing hormone agonists (GnRHas) until an appropriate time when GAHT can be introduced. GAHT with feminine embodiment goals typically consists of estrogen and an androgen-lowering medication. Masculinizing GAHT typically consists of testosterone. WPATH recommends health care professionals prescribe sex hormone treatment regimens as part of gender-affirming treatment for eligible transgender and gender diverse adolescents who are at least Tanner stage 2, with parental/guardian involvement unless their involvement is determined to be harmful or unnecessary to the adolescent. For TGD adolescents with functioning ovaries who are new to care, GAHT can be accomplished with physiological doses of testosterone alone without the need for concomitant GnRHa administration.

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.

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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).

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