

Policy: MBP 116.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Aveed (testosterone undecanoate)

I. Policy:

Aveed (testosterone undecanoate)

II. Purpose/Objective:

To provide a policy of coverage regarding Aveed (testosterone undecanoate)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Aveed (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

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.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Aveed (testosterone undecanoate) will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
 - Primary hypogonadism (congenital or acquired) **OR**
 - Hypogonadotropic hypogonadism (congenital or acquired) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to testosterone cypionate **AND** testosterone enanthate

For Gender Dysphoria:

- Psychological evaluation for gender dysphoria by a behavioral health professional with a minimum of a master's degree or equivalent who is capable of evaluating the member in accordance with WPATH Guidelines:
 1. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
 2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
 3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
 4. Documented supervised training and competence in psychotherapy or counseling.
 5. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
 6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.
- The member must be post-pubertal as documented by the treating provider
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to testosterone cypionate **AND** testosterone enanthate

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Aveed (testosterone undecanoate) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- Medical record documentation of use for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
 - Primary hypogonadism (congenital or acquired) **OR**
 - Hypogonadotropic hypogonadism (congenital or acquired)

For Gender Dysphoria:

- Psychological evaluation for gender dysphoria by a behavioral health professional with a minimum of a master's degree or equivalent who is capable of evaluating the member in accordance with WPATH Guidelines:
 1. A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
 2. Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
 3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
 4. Documented supervised training and competence in psychotherapy or counseling.
 5. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
 6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.
- The member must be post-pubertal as documented by the treating provider

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Aved [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; August 2021.
2. Coleman EA, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. World Professional Association of Transgender Health. *International Journal of Transgender Health*. 2022 Sep 15. 23(1): S1-S259 [cited 2023 Dec 26]. Available from: <https://www.wpath.org/soc8>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/16/14

Revised: 3/24/15 (formatting, auth duration), 6/5/17 (gender dysphoria), 1/16/23 (LOB carve out), 12/30/23 (references added), 1/8/24 (Medicaid business segment)

Reviewed: 3/16, 3/30/17, 3/29/18, 2/28/19, 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23