Mass General Brigham
Health Plan

Androgen Therapy
Aveed (testosterone undecanoate injectable)
Effective 11/12/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations			
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Aveed (testosterone undecanoate injectable) is indicated for testosterone replacement in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

Coverage Guidelines
Authorization may be granted for new members to the plan who are currently receiving treatment with Aveed excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members diagnosed with any of following conditions when all the criteria are met, and documentation is provided:

Delayed Puberty
1. Diagnosis of delayed puberty
2. Prescriber is a pediatric endocrinologist or consult notes from a specialist are provided
3. Member is ≥ 14 years of age and <17 years of age
4. **ONE** of the following:
    a. Tanner staging of I or II for sexual maturation ratings
    b. Other physical signs of delayed puberty such as: arm span exceeding the member's height by > 5 cm, abnormal testicular growth (testicular volume < 4 mL), bone ages documented as less than the member's current age
5. Low testosterone level provided via medical records or written on PA with dates drawn and reference ranges (< 300 ng/dL total serum testosterone)* *Please note, provided levels should be drawn within one year of testosterone request.*
6. Inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to **BOTH** of the following:
    a. testosterone cypionate intramuscular injection
    b. testosterone enanthate intramuscular injection

Other Indications

1. **ONE** of the following:
    a. Diagnosis of **ONE** of the following:
        i. gender dysphoria (gender identity disorder)
        ii. transgenderism
        iii. therapy after gender reassignment surgery
    b. **BOTH** of the following:
        i. Diagnosis of **ONE** of the following:
            1. Primary hypogonadism
            2. Hypogonadotropic hypogonadism
        ii. Low testosterone level provided via medical records or written on PA with dates drawn and reference ranges (< 300 ng/dL total serum testosterone)* *Please note, provided levels should be drawn within one year of testosterone request.*
2. Inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to **BOTH** of the following:
    a. testosterone cypionate intramuscular injection
    b. testosterone enanthate intramuscular injection

Continuation of Therapy

Delayed Puberty

Recertifications beyond six months require documentation of low testosterone levels after discontinuation of therapy.

Other Indications

Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial and reauthorization approvals will be granted for:
    a. Delayed puberty: 6 months
    b. All other indications: 12months.

References

1. Aveed (testosterone undecanoate) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; June 2020

Review History

07/21/2021- Reviewed at July P&T; switched from CVS standard criteria to custom criteria; moved gender criteria from compendial to FDA indication; added reauth criteria for hypogonadism
11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.
10/09/2024 – Reviewed and updated for P&T. Adopted MH criteria for Aveed. Effective 11/12/24