Mass General Brigham
Health Plan

Testosterone Products Requiring Skilled Administration: Aveed (testosterone undecanoate injection) Azmiro (testosterone cypionate injection) Effective 07/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
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		
Exceptions	N/A		

Overview

Aveed (testosterone enanthate) injection and Azmiro (testosterone cypionate) injection are androgens indicated for testosterone replacement in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

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

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

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

1. Member is 18 years of age or older
2. ONE of the following:
    a. Medication will be used for endocrine treatment of gender dysphoric/gender incongruent persons
    b. ALL of the following:
        i. Provider has submitted at least two confirmed low pretreatment morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines
        ii. Member has ONE of the following diagnoses:
            1. Member is diagnosed with 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. Member is diagnosed with 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.

Continuation of Therapy

1. Primary or hypogonadotropic hypogonadism:
    a. The member is not currently receiving the requested therapy through samples or a manufacturer's patient assistance program
    b. Documentation is submitted which shows the member's testosterone levels are maintained within normal range
2. Gender dysphoria: the member must meet all initial criteria

Limitations

1. Initial and reauthorization approvals will be granted for 12 months.
2. Coverage will not be provided for members using the requested medication for age-related hypogonadism or late-onset hypogonadism.

References

1. Aveed (testosterone undecanoate) [prescribing information]. Malvern, PA: Endo USA; August 2021.
2. Azmiro (testosterone cypionate) [prescribing information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; May 2024.

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.
05/14/2025 – Reviewed and updated at May P&T. Added Azmiro to the policy. Updated policy title to "Testosterone Products Requiring Skilled Administration." Updated policy to not require low pretreatment testosterone levels prior to initiating therapy for gender dysphoria. Effective 07/01/2025.