Mass General Brigham
Health Plan

Aveed (testosterone undecanoate injectable)
Effective 10/01/2021

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations			
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview
Aveed 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:

1. The member is ≥ 18 years of age
2. The provider has submitted at least two confirmed low pretreatment morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines
3. The member meets ONE of the following diagnosis:
    a. The 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.
    b. The 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.

c. The medication will be used for endocrine treatment of gender dysphoric/gender incongruent persons

Continuation of Therapy

1. Primary or hypogonadotropic hypogonadism:
    a. The member is not currently receiving Aveed 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. For Gender dysphoria: the member must meet all initial criteria

Limitations

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

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.