

## Testosterone enanthate (Xyosted™)

**Place of Service**  
**Self-Administration**  
*Pharmacy Benefit*

**HCPCS: J3490**

### **NDCs:**

- 54436-200-02: 100 mg/0.5 mL single-dose autoinjector syringe
- 54436-200-04: 100 mg/0.5 mL single-dose autoinjector syringe (carton of 4)
- 54436-250-02: 50 mg/0.5 mL single-dose autoinjector syringe
- 54436-250-04: 50 mg/0.5 mL single-dose autoinjector syringe (carton of 4)
- 54436-275-02: 75 mg/0.5 mL single-dose autoinjector syringe
- 54436-275-04: 75 mg/0.5 mL single-dose autoinjector syringe (carton of 4)

### **Condition(s) listed in policy (see criteria for details)**

- [Testosterone replacement](#):
  - Hypogonadism in adult males
  - Testosterone replacement therapy for transgender patient

**AHFS therapeutic class:** androgen

**Mechanism of action:** testosterone replacement

### **(1) Special Instructions and Pertinent Information**

**Xyosted is managed under the Outpatient Pharmacy Benefit.** If the patient has a prescription drug benefit, please contact Blue Shield Pharmacy services to obtain a prior authorization.

**To submit a request to the medical benefit,** please submit clinical information for prior authorization review via fax, including medical rationale why the patient cannot self-administer Xyosted in the home.

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

**All requests for testosterone enanthate (Xyosted™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

#### **Testosterone replacement**

1. Being used for male hypogonadism or testosterone replacement therapy for transgender patient, **AND**
2. Inadequate response or intolerance to a generic long-acting testosterone injection (e.g. IM testosterone cypionate, IM testosterone enanthate), **AND**
3. Inadequate response or intolerance to a topical testosterone (e.g. testosterone 1% gel)

#### **Covered Doses**

Up to 100 mg SC weekly

Commercial

testosterone enanthate (Xyosted™)

**Coverage period**

Yearly based on continued response to therapy

**ICD-10:**

E29.1, F64.x

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

**All requests for testosterone enanthate (Xyosted™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s):**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 50 mg/0.5 mL single-dose autoinjector syringe
- 75 mg/0.5 mL single-dose autoinjector syringe
- 100 mg/0.5 mL single-dose autoinjector syringe

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. J Urol. 2018;200(2):423-432.
- Qaseem A, Horwitch CA, Vijan S, et al. Testosterone treatment in adult men with age-related low testosterone: a clinical guideline from the American College of Physicians. Ann Intern Med 2020;172:126-133.
- World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 7). 2012. Available at: [http://www.wpath.org/uploaded\\_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf](http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf)
- Xyosted® (testosterone enanthate) [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; 6/2021.

**(7) Policy Update**

Date of last review: 3Q2021

Date of next review: 3Q2022

Changes from previous policy version:

- No clinical change to policy following routine annual review.