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

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
- Xyosted™ Prescribing Information. Antares Pharma, Inc., Ewing, NJ. 2018.

(7) Policy Update

Date of last review: 3Q2020
Date of next review: 3Q2021
Changes from previous policy version:

- No clinical change to policy following routine annual review.