Pharmacy Medical Necessity Guidelines: Testosterone Replacement Therapies

Effective: January 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

- The table below outlines the coverage and FDA-approved indications for the different testosterone-replacement therapies.

Medication Name	Coverage Status	FDA-Approved Indications			
		Delayed Puberty	Hypogonadotropic Hypogonadism	Primary Hypogonadism	Breast Cancer, Metastatic
First-Line Therapies					
Testosterone cypionate injection (generic Depo-Testosterone)	Covered		X	X	
Testosterone enanthate mg/mL injection	Covered	X	X	X	X
Testesterone 1% gel (generic Androgel, generic Vogelxo, generic Testim)	Covered		X	X	
Testosterone 10 mg/ actuation pump (generic Fortesta)	Covered		X	X	
Second-Line Therapies					
Jatenzo (testosterone undecanoate) capsule	PA;QL		X	X	
Kyzatrex (testosterone undecanoate)	PA		X	X	
Testosterone 1.62% gel, pump (generic Androgel 1.62%)	PA		X	X	
Testopel (testosterone) pellet implant	MB;PA	X*	X	X	
Testosterone 30 mg solution (generic Axiron)	PA		X	X	
Tlando (testosterone undecanoate) capsule	PA;QL		X	X	
Xyosted (testosterone enanthate) auto-injector	PA		X	X	
Third-Line Therapies					
Aveed (testosterone undecanoate) IM injection	MB;PA		X	X	
Methyltestosterone capsule (generic Methitest)	PA	X	X	X	X
Methitest (methyltestosterone) tablet	PA		X	X	X

PA =Prior Authorization; QL = Quantity Limit

*Testopel is indicated to stimulate puberty in carefully selected males with delayed puberty.

The Plan will approve requests for methyltestosterone capsules for the treatment of hereditary angioedema (HAE). Requests for methyltestosterone tablets must include documentation that the member had an inadequate response, intolerance, or contraindication to the capsules.

COVERAGE GUIDELINES

The plan may authorize coverage of a testosterone replacement therapy for Members when the following criteria are met and limitations do not apply:

Diagnosis of Hereditary Angioedema (HAE):

1. The member has a diagnosis of hereditary angioedema (HAE)

AND

2. The request is for methyltestosterone

AND

3. **Requests for methyltestosterone tablets:** The member has had an inadequate response, intolerance, or contraindication to methyltestosterone capsule

Other Diagnoses:

1. Member is diagnosed with one of the following conditions:
   a) Hypogonadism (primary or secondary) and is 18 years of age or older

   OR

   b) AIDS wasting syndrome

   OR

   c) Delayed puberty

   OR

   d) Metastatic breast cancer

   OR

   e) Gender affirmation or status-post gender-affirming surgery

   AND

2. **If the request is for a second line therapy:**
   a) The member has had an inadequate response with or intolerance to at least one first line therapy OR the member has a contraindication to all first line therapies

   If the request is for a third-line therapy:
   a) The member has had an inadequate response with or intolerance to at least one first-line therapy OR the member has a contraindication to all first-line therapies

   AND

   b) The member has had an inadequate response or intolerance to at least one second-line therapy or the member has a contraindication to all second-line therapies

   AND

3. **If the request is for a brand name medication:** Documentation that the member has had an inadequate response or intolerance to at least two generic testosterone replacement therapies for the member has a contraindication to all generic testosterone replacement therapies.

   AND

4. **Methyltestosterone tablet only:** The member has had an inadequate response, intolerance, or contraindication to methyltestosterone capsule.

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
2. Quantity limits apply as follows:

Jatenzo 158 mg capsule	2 capsules/day
Jatenzo 237 mg capsule	2 capsules/day
Jatenzo 198 mg capsule	4 capsules/day
Tlando 112.5 mg capsule	4 capsules/day

CODES

None

REFERENCES

1. Androderm [prescribing information]. Madison, NJ; Allergan, Inc: May 2020.
2. AndroGel 1% (testosterone gel) [prescribing information]. North Chicago, IL; AbbVie Inc: May 2019.
3. AndroGel 1.62% (testosterone gel) [prescribing information]. North Chicago, IL; AbbVie Inc: November 2020.
4. Aveed (testosterone) [prescribing information]. Malvern, PA; Endo Pharmaceuticals, Inc: August 2021.
5. Depo-Testosterone (testosterone cypionate) [prescribing information]. New York, NY; Pfizer; August 2018.
6. Fortesta [prescribing information]. Malvern, PA; Endo Pharmaceuticals Inc: January 2022.
7. Jatenzo [prescribing information]. Fort Collins, CO; Tolmar, Inc.: August 2023.
8. Methyltestosterone capsule [prescribing information]. Novitium Pharma LLC; East Windsor, NJ: June 2021.
9. Kyzatrex [prescribing information]. Raleigh, NC; Marius Pharmaceuticals LLC: September 2022.
10. Methitest (methyltesterone tablet) [prescribing information]. Amneal Pharmaceuticals LLC; Bridgewater, NJ: October 2018.
11. Testim (testosterone gel) [prescribing information]. Malvern, PA; Endo Pharmaceuticals: August 2021.
12. Testopel [prescribing information]. Malvern, PA; Endo Pharmaceuticals, Inc: August 2018.
13. Testosterone enanthate [prescribing information]. Berkeley Heights, NJ; Hikma Pharmaceuticals US Inc.: January 2021.
14. Testosterone solution [prescribing information]. Parsippany, NJ; Actavis Pharma, Inc.: February 2019.
15. Tlando (testosterone undeconate) [prescribing information]. Ewing, NJ; Antares Pharma, Inc: March 2022.
16. Vogelxo (testosterone gel) [prescribing information]. Maple Grove, MN; Upsher-Smith Pharmaceuticals: April 2020.
17. Xyosted [prescribing information]. Ewing, NJ; Antares Pharma: November 2019.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:

1. November 8, 2022: Added Kyzatrex to the MNG as a second-line therapy.
2. December 13, 2022: Administrative update; added medical benefit drugs Aveed and Testopel to the MNG to indicate where they fall in terms of second- and third-line therapies.
3. November 14, 2023: Effective December 1, 2023, removed Striant from the MNG due to product discontinuation. Updated fax number for RxUM.
4. December 10, 2024: No changes.
5. December 9, 2025: Effective January 1, 2026, removed Androderm from MNG due to product discontinuation

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.