Pharmacy Medical Necessity Guidelines: Testosterone Replacement Therapies

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX/ MED	Department to Review	RXUM /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
Administered by healthcare professional:
MM: 888.415.9055

Self-administered:
RXUM: 617.673.0988

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					
Androderm (testosterone transdermal system)	PA		X	X	
Jatenzo (testosterone undecanoate) capsule	PA;QL		X	X	
Testosterone 1.62% gel, pump (generic Androgel 1.62%)	PA		X	X	
Testosterone 30 mg solution (generic Axiron)	PA		X	X	
Testopel (testosterone) pellet implant	MB;PA	X	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
Striant (testosterone) buccal	PA		X	X	

MB = Medical Benefit; PA =Prior Authorization; QL = Quantity Limit

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 tablets.

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) Transgender or status-post transgender 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. **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

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J3145	Injection, testosterone undecoanate, 1 mg
J3490	Testopel 75 mg pellet

REFERENCES

1. Androderm [prescribing information]. Madison, NJ: Allergan, Inc; June 2018.
2. Testim [prescribing information]. Malvern, PA: Endo Pharmaceuticals; April 2018.
3. AndroGel 1% [prescribing information]. North Chicago, IL: AbbVie Inc; February 2019.
4. AndroGel 1.62% [prescribing information]. North Chicago, IL: AbbVie Inc; February 2019.
5. Axiron [prescribing information]. Indianapolis, IN: Eli Lilly; July 2017.
6. Fortesta [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; July 2017.
7. Jatenzo [prescribing information]. Northbrook, IL: Clarus Therapeutics Inc; March 2019.
8. Testopel [prescribing information]. Malvern, PA; Endo Pharmaceuticals, Inc; August 2018.
9. Striant [prescribing information]. Malvern, PA; Actient Pharmaceuticals: October 2016.
10. Xyosted [prescribing information]. Ewing, NJ; Antares Pharma: November 2019.

APPROVAL HISTORY

December 9, 2014: Reviewed by Pharmacy & Therapeutics Committee: Modified for transgender diagnoses for Members enrolled in MassHealth; required use with generic product(s) prior to brand-name products.

Subsequent endorsement date(s) and changes made:

1. July 8, 2014: Modified for transgender diagnoses for Members enrolled in a commercial plan.
2. November 10, 2015: Incorporated a table with Preferred Drug List status of the available medications; modified criteria if a request is for a brand name medication so that the Member must fail a course of therapy with a generic product of similar strength and formulation.
3. January 1, 2016: Administrative change to rebranded template.
4. October 18, 2016: No changes
5. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template
6. November 14, 2017: No changes.
7. December 11, 2018: Effective 12/17/18, removed "male gender" from hypogonadism diagnosis. Indicated generic availability of Androgel 1.62%. Administrative changes made to template.
8. February 12, 2019: Added Xyosted to Medical Necessity Guideline.
9. February 11, 2020: Added Jatenzo to the Medical Necessity Guideline. For non-preferred products, updated the criteria to remove the requirement that the member must try and fail a generic product of similar formulation and strength.
10. April 14, 2020: Effective 7/1/2020, updated stratification of therapies into first-, second-, and third-line. Updated criteria for second-line therapies to require trial and failure with a first-line agent, and updated criteria for third-line therapies to require trial and failure with a first- and second-line agent. Updated the limitations section to indicate that requests for brand-name products with AB-rated generics will be reviewed against the Brand Name criteria. Added J codes for Aveed and Testopel.
11. July 14, 2020: Updated MNG to include approval criteria for methyltestosterone for the treatment of HAE.

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.

Provider Services