Pharmacy Medical Necessity Guidelines:
Testosterone Replacement Therapies

Effective: February 18, 2019

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Not Covered</th>
<th>Type of Review – Clinical Review</th>
<th>√</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RXUM</td>
<td>RX</td>
<td>Department to Review</td>
<td>RXUM</td>
</tr>
</tbody>
</table>

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
- CareLinkSM – 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:
RXUM: 617.673.0988

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

**OVERVIEW**

**FDA-APPROVED INDICATIONS**
- Testosterone topical gel, buccal system, topical solution, transdermal system are indicated for male hypogonadism (primary or hypogonadotropic).
- Testosterone injection is indicated for androgen replacement therapy in the treatment of delayed male puberty, male hypogonadism (primary or hypogonadotropic), and in inoperable metastatic female breast cancer (enanthate formulation only).
- Testosterone enanthate injection auto-injector (Xyosted) is approved for the testosterone replacement therapy in adult males for conditions associated with deficiency or absence of endogenous testosterone.
- Testosterone pellet is indicated for androgen replacement therapy in the treatment of delayed male puberty, and male hypogonadism (primary or hypogonadotropic).

<table>
<thead>
<tr>
<th>Medication</th>
<th>Preferred Drug List Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred First-Line Therapies</strong></td>
<td></td>
</tr>
<tr>
<td>METHYLTESTOSTERONE 10 MG CAPSULE</td>
<td>Covered</td>
</tr>
<tr>
<td>TESTOSTERONE GEL (1%)</td>
<td>PA</td>
</tr>
<tr>
<td>TESTOSTERONE (2%)</td>
<td>PA</td>
</tr>
<tr>
<td>TESTOSTERONE CYCIONATE INJ</td>
<td>PA</td>
</tr>
<tr>
<td>TESTOSTERONE ENANTHATE INJ</td>
<td>PA</td>
</tr>
<tr>
<td><strong>Non-Preferred Second-Line Therapies</strong></td>
<td></td>
</tr>
<tr>
<td>ANDRODERM PATCH</td>
<td>PA</td>
</tr>
<tr>
<td>ANDROGEL (1%<em>, 1.62%</em>)</td>
<td>PA</td>
</tr>
<tr>
<td>ANDROXY</td>
<td>Covered</td>
</tr>
<tr>
<td>AVEED INJ</td>
<td>PA</td>
</tr>
<tr>
<td>AXIRON SOLN*</td>
<td>PA</td>
</tr>
<tr>
<td>DEPO-TESTOSTERONE INJ*</td>
<td>PA</td>
</tr>
<tr>
<td>FIRST-TESTOSTERONE (2%) CREAM, OINT.</td>
<td>Covered</td>
</tr>
<tr>
<td>FORTESTA GEL (2%)*</td>
<td>PA</td>
</tr>
<tr>
<td>METHITEST 10 MG TAB</td>
<td>PA</td>
</tr>
<tr>
<td>STRIANT BUCCAL</td>
<td>PA</td>
</tr>
<tr>
<td>TESTIM GEL (1%)*</td>
<td>PA</td>
</tr>
</tbody>
</table>
**Pharmacy Medical Necessity Guidelines:**

**Testosterone Replacement Therapies**

<table>
<thead>
<tr>
<th>TESTOPEL IMPLANT</th>
<th>PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>VOGELXO (1%)*</td>
<td>PA</td>
</tr>
<tr>
<td>XYOSTED INJ</td>
<td>PA</td>
</tr>
</tbody>
</table>

* Available generically

**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:

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 dysphoria or status-post transgender surgery

   AND

2. If the request is for a non-preferred medication, the Member failed therapy with a generic product of similar strength and formulation (e.g., topical, intramuscular)

**LIMITATIONS**

None

**CODES**

None

**REFERENCES**

5. AndroGel [prescribing information]. North Chicago, IL: AbbVie Inc; October 2016.

**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

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.