Medical Necessity Guidelines

Medical Benefit Drugs

Testosterone Replacement Therapies: Aveed® (testosterone undecanoate IM injection) Testopel® (testosterone pellet implant)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration-Approved Indications

- Aveed (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
  - Primary hypogonadism (congenital or acquired)
  - Hypogonadotropic hypogonadism (congenital or acquired)

- Testopel (testosterone pellet implant) is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:
  - Primary hypogonadism (congenital or acquired)
  - Hypogonadotropic hypogonadism (congenital or acquired)
  - Stimulating puberty in carefully selected males with delayed puberty

Clinical Guideline Coverage Criteria

Aveed

The Plan may cover Aveed when **ALL** the following clinical criteria are met:

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. The Member has had an inadequate response with or intolerance to at least **one** testosterone replacement therapy covered without prior authorization **OR** the member has a contraindication to **ALL** testosterone replacement therapies covered without prior authorization (e.g., testosterone cypionate injection [generic Depo-Testosterone], testosterone enanthate injection, testosterone 1% gel [generic Androgel, Vogelxo, Testim], testosterone 10mg/actuation pump [generic Fortesta])

AND

3. The Member has had an inadequate response or intolerance to at least one of the following therapies OR contraindication to ALL of the following therapies: Jatenzo (testosterone undecanoate capsule), Kyzatrex (testosterone undecanoate) capsule, testosterone 1.62% gel, pump (generic Androgel 1.62%), testosterone 30mg solution (generic Axiron), Testopel (testosterone pellet implant), Tlando (testosterone undecanoate) capsule, Xyosted (testosterone enanthate auto-injector)

Testopel

The Plan may cover Testopel when **ALL** the following clinical criteria are met:

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. The Member has had an inadequate response with or intolerance to at least **one** testosterone replacement therapy covered without prior authorization **OR** the member has a contraindication to **all** testosterone replacement therapies covered without prior authorization (e.g., testosterone cypionate injection [generic Depo-Testosterone], testosterone enanthate injection, testosterone 1% gel [generic Androgel, Vogelxo, Testim], testosterone 10mg/actuation pump [generic Fortesta])

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3145	Injection, testosterone undecanoate, 1 mg
J1073	Testosterone pellet, implant, 75 mg

References:

1. Aveed® (testosterone undecanoate IM injection). [package insert]. Malvern, PA; Endo Pharmaceuticals, Inc. August 2021.
2. Testopel® (testosterone pellet implant). [package insert]. Malvern, PA; Endo Pharmaceuticals, Inc. August 2018.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- December 12, 2023: Effective January 1, 2024, removed references to first- and second-line therapies in previous trial

language and updated Aveed criteria to include Kyzatrex and Tlando as previous trial options. Updated the Pharmacy Utilization Management fax numbers for Tufts Health Together and Tufts Health RITogether.

- December 10, 2024: No changes
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: Effective 1/1/26, Administrative Update: Added J Code, J1073, and removed J Code, S0189, effective 1/1/26. Updated Aveed criteria to removed Androdem from previous trial options due to product discontinuation.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.