

**Androgen Therapy**  
**Testopel (testosterone pellets)**  
**Effective 06/01/2025**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	Testopel is also available on the pharmacy benefit. Please see the <a href="#">MassHealth Drug List</a> for coverage and criteria.		

## Overview

Testopel can be approved for the following diagnoses:

1. **Delayed Puberty:** To stimulate puberty in males with delayed puberty
2. **Hypogonadism, Hypogonadotropic (Congenital or Acquired):** Treatment of gonadotropin or luteinizing hormone-releasing hormone deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation
3. **Hypogonadism, Primary (Congenital or Acquired):** Treatment of testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals
4. **Transgender Dysphoria or Status-Post Transgender Surgery**

## Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

### OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

#### *Hypogonadism*

1. Diagnosis of ONE of the following:
  - a. Primary hypogonadism
  - b. Hypogonadotropic hypogonadism
2. Lab results of TWO tests (dated  $\leq$  3 months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone  $< 300\text{ng/dL}$ ) \*

#### *Gender Dysphoria/Transgenderism/Therapy after gender reassignment surgery (off label)*

1. Diagnosis of ONE of the following:
  - a. gender dysphoria (gender identity disorder)
  - b. transgenderism

c. therapy after gender reassignment surgery

***Delayed Puberty (off label)***

1. Individual drug PA criteria must be met first where applicable
2. Diagnosis of delayed puberty
3. Prescriber is a pediatric endocrinologist or consult notes from a specialist are provided.
2. Member is  $\geq 14$  years of age and  $<17$  years of age
3. ONE of the following:
  - a. Tanner staging of I or II for sexual maturation ratings
4. b. Other physical signs of delayed puberty such as: arm span exceeding the member's height by  $> 5$  cm, abnormal testicular growth (testicular volume  $< 4$  mL), bone ages documented as less than the member's current age
5. Lab results of TWO tests (dated  $\leq 3$  months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone  $<300$  ng/dL)\*

*\*Please see appendix regarding lab values that vary from these levels*

**Continuation of Therapy**

*Delayed Puberty:* Reauthorizations beyond six months require documentation of low testosterone levels after discontinuation of therapy.

*All other diagnoses:* Reauthorization by physician will infer a positive response to therapy.

**Limitations**

1. Initial approvals and reauthorizations will be granted:
  - a. Delayed puberty: 6 months
  - b. All other diagnoses: 1 year

**Appendix**

*Lab values*

If providers document a low free testosterone (with noted reference ranges attached) and a normal Total testosterone level, requests for androgen therapy can be approved.

In addition, if the member has been stable on testosterone therapy it is expected that the testosterone levels will be within a normal range.

The normative ranges may vary among laboratories and assays. Any value provided outside of the Endocrine Society levels need to be accompanied by the range used by the lab that did the test.

**References**

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#### **Review History**

05/18/2022 – Created and Reviewed for May P&T; separated out Comm/Exch criteria from MH. Effective 08/01/2022

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria. Effective 4/1/23.

05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Updated to remove the requirement to provide reference ranges and expanded to require two low testosterone levels be provided. Incorporated off label criteria. Effective 6/1/25

