Mass General Brigham
Health Plan

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

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	Testopel is also available on the pharmacy benefit. Please see the MassHealth Drug List 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 ≤ 3 months apart and drawn within one year of the PA request) documenting low testosterone levels (defined as total serum testosterone < 300ng/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 ≥ 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 ≤ 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