Mass General Brigham
Health Plan

TESTOPEL® (testosterone pellets)
Effective 04/01/2023

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		
Exceptions	N/A		

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**

No PA	Require PA
	Testopel® (testosterone intramuscular pellet)

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:

1. Appropriate diagnosis *†
2. A low testosterone level provided via medical records or written on PA with dates drawn (within 1 year of testosterone request) and reference ranges (< 300ng/dL total serum testosterone) ‡

Notes:

**Please see appendix regarding use of androgen therapy in Gender Identity Disorder*

† Please see appendix regarding diagnosis of delayed puberty

‡Please see appendix regarding lab values that vary from these levels

Continuation of Therapy
Females: Reauthorization requires physician documentation of response to therapy.
Males: Reauthorization by physician will infer a positive response to therapy.

Limitations
1. Initial approvals and reauthorizations will be granted for 12 months

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.

Gender Identity Disorder
Requests for any of the following diagnoses will be approved if the dose and frequency of the requested agent is determined to be appropriate based on the recommended dosage and administration for hypogonadism for the individual agent:
- gender identity disorder
- gender dysphoria
- transsexualism
- therapy after gender reassignment surgery

Testosterone levels will not be required for approval.

Delayed Puberty
Requests for androgen therapy in a member ≥14 years old may be approved with a diagnosis of delayed puberty if the PA or medical records indicate any of the following:
- Tanner Staging of I or II for sexual maturation ratings
- 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
- Prescribing physician is a pediatric endocrinologist or member has consultation notes from a pediatric endocrinologist attached with PA.

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.