Mass General Brigham
Health Plan

TESTOPEL® (testosterone pellets)
Effective 08/01/2022

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**

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with TESTOPEL, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization of TESTOPEL will be granted if the member meets all following diagnosis specific criteria and documentation has been submitted:

Delayed Puberty

1. The member has an appropriate diagnosis
2. The prescriber is a pediatric endocrinologist
3. The member is at least 14 years of age
4. The member has had an inadequate response (after at least 6 months) OR an intolerance to an injectable generic testosterone agent.

Hypogonadism (Primary or Hypogonadotropic)

1. The member has an appropriate diagnosis
2. The prescriber has submitted at least two confirmed low testosterone levels obtained within the past 6 months
3. The member has had one of the following:
    a. an inadequate response to one injectable AND one topical testosterone agent (trial of at least 6-months duration)
    b. intolerance to one injectable AND one topical testosterone agent

Transgender Dysphoria or Status-Post Transgender Surgery:

1. The member is 14 years of age or older (guardian or custodial consent required for minors age 14-18)
2. The member has a diagnosis of gender dysphoria/incongruence or gender identity disorder or is status-post gender reassignment surgery
3. The medication is being prescribed by or in consultation with an endocrinologist or physician who specializes in the treatment of transgender patients
4. The goal of treatment is female-to-male gender reassignment

Continuation of Therapy

Reauthorization of TESTOPEL will be granted based on the following diagnosis specific criteria:

1. **Delayed Puberty:** May be approved upon receipt of clinical information evidencing normal skeletal maturation (x-rays of the hand and wrist)

2. **Primary or Hypogonadotropic Hypogonadism:** May be approved upon receipt of serum testosterone tests confirming testosterone levels are within normal range according to current practice guidelines or your standard lab reference values

3. **Transgender Related Diagnosis:** May be approved upon receipt of clinical information evidencing patient status and continued efficacy

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations for delayed puberty will be granted for 6 months
3. Reauthorizations for primary/hypogonadotropic hypogonadism or transgender related diagnosis will be granted for 12 months.

References

1. TESTOPEL (testosterone pellets) [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc; August 2018.
2. Fortesta (testosterone) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc;
3. October 2016.
4. AndroGel 1.62% (testosterone) [prescribing information]. North Chicago, IL: AbbVie Inc;
5. October 2016.
6. Soliman AT, Khadir MM, Asfour M. Testosterone treatment in adolescent boys with constitutional delay of growth and development. Metabolism 1995; 44:1013.
7. Muram D, Zhang X, Cui Z, Matsumoto AM. Use of Hormone Testing for the Diagnosis and Evaluation of Male Hypogonadism and Monitoring of Testosterone Therapy: Application of Hormone Testing Guideline Recommendations in Clinical Practice. J Sex Med 2015; 12:1886.

8. Rosenfield RL. Clinical review 6: Diagnosis and management of delayed puberty. J Clin Endocrinol Metab 1990; 70:559. 2. Kaplowitz PB. Delayed puberty. Pediatr Rev 2010; 31:189.
9. Depo-Testosterone (testosterone cypionate injection) [prescribing information]. New York, NY: Pharmacia & Upjohn; June 2014
10. Testosterone enanthate [prescribing information]. Eatontown, NJ: West-Ward Pharmaceutical; July 2014
11. Coleman E, Bockting W, Botzer M, et al. World Professional for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. Int J Transgen. 2012; 13:165-232. Available at: http://www.wpath.org/site_page.cfm?pk_association_w ebpage_menu=1351&pk_association_w ebpage=4655
12. Hembree WC. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. The journal of clinical endocrinology and metabolism. 2009-09;94:3132-3154
13. Knezevich EL, Viereck LK, Drincic AT. Medical Management of Adult Transsexual Persons. Pharmacotherapy. 2012;32(1):54-66

Review History

02/20/19 – Approved by P&T
09/18/19 – Added coverage for Transgender Dysphoria and Status-Post Transgender Surgery
05/18/2022 – Reviewed and Updated for May P&T; separated out Comm/Exch criteria from MH. Effective 08/01/2022.