

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

<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 checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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:

1. Appropriate diagnosis
2. A low testosterone level with dates drawn and reference range (< 300ng/dL total serum testosterone)

**Continuation of Therapy**



Reauthorization of TESTOPEL will be granted upon receipt of serum testosterone tests confirming testosterone levels are within normal range according to current practice guidelines and continued efficacy

### Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations 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; October 2016.
3. October 2016.
4. AndroGel 1.62% (testosterone) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2016.
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](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

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