

**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
  - 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**

1. Testopel [package insert]. Malvern (PA): Endo Pharmaceuticals; 2024 Mar.
2. Bhasin S, Brito JP, Cunningham GR, Hayes FJ, Hodis HN, Matsumoto AM, et al. Testosterone therapy in men with hypogonadism: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018 May 1;103(5):1715-44.
3. Dandona P, Rosenberg MT. A practical guide to male hypogonadism in the primary care setting. *Int J Clin Pract* 2010; 64(6):682-696.
4. Beg S, Al-Khoury L, Cunningham GR. Testosterone replacement in men. *Curr Opin Endocrinol Diabetes Obes* 2008; 15:364-370.
5. Cunningham GR, Toma SM. Why is androgen replacement in males controversial? *J Clin Endocrinol Metab* 2011; 96:38-52.



6. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau, LJ; American Association of Clinical Endocrinologists. Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients. *Endocrine Practice*. 2002 Dec; 8(6):439-56.
7. Lunenfeld B, Mskhalaya G, Zitzmann M, Arver S, Kalinchenko S, Tishova Y, Morgentaler A. Recommendations on the diagnosis, treatment and monitoring of hypogonadism in men. *Aging Male*. 2015; 18(1): 5 to 15. Doi: 10.3109/13685538.2015.1004049.
8. Dohle GR, Arver S, Bettocchi C, Jones TH, Kliesch S, Punab M. European Association of Urology: Guidelines on male hypogonadism. *Male hypogonadism*. 2015 Mar [cited 2021 Nov 5]. Available from: [http://uroweb.org/wp-content/uploads/18-Male-Hypogonadism\\_LR1.pdf](http://uroweb.org/wp-content/uploads/18-Male-Hypogonadism_LR1.pdf).
9. Mulhall JP, Trost LW, Brannigan RE, Kurtz EG, Redmon JB, Chiles KA, et al. American Urological Association (AUA). Evaluation and management of testosterone deficiency (2018). Available from: <https://www.auanet.org/guidelines/testosterone-deficiency-guideline>.
10. Qaseem A, Horwitch CA, vijan S, Etzeandia-Ikobaltzeta I, Kansagara D. Testosterone treatment in adult men with age-related low testosterone: A clinical guideline from the American College of Physicians. *Annals of Internal Medicine*. 2020 Jan 21;172(2): 126-134.
11. Snyder PJ. Testosterone treatment of male hypogonadism. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2020 [cited 2021 Nov 5]. Available from: <http://www.utdol.com/utd/index.do>.
12. Traish AM, Guay A, Feeley R, Saad F. The dark side of testosterone deficiency: I. Metabolic syndrome and erectile dysfunction. *J Androl* 2009; 30:10-20.
13. Traish AM, Saad F, Guay A. The dark side of testosterone deficiency: II. Type 2 diabetes and insulin resistance. *J Androl* 2009; 30:23-32.
14. Traish AM, Saad F, Feeley RJ, Guay A. The dark side of testosterone deficiency: III. Cardiovascular disease. *J Androl* 2009; 30:477-494.
15. Goodman N, Guay A, Dandona P, Dhindsa S, Faiman C, and Cunningham G, for the AACE Reproductive Endocrinology Scientific Committee. American Association of Clinical Endocrinologists and American College of Endocrinology position statement on the association of testosterone and cardiovascular risk. *Endocr Pract*. 2015; 21(9):1066-73.
16. FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use [press release on the internet]. Silver Spring (MD): Food and Drug Administration (US); 2015 Mar 3 [cited 2016 Jun]. Available from: <http://www.fda.gov/Drugs/DrugSafety/ucm436259.htm>.
17. American Medical Association. Removing financial barriers to care for transgender patients. Policy H-185.950 [cited 2012 Dec 17]. Available from: [www.tgender.net/taw/ama\\_resolutions.pdf](http://www.tgender.net/taw/ama_resolutions.pdf).
18. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ, Spack NP, Tangpricha V, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2009; 94:3132-3154.
19. American Psychological Association. Position statement on access to care for transgender and gender variant individuals [position statement on the internet]. 2012 [cited 2012 Dec 17]. Available from: <http://www.psychiatry.org/advocacy—newsroom/positions-statements>.
20. Crowley, WF, Pitteloud N. Approach to the patient with delayed puberty. In: Basow DS (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2020 [cited 2020 Dec 17]. Available from : [http://www.uptodate.com/contents/diagnosis-and-treatment-of-delayedpuberty?source=search\\_result&search=delayed+puberty&selectedTitle=1%7E61](http://www.uptodate.com/contents/diagnosis-and-treatment-of-delayedpuberty?source=search_result&search=delayed+puberty&selectedTitle=1%7E61)
21. Jospe N. Delayed Puberty. *Merck Manual* 2012 Feb. [cited 2014 Jul 23]. Available from: [http://www.merckmanuals.com/professional/pediatrics/endocrine\\_disorders\\_in\\_children/delayed\\_puberty.html](http://www.merckmanuals.com/professional/pediatrics/endocrine_disorders_in_children/delayed_puberty.html).



22. Snyder PJ. Clinical features and diagnosis of male hypogonadism. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2020 [cited 2020 Dec 17]. Available from: <http://www.utdol.com/utd/index.do>

#### **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

