

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

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations			
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions			

Overview

TESTOPEL can be approved for the following diagnoses:

- Delayed Puberty:** To stimulate puberty in males with delayed puberty
- Hypogonadism, Hypogonadotropic (Congenital or Acquired):** Treatment of gonadotropin or luteinizing hormone-releasing hormone deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation
- 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
- 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:

- 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

1. Testopel® [package insert]. Malvern (PA): Endo Pharmaceuticals; 2018 Aug.
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.
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, Etxeandia-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.
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
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.
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>
23. Xyosted® [package insert]. Ewing (NJ): Antares Pharma, Inc; 2020 Nov.
24. Jatenzo® [package insert]. Northbrook (IL): Clarus Therapeutics, Inc.; 2021 Jan

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.

