
Prior Authorization DRUG Guidelines

TESTOPEL® (testosterone)

Effective Date: 10/23/12

Date Developed: 10/15/12 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Formulary Exclusion – For Exception Review Use Only)

TESTOPEL® is a unique implantable delivery form of Testosterone limited to use by urologists or endocrinologists. It is a controlled substance C-II.

Pre-Authorization Criteria:

VCHCP will authorize TESTOPEL® for FDA indicated treatment of Androgen replacement therapy in the treatment of delayed male puberty; male hypogonadism (primary or hypogonadotropic); inoperable metastatic female breast cancer (enanthate only).

VCHCP requires that TESTOPEL® be prescribed by a urologist or endocrinologist.

Dosing: Adult

Dosage varies depending on patient's condition. Please refer to dosage information in uptodate.com (website: <http://www.uptodate.com>).

Dosage Forms and Strengths:

Testopel® Pellets (testosterone) are cylindrically shaped pellets 3.2mm (1/8 inch) in diameter and approximately 8-9mm in length. Each sterile pellet weighs approximately 77mg (75mg testosterone) and is ready for implantation.

Testosterone pellets of 75mg. One pellet per vial in boxes of 10 (NDC: 43773-1001-2). 24 (NDC: 43773-1001-4) and 100 (NDC: 43773-1001-3). Store in a cool dry place.

Warnings/Precautions

Concerns related to adverse effects:

- Gynecomastia: May cause gynecomastia.
- Hepatic effects: Prolonged use of high doses of androgens has been associated with serious hepatic effects (peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, jaundice).
- Hyper calcemia: May cause hypercalcemia in patients with prolonged immobilization or cancer.
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- Hypercholesterolemia: May alter serum cholesterol; use caution with history of MI or coronary artery disease.
- Hypoglycemia: Has both androgenic and anabolic activity, the anabolic action may enhance hypoglycemia.
- Polycythemia: May increase hematocrit requiring dose adjustment or discontinuation
- Prostate cancer: May increase the risk of prostate cancer.
- Spermatogenesis: Large doses may suppress spermatogenesis.

REFERENCES

1. American Geriatrics Society 2012 Beers Criteria Update Expert Panel, "American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults," *J Am Geriatr Soc*, 2012, 60(4):616-31. [PubMed 22376048]
2. Bhasin S, Cunningham GR, Hayes FJ, et al, "Testosterone Therapy In Men With Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline," *J Clin Endocrinol Metab*, 2010, 95(6):2536-59. [PubMed 20525905]
3. Petak SM, Nankin HR, Spark RF, et al, "American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 Update," *Endocr Pract*, 2002, 8(6):440-56. [PubMed 15260010]
4. Wierman ME, Basson R, Davis SR, et al, "Androgen therapy in Women: An Endocrine Society Clinical Practice Guideline," *J Clin Endocrinol Metab*, 2006, 91(10):3697-710. [PubMed 17018650]
5. ©2013 UpToDate® - www.uptodate.com

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