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 hypogonadotrophic); 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


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**Revision History:**

Date Reviewed/No Updates: 1/16/13 by A. Reeves MD  
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Date Reviewed/No Updates: 1/28/14 by C. Sanders MD  
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Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD  
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Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD, R. Sterling, MD  
Date Approved by P&T Committee: 1/22/19

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