



Prior Authorization Approval Criteria

Striant/Testim (testosterone)

Generic name: testosterone
Brand name: Testim (transdermal gel), Striant (buccal system)
Medication class: androgen
FDA-approved uses: For replacement in males for conditions associated with a deficiency or absence of endogenous testosterone including primary hypogonadism and hypogonadotropic hypogonadism, both congenital or acquired.

Available dosage forms: Testim: 1% gel tubes (tube contains 50 mg testosterone in 5 gm of gel)
Striant: 30 mg buccal system

Usual dose: Testim: Initial dose: 5 g packet once a day
Maintenance dose: 5 g-10 gm per day
Striant: One buccal system (30 mg) to the gum region twice daily; morning and evening (about 12 hours apart).

Approximate monthly cost: Testim: \$285.65 (based on one 5 g tube daily)
(based on AWP 2009) Striant: \$256.25

Duration of therapy: indefinite

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Failed/intolerant to FCHP preferred alternative: Androderm, or injectable testosterone
- Clinically diagnosed testosterone deficiency or absence in males with primary hypogonadism from the following clinical diseases/therapies: cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelters syndrome, chemotherapy, toxic damage from alcohol or heavy metals. (can have low serum testosterone levels and gonadotropins FSH, LH above normal range)

Or

- Clinically diagnosed testosterone deficiency or absence in males with hypogonadotropic hypogonadism such as idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation (low serum testosterone levels and either normal or low gonadotropin levels)

Contraindications:

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate
- Female patients
- Patients with known hypersensitivity to any of product's ingredients, including testosterone USP that is chemically synthesized from soy

Not approved if:

- Patient has any contraindications to testosterone
- Patient is not testosterone-deficient

- Currently diagnosed with breast or prostate cancer

Special considerations:

- Testosterone supplements may cause fetal harm.
- In diabetic patients, the metabolic effects of androgens may decrease blood glucose and therefore, insulin requirements
- Testim: Pregnant and nursing women should avoid skin contact with Testim application sites on men. In the event that unwashed or unclothed skin to which Testim has been applied comes in direct contact with the skin of a pregnant or nursing woman (or of any other person), the general area of contact on the woman (or person) should be immediately washed with soap and water.
- Striant: It is recommended that patients regularly inspect their own gum region where Striant is applied. Any abnormal finding should be brought promptly to the attention of the patient's physician. In such circumstances, dental consultation may be appropriate.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/11/2009