



## 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*):

- Confirmed diagnosis of testosterone deficiency or absence of endogenous testosterone in males over the age of 18 with:
  - Primary hypogonadism (congenital or acquired): Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range.
  - Or**
  - Hypogonadotropic hypogonadism (congenital or acquired): Idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. These patients have low serum testosterone levels but have gonadotropins in the normal or low range.
- Must have failed or was intolerant to FCHP-preferred alternatives: Androderm, Androgel or injectable testosterone

**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
- Male patients diagnosed with breast or prostate cancer or suspected of carcinoma of the prostate
- Female patient

**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