Prior Authorization Approval Criteria

Striant/Testim/Axiron (testosterone)

Generic name: testosterone

Brand name: Testim (transdermal gel), Striant (buccal system), Axiron (topical solution)

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 (contains 50 mg testosterone in 5 gm of gel)
Striant: 30 mg buccal system
Axiron: metered-dose pump with an applicator, 30mg testosterone/pump actuation

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)
Axiron: Initial dose: 60 mg (1 pump actuation of 30 mg to each axilla) applied once daily at the same time each morning

Approximate monthly cost: (based on AWP 2012) Testim: $380.44 (based on one 5 g tube daily)
Striant: $409.86
Axiron: $361.20

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:

- Black Box Warning:
    - Virilization has been reported in children who were secondarily exposed to testosterone gel and topical testosterone products
    - Children should avoid contact with unwashed or unclothed testosterone application sites
    - Healthcare providers should advise patients to strictly adhere to recommended instruction for use
- Testosterone supplements may cause fetal harm.
- In diabetic patients, the metabolic effects of androgens may decrease blood glucose and therefore, insulin requirements
- Edema, with or without congestive heart failure, may be a complication in patients with preexisting cardiac, renal, or hepatic disease
- 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.
- Axiron:
    - The application site and dose of Axiron are not interchangeable with other topical testosterone products
    - Use of antiperspirant or deodorant (stick or roll-on) should be applied prior to the application of Axiron to avoid contamination of the stick or roll-on product.
    - The Axiron pump should be primed by depressing it 3 times prior to its first use.
    - Axiron is flammable until dry
    - Axiron can worsen signs and symptoms of benign prostate hyperplasia
    - There are insufficient long-term efficacy data in geriatric patients using Axiron to assess the potential risks of cardiovascular disease and prostate cancer
    - No formal studies were conducted involving patients with renal or hepatic impairment.
    - Safety and efficacy of Axiron in males with BMI>35 kg/m^2 has not been established.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/11/2009
Revised: 06/13/12