



Prior Authorization Approval Criteria

Fortesta (testosterone)

Generic name:	testosterone
Brand name:	Fortesta
Medication class:	Androgen
FDA-approved uses:	Replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone including primary hypogonadism and hypogonadotropic hypogonadism
Available dosage forms:	Metered dose pump; 10mg per actuation; 120 actuations per canister
Usual dose:	Starting dose is 40mg/daily; maintenance dose is 10mg to 70mg daily
Approximate monthly cost: (based on AWP 2011)	\$300 per canister
Duration of therapy:	Indefinite

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- 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

Monitoring:

- Periodic assessment of serum testosterone concentration

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/07/2011