



Commercial/Healthcare Exchange PA Criteria

Effective: June 3, 2020

Prior Authorization: Testosterone undecanoate capsules

Products Affected: Jatenzo (testosterone undecanoate) oral capsules, Tlando (testosterone undecanoate) oral capsules

Medication Description: testosterone undecanoate is a testosterone prodrug that the body converts to testosterone.

Covered Uses:

1. Primary hypogonadism (congenital or acquired)
2. Hypogonadotropic hypogonadism (congenital or acquired)

Exclusion Criteria:

1. Men with breast cancer or known or suspected prostate cancer
2. Men with hypogonadal conditions, such as “age-related hypogonadism”, that are not associated with structural or genetic etiologies.

Required Medical Information:

1. Diagnosis
2. Two pre-treatment serum testosterone lab value, each taken in the morning, on two separate days
3. Previous medications tried and failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions: None

Coverage Duration: 12 months

Other Criteria:

1. **Primary hypogonadism** (congenital or acquired):
 - A. Initial Therapy – Approve for 1 year in patients with hypogonadism as confirmed by the following criteria (i, ii **AND** iii)
 - i. Patient has a diagnosis of primary hypogonadism (congenital or acquired) testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metal, or orchiectomy; **AND**
 - ii. Patient has had two pre-treatment serum testosterone measurements, each taken in the morning, on two separate days with a level less than 300 ng/dL; **AND**

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- iii. Patient must have tried and failed, or have a contraindication or intolerance to, **THREE** generic testosterone formulations (e.g. testosterone gel, testosterone intramuscular injection, testosterone topical solution)
 - B. Patients Continuing Therapy: Approve for 1 year if the patient meets the following criteria (i and ii):
 - i. Patient has had persistent signs and symptoms (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido) of androgen deficiency (pre-treatment); **AND**
 - ii. Patient has had at least one pre-treatment serum testosterone level, which was low, as defined by the normal laboratory reference values.
- 2. Hypogonadotropic hypogonadism** (congenital or acquired):
- A. Initial Therapy – approve for 1 year in patients with hypogonadism as confirmed by the following criteria (i, ii **AND** iii)
 - i. Patient has a diagnosis of hypogonadotropic hypogonadism (congenital or acquired) idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation; **AND**
 - ii. Patient has had two pre-treatment serum testosterone measurements, each taken in the morning, on two separate days with a level less than 300 ng/dL; **AND**
 - iii. Patient must have tried and failed, or have a contraindication or intolerance to, **THREE** generic testosterone formulations (e.g. testosterone gel, testosterone intramuscular injection, testosterone topical solution)
 - B. Patients Continuing Therapy: Approve for 1 year if the patient meets the following criteria (i and ii):
 - i. Patient has had persistent signs and symptoms (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido) of androgen deficiency (pre-treatment); **AND**
 - ii. Patient has had at least one pre-treatment serum testosterone level, which was low, as defined by the normal laboratory reference values.

References:

1. Jatenzo [package insert]. Northbrook, IL: Clarus Therapeutics, Inc.; 2019.
2. Tlando [prescribing information]. Ewing, NJ. Antares Pharma Inc. 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/3/2020
2	Update	<p>Updated required medical information Two <u>pre-treatment</u> serum testosterone lab value, each taken in the morning, on two separate days.</p> <p>Updated criteria to reflect initial therapy criteria and continuation therapy criteria</p> <p>Added Tlando, Name change from Jatenzo to Testosterone undecanoate</p>	<p>Prior Authorization, Products Affected, Required Medical Information, Criteria</p>	5/6/2022