

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Testosterone Undecanoate (Oral) Drug Quantity Management Policy – Per Rx
- Jatenzo® (testosterone undecanoate capsules – Clarus)
  - Kyzatrex® (testosterone undecanoate capsules – Marius)
  - Tlando™ (testosterone undecanoate capsules – Antares)

**REVIEW DATE:** 11/02/2022

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### OVERVIEW

Jatenzo, Kyzatrex, and Tlando are oral androgens, that are indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.<sup>1-3</sup> The Prescribing Information defines those patients and/or conditions for which use of these agents are indicated:

- **Primary hypogonadism (congenital or acquired):** testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- **Hypogonadotropic hypogonadism (congenital or acquired):** gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range.

### Dosing

#### *Jatenzo Dosing*

The recommended starting dose of Jatenzo is 237 mg twice daily (BID), once in the morning and once in the evening.<sup>1</sup> Jatenzo should be taken with food. The dose of Jatenzo should be individualized based on the patient's serum testosterone concentration response to the drug (Table 1). The minimum recommended dose is 158 mg BID. The maximum recommended dose is 396 mg (two 198 mg capsules) BID.

**Table 1. Jatenzo Dose Adjustment Scheme.<sup>1</sup>**

Testosterone Concentration in Serum from Plain Tube Drawn 6 hours after Morning Dose	Current Jatenzo dose (BID)	New Jatenzo Dose (BID)
< 425 ng/dL	158 mg	198 mg
	198 mg	237 mg
	237 mg	316 mg (2 x 158 mg capsules)
	316 mg (2 x 158 mg capsules)	396 mg (2 x 198 mg capsules)
425 ng/dL to 970 ng/dL	No Dose Change	
> 970 ng/dL	396 mg (2 x 198 mg capsules)	316 mg (2 x 158 mg capsules)
	316 mg (2 x 158 mg capsules)	237 mg
	237 mg	198 mg
	198 mg	158 mg
	158 mg	Discontinue Treatment

BID – Twice daily.

### *Kyzatrex Dosing*

The recommended starting dose of Kyzatrex is 200 mg BID, once in the morning and once in the evening.<sup>2</sup> Kyzatrex should be taken with food. The dose of Kyzatrex should be individualized based on the patient's serum testosterone concentration response to the drug (Table 2). The minimum recommended dose is 100 mg once daily (QD), in the morning. The maximum recommended dose is 400 mg (two 200 mg capsules) BID. Kyzatrex is not substitutable with other oral testosterone undecanoate products.

**Table 2. Kyzatrex Dose Adjustment Scheme.<sup>2</sup>**

Serum Testosterone Concentration	Current Kyzatrex Dose	New Kyzatrex Dose
< 460 ng/dL	100 mg QD	100 mg BID
	100 mg BID	200 mg BID
	200 mg BID	300 mg BID
	300 mg BID	400 mg BID
460 ng/dL to 971 ng/dL	No Dose Change	
> 971 ng/dL	400 mg BID	300 mg BID
	300 mg BID	200 mg BID
	200 mg BID	100 mg BID
	100 mg BID	100 mg QD
	100 mg QD	Discontinue Treatment

BID – Twice daily.

### *Tlando Dosing*

The recommended dosage of Tlando is 225 mg (taken as two 112.5 mg capsules) BID, once in the morning and once in the evening. Tlando should be taken with food. Tlando is not substitutable with other oral testosterone undecanoate products.

Continuation or discontinuation of Tlando is based on serum testosterone measurements:

- Serum testosterone 300 to 1,080 ng/dL: continue Tlando.
- Serum testosterone < 300 ng/dL: discontinue Tlando.
- Serum testosterone > 1,080 ng/dL: discontinue Tlando.

### **Availability**

Jatenzo is available as 158 mg, 198 mg, and 237 mg capsules supplied in bottles of 120 capsules each.<sup>1</sup>

Kyzatrex is available as 100 mg, 150 mg, and 200 mg capsules supplied in bottles of 90 capsules each.<sup>2</sup>

Tlando is available as 112.5 mg capsules supplied in bottles of 120 capsules each.<sup>3</sup>

### **POLICY STATEMENT**

This Drug Quantity Management program has been developed to manage potential dose escalation of the oral testosterone undecanoate products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted.

**Automation:** None.

**Drug Quantity Limits**

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Jatenzo® (testosterone undecanoate capsules)	158 mg capsules	60 capsules	180 capsules
	198 mg capsules	60 capsules	180 capsules
	237 mg capsules	60 capsules	180 capsules
Kyzatrex® (testosterone undecanoate capsules)	100 mg capsules	60 capsules	180 capsules
	150 mg capsules	120 capsules	360 capsules
	200 mg capsules	60 capsules	180 capsules
Tlando™ (testosterone undecanoate capsules)	112.5 mg capsules	120 capsules	360 capsules

**CRITERIA**

Jatenzo 158 mg capsules

1. If the patient requires a dose of 316 mg twice daily, approve 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Jatenzo 198 mg capsules

1. If the patient requires a dose of 396 mg twice daily, approve 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Jatenzo 237 mg capsules

No overrides recommended.

Kyzatrex 100 mg, 150 mg capsules

No overrides recommended.

Kyzatrex 200 mg capsules

1. If the patient requires a dose of 400 mg twice daily, approve 120 capsules per dispensing at retail or 360 capsules per dispensing at home delivery.

Tlando 112.5 mg capsules

No overrides recommended.

**REFERENCES**

1. Jatenzo® capsules [prescribing information]. Northbrook, IL: Clarus; March 2019.
2. Kyzatrex® capsules [prescribing information]. Raleigh, NC: Marius; July 2022.
3. Tlando® capsules [prescribing information]. Ewing, NJ: Antares; March 2022.

