



## DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

**REVIEW DATE:** 02/28/2024

### **INSTRUCTIONS FOR USE**

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## **CIGNA NATIONAL FORMULARY COVERAGE:**

### **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 patients 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

patients 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 120 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.

### **Drug Quantity Limits**

<b>Product</b>	<b>Strength and Form</b>	<b>Retail Maximum Quantity per Rx</b>	<b>Home Delivery Maximum Quantity per Rx</b>
Jatenzo® (testosterone undecanoate capsules)	158 mg capsules	120 capsules	360 capsules
	198 mg capsules	120 capsules	360 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	120 capsules	360 capsules
Tlando® (testosterone undecanoate capsules)	112.5 mg capsules	120 capsules	360 capsules

**Testosterone Undecanoate (Oral) Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.**

### **CRITERIA**

Jatenzo 158 mg capsules

No overrides recommended.

Jatenzo 198 mg capsules

No overrides recommended.

Jatenzo 237 mg capsules

No overrides recommended.

Kyzatrex 100 mg, 150 mg capsules

No overrides recommended.

Kyzatrex 200 mg capsules

No overrides recommended

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.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/03/2023
Early Annual Revision	<b>Jatenzo (testosterone undecanoate 158 mg capsules);</b> Quantity limits were increased to 120 capsules per dispensing at retail and 360 capsules per dispensing at home delivery (previously 60 capsules per dispensing at retail and 180 capsules per dispensing at home delivery). Override criteria were removed as they are no longer necessary with the higher initial limit. <b>Jatenzo (testosterone undecanoate 198 mg capsules);</b> Quantity limits were increased to 120 capsules per dispensing at retail and 360 capsules per dispensing at home delivery (previously 60 capsules per dispensing at retail and 180 capsules per dispensing at home delivery). Override criteria were removed as they are no longer necessary with the higher initial limit. <b>Kyzatrex (testosterone undecanoate 200 mg capsules);</b> Quantity limits were increased to 120 capsules per dispensing at retail and 360 capsules per dispensing at home delivery (previously 60 capsules per dispensing at retail and 180 capsules per dispensing at home delivery). Override criteria were removed as they are no longer necessary with the higher initial limit.	02/28/2024

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