TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Testosterone (Testopel, Jatenzo, Kyzatrex, Tlando)	**CRITERIA ID:** TX.CC.PHAR.38
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 7/9/2024	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 7/9/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for testosterone (Testopel, Jatenzo, Kyzatrex, Tlando).

PURPOSE:
To provide clinical criteria standards which align with FDA approved indication(s) and/or established practice guidelines for prior authorization review. Prior authorization is required to determine medical necessity of the requested drug(s), which ensures safety, clinical appropriateness and cost-effectiveness while maintaining optimal therapeutic outcomes.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
FDA: Food and Drug Administration
LHRH: luteinizing hormone-releasing hormone

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of testosterone pellet (Testopel®) and testosterone undecanoate capsule (Jatenzo®, Kyzatrex, Tlando™).

Description/Mechanism of Action:
Testosterone pellet (Testopel®) is an implantable androgen. Testosterone undecanoate capsule (Jatenzo®, Kyzatrex®, Tlando™) is an oral androgen.

FDA Approved Indication(s):
Testopel is indicated for:
Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:
- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, or orchiectomy
- Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic lutenizing hormone-releasing hormone (LHRH) deficiency, or pituitary - hypothalamic injury from tumors, trauma, or radiation

Treatment of delayed puberty in carefully selected males

Jatenzo, Kyzatrex, and Tlando are indicated for:
Replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, or orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals
- Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma, or radiation

Limitation(s) of use:

Testopel: Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Jatenzo, Kyzatrex, and Tlando: Safety and efficacy in males less than 18 years old have not been established.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Hypogonadism (must meet all)**:**

1. Diagnosis of primary hypogonadism or hypogonadotropic hypogonadism;
2. If request is for Jatenzo, Kyzatrex, or Tlando, age ≥ 18 years;
3. Documentation of serum testosterone level < 300 ng/dL on at least 2 separate days within the last 6 months;
4. Member must use transdermal testosterone (e.g., patch, gel), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Member must use injectable testosterone, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Dose does not exceed one of the following (a, b, c, or d):
   a. For Testopel: 450 mg (6 pellets) every 3 months;
   b. For Jatenzo, both of the following (i and ii):
      i. 792 mg per day;
      ii. 4 capsules per day;
   c. For Kyzatrex, both of the following (i and ii):
      i. 800 mg per day;
      ii. 4 capsules per day;
   d. For Tlando: 450 mg (4 capsules) per day.

Approval duration:
Testopel – 6 months
All other agents – 12 months

B. Delayed Puberty (must meet all)**:**

1. Diagnosis of delayed puberty;
2. Request is for Testopel;
3. Prescribed by or in consultation with an endocrinologist;
4. Member must use injectable testosterone, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Dose does not exceed 450 mg (6 pellets) every 3 months.

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to: CP.PMN.255 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Hypogonadism (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, or d):
   a. For Testopel: 450 mg (6 pellets) every 3 months;
   b. For Jatenzo, both of the following (i and ii):
      i. 792 mg per day;
      ii. 4 capsules per day;
   c. For Kyzatrex, both of the following (i and ii):

i. 800 mg per day;
ii. 4 capsules per day;

d. For Tlando: 450 mg (4 capsules) per day.

Approval duration:
Testopel – 6 months
All other agents – 12 months

B. Delayed Puberty:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to: CP.PMN.255 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

B. The following are conditions for which treatment with Testopel is considered NOT medically necessary:

1. Transsexualism (F64.0);
2. Dual role transvestism (F64.1);
3. Gender identity disorder of childhood (F64.2);
4. Other gender identity disorders (F64.8);
5. Gender identity disorder, unspecified (F64.9);

REFERENCES:

CP.PHAR.354 Testosterone (Testopel, Jatenzo, Kyzatrex, Tlando)
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	Created from Corporate criteria to align with TMHP guidance on Senate Bill 14 – Section III. B. added.	07/09/2024