



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Testosterone Agents

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Effective Date: 1/1/2024

Last Review Date: 11/2023

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> Florida Kids
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**Intent:**

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for testosterone products under the patient’s prescription drug benefit.

**Description:**

**FDA-APPROVED INDICATIONS**

**Androderm, AndroGel, Fortesta, Natesto, Testim, testosterone topical solution, Vogelxo**

Topical, nasal, and injectable testosterone products 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 conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, 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.

Limitations of Use

- Safety and efficacy of topical, nasal, and injectable testosterone products in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.
- Safety and efficacy of topical, nasal, and injectable testosterone products in males less than 18 years old have not been established.
- Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

**Depo-Testosterone**

Depo-Testosterone Injection is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone:

1. Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy.



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2. Hypogonadotropic hypogonadism (congenital or acquired)-gonadotropin or LHRH deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

### Jatenzo, Kyzatrex, Tlando

Testosterone undecanoate is indicated for testosterone 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 conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter 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.

### Limitations of Use

Safety and efficacy of testosterone undecanoate in males less than 18 years old have not been established.

### Testopel

#### Males

Androgens are 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 LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

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



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- c. Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An x-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

### Testosterone Enanthate Injection

#### Males

Testosterone Enanthate Injection (generic Delatestryl), USP 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 testis syndrome, or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testosterone Enanthate Injection (generic Delatestryl), USP in men with age-related hypogonadism have not been established.

Delayed puberty - Testosterone Enanthate Injection (generic Delatestryl), USP may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

#### Females



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Metastatic mammary cancer - Testosterone Enanthate Injection (generic Delatestryl), USP may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in pre-menopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

### **Xyosted**

Xyosted (testosterone enanthate) injection is an androgen indicated for testosterone 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 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 low or normal range.

### Limitations of Use

Safety and efficacy of Xyosted in males less than 18 years of age have not been established.

### **Applicable Drug List:**

ANDRODERM

ANDROGEL

FORTESTA

TESTIM

VOGELXO

TESTOSTERONE TRANSDERMAL GEL 10 mg/act (2%)

TESTOSTERONE TRANSDERMAL GEL 12.5 mg/act (1%)

TESTOSTERONE TRANSDERMAL GEL 20.25 mg/act (1.62%)



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TESTOSTERONE TRANSDERMAL GEL 25 mg/2.5gm (1%)  
 TESTOSTERONE TRANSDERMAL GEL 50 mg/5gm (1%)  
 TESTOSTERONE TRANSDERMAL SOLUTION 30MG/ACT  
 DELATESTRYL  
 XYOSTED  
 TESTOSTERONE ENANTHATE IM SOLUTION 200 mg/ml  
 DEPO-TESTOSTERONE  
 TESTOSTERONE CYPIONATE IM SOLUTION 100 mg/ml  
 TESTOSTERONE CYPIONATE IM SOLUTION 200 mg/ml  
 JATENZO  
 KYZATREX  
 TLANDO  
 NATESTO  
 TESTOPEL

**Policy/Guideline:**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is unable to take the required number of preferred formulary alternatives for the given diagnosis, due to a trial and inadequate treatment response, or intolerance, or a contraindication

**AND**

- The requested drug is NOT being prescribed for “age-related hypogonadism” (also referred to as “late-onset hypogonadism”)

**AND**

- The requested drug is being prescribed for primary or hypogonadotropic hypogonadism

**AND**

- The request is NOT for continuation of therapy

**AND**

- Before the start of testosterone therapy, the patient has at least two confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values

**OR**

- The request is for continuation of therapy



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**AND**

- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values

**OR**

- The request is for testosterone propionate implant pellet (Testopel)

**AND**

- The requested drug is being prescribed for delayed puberty

**OR**

- The request is for intramuscular testosterone enanthate injection (generic Delatestryl)

**AND**

- The requested drug is being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal and had an incomplete response to other therapy for metastatic breast cancer

**OR**

- The requested drug is being prescribed for a premenopausal patient with breast cancer who has benefited from oophorectomy and is considered to have a hormone-responsive tumor

**OR**

- The requested drug is being prescribed for delayed puberty

**Approval Duration and Quantity Restrictions:**

**Approval:** 12 months

**Quantity Level Limit:**

Testosterone cypionate IM solution 100mg/mL – 10mL per 90 days

Testosterone cypionate IM solution 200mg/mL – 10mL per 90 days

Testosterone transdermal gel 10mg/act (2%) - 2 canisters per 30 days

Testosterone transdermal gel 12.5mg/act (1%) - 4 canisters per 30 days

Testosterone transdermal gel 20.25mg/act (1.62%) – 5gm per 1 day

Testosterone transdermal gel solution 30mg/act – 6mL

Reference Formulary for drug specific quantity level limits

**References:**

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6. Jatenzo [package insert]. Northbrook, IL: Clarus Therapeutics, Inc.; June 2019.
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9. Testim [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2021.
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12. Testosterone Topical Solution [package insert]. Bedminster, NJ: Alembic Pharmacueticals, Inc.; December 2022.
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14. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; April 2020.
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19. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2018;103(5):1715-1744.