

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Testosterone Injectable

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Aveed Injection (testosterone undecanoate) 750mg/3mL
Delatestryl Injection (testosterone enanthate) 200mg/mL
Depo-Testosterone Injection (testosterone cypionate) 100mg/mL, 200mg/mL
Xyosted Injection (testosterone enanthate) 50mg/0.5mL, 75mg/0.5mL, 100mg/0.5mL

APPROVAL CRITERIA

Testosterone injections for replacement therapy:

- I. Requests for testosterone injections used **for initiation of replacement therapy** may be approved if the following criteria are met:
 - A. Individual is a male; **AND**
 - B. Individual is 18 years or older; **AND**
 - C. Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level confirms a low testosterone serum level indicating one of the following (1 or 2);
 1. Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; **OR**
 2. Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL; **AND**
 - D. Individual has a diagnosis of **one** of the following (1 or 2):
 - A. Primary hypogonadism (congenital or acquired) (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefelter Syndrome, orchitis, orchiectomy, toxic damage from alcohol or heavy metals, Vanishing Testis Syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]);

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CRX-ALL-0320-19

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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OR

- B. Hypogonadotropic hypogonadism (congenital or acquired) (for example, idiopathic gonadotropic or luteinizing hormone-releasing hormone (LHRH) deficiency, pituitary- hypothalamic injury); **AND**
- E. Individual presents with symptoms associated with hypogonadism, such as, but not limited, to at least **one** of the following (1 through 9):
 - 1. Reduced sexual desire (libido) and activity; **OR**
 - 2. Decreased spontaneous erections; **OR**
 - 3. Breast discomfort/gynecomastia; **OR**
 - 4. Loss of body (axillary and pubic) hair, reduced need for shaving; **OR**
 - 5. Very small (especially less than 5 mL) or shrinking testes; **OR**
 - 6. Inability to father children or low/zero sperm count; **OR**
 - 7. Height loss, low trauma fracture, low bone mineral density; **OR**
 - 8. Hot flushes, sweats; **OR**
 - 9. Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.
- F. Requests for testosterone injections **for continuation of replacement therapy** may be approved if the following criteria are met:
 - 1. Individual met all diagnostic criteria for initial therapy; **AND**
 - 2. Individual has had serum testosterone level measured in the previous 180 days; **AND**
 - 3. Individual has obtained clinical benefits as noted by symptom improvement.

Testosterone injections **for replacement therapy** may **not** be approved for the following:

- I. Untreated obstructive sleep apnea (OSA); **OR**
- II. Polycythemia as defined by hematocrit greater than 48% and 50% for men living at higher altitudes (Bhasin et al, 2018); **OR**
- III. Severe congestive heart failure (CHF); **OR**
- IV. Known, suspected, or history of prostate cancer unless individual has undergone radical prostatectomy, prostate cancer was organ-confined, has been disease free for two (2) years and has an undetectable prostate-specific antigen (PSA) level (such as <0.1 ng/dL).

Testosterone injections for delayed puberty:

- I. Requests for **testosterone enanthate** (Delatestryl) **injections for treatment of delayed puberty** may be approved if the following criteria are met:

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- A. Individual is a male 14 years of age or older; **AND**
- B. Individual is using to stimulate puberty; **AND**
- C. Individual has few to no signs of puberty.

Testosterone injections for breast cancer:

- I. Requests for **testosterone enanthate** (Delatestryl) **injections for treatment of breast cancer** may be approved for treatment if the following criteria are met:
 - A. Female 1-5 years post-menopause; **AND**
 - B. Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer;**OR**
 - C. Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor.

Testosterone injections for HIV-associated weight loss and wasting:

- I. Requests for **testosterone enanthate** (Delatestryl) **OR testosterone cypionate** (Depo-Testosterone) **injections for treatment of HIV-associated weight loss and wasting** may be approved if the following criteria are met:
 - A. Individual has been diagnosed with low testosterone; **AND**
 - B. Individual has HIV-associated weight loss and wasting.

Testosterone injections for transgender individuals:

- I. Requests for **testosterone injections for transgender individuals** may be approved if the following criteria are met:
 - A. Individual is 16 years of age or older; **AND**
 - B. Individual has a diagnosis of gender dysphoria/incongruence or gender identity disorder (DrugDex B, IIa); **AND**
 - C. The goal of treatment is female-to-male gender reassignment.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018; 103(5): 1715-1744. Available at: <https://academic.oup.com/jcem/article/103/5/1715/4939465>. Accessed on June 8, 2018.
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