

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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 Symptomatic Hypogonadism (Primary or Secondary) in Adults:

- I. Requests for testosterone injections **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):
 1. 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]);**OR**

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2. Hypogonadotropic hypogonadism (also called secondary 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.
- II. Requests for testosterone injections **for continuation of replacement therapy** may be approved if the following criteria are met:
 - A. Individual met all diagnostic criteria for initial therapy; **AND**
 - B. Individual has had serum testosterone level measured in the previous 180 days; **AND**
 - C. 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); **OR**
- V. Individual is requesting Xyosted (testosterone enanthate) subcutaneous autoinjector for hypogonadal conditions, such as “age-related hypogonadism,” that are not associated with structural or genetic etiologies.

Testosterone injections for delayed puberty:

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- I. Requests for **testosterone enanthate** (Delatestryl) **injections for treatment of delayed puberty** may be approved if the following criteria are met:
 - 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 enanthate injections **for treatment of delayed puberty** may not be approved for the following:

- I. Individual is requesting Xyosted (testosterone enanthate) subcutaneous autoinjector.

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 enanthate injections **for treatment of breast cancer** may not be approved for the following:

- I. Individual is requesting Xyosted (testosterone enanthate) subcutaneous autoinjector.

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 (AHFS):
 - A. Individual has been diagnosed with low testosterone; **AND**
 - B. Individual has HIV-associated weight loss and wasting.

Testosterone injections **for treatment of HIV-associated weight loss and wasting** may not be approved for the following:

- I. Individual is requesting Xyosted (testosterone enanthate) subcutaneous autoinjector.

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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.

Testosterone injections **for transgender individuals** may not be approved for the following:

- I. Individual is requesting Xyosted (testosterone enanthate) subcutaneous autoinjector.

Requests for testosterone injections may not be approved when the above criteria are not met and for all other indications.

Notes:

Aveed (testosterone undecanoate) is an intramuscular injection approved in May 2015. Because Aveed is an oil based injection, it has a black box warning regarding the risks for serious pulmonary oil microembolism (POME) reactions and anaphylaxis. Individuals should be observed in the healthcare setting for 30 minutes post-injection in order to monitor and, if needed, provide for medical treatment in the event of POME or anaphylaxis. Because of this, Aveed is available only through a restricted REMS program (www.aveedrems.com).

Xyosted has a black box warning regarding possible blood pressure increases that can lead to major adverse cardiovascular events (MACE). Prior to initiation, baseline cardiovascular risk should be assessed and blood pressure should be adequately controlled. New onset hypertension or exacerbation of existing hypertension should be cause for re-evaluation of risk versus benefit for continuation of therapy. Due to this risk, Xyosted should only be used for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.

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

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N/A	N/A	N/A
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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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