

Testosterone Injectable

Override(s)	Approval Duration
Prior Authorization	1 year

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

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

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 delayed puberty:

- I. Requests for **testosterone enanthate** intramuscular **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** intramuscular **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** intramuscular **OR testosterone cypionate injections for treatment of HIV-associated weight loss and wasting** may be approved if the following criteria are met (IDSA):
 - 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.

Testosterone injections for gender dysphoria/incongruence individuals:

- I. Requests for **testosterone injections for gender dysphoria/incongruence individuals** may be approved if the following criteria are met (WPATH 2022):
 - A. Individual has a diagnosis of gender dysphoria/incongruence (WPATH 2022, Hembree 2017); **AND**
 - B. Individual fulfills the DSM V criteria for gender dysphoria (American Psychiatric Association 2013); **AND**
 - C. Individual has experienced puberty to at least Tanner Stage 2 Individual has (early) pubertal changes that have resulted in an increase of their gender dysphoria (Hembree 2017, WPATH 2022); **AND**
 - D. Individual does not suffer from a comorbidity that interferes with the diagnostic work-up or treatment (Hembree 2017); **AND**
 - E. Individual has psychological and social support before and during treatment (Hembree 2017); **AND**
 - F. Individual has demonstrated knowledge and understanding of the expected risks and outcomes of hormone therapy (Hembree 2017).

Requests for Aveed Injection (testosterone undecanoate), Azmiro Injection (testosterone cypionate), or Xyosted Injection (testosterone enanthate) must also meet the following criteria:

- I. Individual has had a trial and inadequate response or intolerance to two preferred testosterone agents. Medication samples/coupons/discount cards are excluded from consideration as a trial.

Preferred testosterone agents: testosterone gel (generic AndroGel, generic Fortesta, generic Testim, generic Vogelxo), testosterone solution, Depo-testosterone, generic testosterone cypionate IM, generic testosterone enanthate IM, Testopel.

Testosterone injections 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. Uncontrolled hypertension; **OR**
- V. Known, suspected, or history of prostate cancer unless individual has undergone radical prostatectomy or radiation therapy for prostate cancer, 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**
- VI. Individual is trying to conceive (Mulhall JP, et al, 2018); **OR**
- VII. 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).

Key References:

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3. Coleman E, Bockting W, Botzer M, et al. World Professional for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *Int J Transgen*. 2012; 13:165-232. Available at: http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=4655.
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14. Michael H, Melanie T, Allison A, et al. On behalf of the HIV Medicine Association, Primary Care Guidance for Providers of Care for Persons With Human Immunodeficiency Virus: 2024 Update by the HIV Medicine Association of the Infectious Diseases Society of America (IDSA), *Clinical Infectious Diseases*, 2024; ciae479, <https://doi.org/10.1093/cid/ciae479>
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