

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

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# Testosterone Injectable

CG-DRUG-59

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

## APPROVAL CRITERIA

### Symptomatic Hypogonadism (Primary or Secondary) in Adults:

- I. Testosterone injection used for initiation of replacement therapy may be approved when **ALL** of the following criteria are met (A, B, C, D and E):
  - 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), including, but not but not limited to:
      - a. Bilateral torsion; **OR**
      - b. Cryptorchidism; **OR**
      - c. Chemotherapy; **OR**
      - d. Klinefelter Syndrome; **OR**
      - e. Orchitis; **OR**
      - f. Orchiectomy; **OR**
      - g. Toxic damage from alcohol or heavy metals; **OR**
      - h. Vanishing testis syndrome; **OR**
      - i. Idiopathic primary hypogonadism;
    - OR**
    2. Hypogonadotropic hypogonadism (congenital or acquired), including, but not limited to:

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- a. Idiopathic gonadotropic or luteinizing hormone-releasing hormone (LHRH) deficiency; **OR**
- b. 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. Testosterone injection used for continuation of replacement therapy may be approved when **ALL** the following criteria are met (A, B, and C):
  - 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.

#### Delayed Puberty:

- III. Testosterone enanthate injections may be approved for treatment of delayed puberty when **ALL** the criteria below are met (A, B, and C):
  - 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.

#### Breast Cancer:

- IV. Testosterone enanthate injection may be approved for treatment of breast cancer when the criteria below are met (A and B **or** C):
  - 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.

#### HIV-associated Weight Loss and Wasting:

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- V. Testosterone enanthate or testosterone cypionate injections may be approved for the treatment of HIV-infected male adults with low testosterone and HIV-associated weight loss and wasting.

### Gender Reassignment:

- VI. Testosterone injection may be approved for transgender individuals who meet **ALL** the following criteria (A, B and C):
- A. Individual is 16 years of age or older; **AND**
  - B. Individual has a diagnosis of gender dysphoria or gender identity disorder; **AND**
  - C. The goal of treatment is female-to-male gender reassignment.

### May not be approved:

Testosterone injections may not be approved when criteria are not met and for all other indications.

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

### Key References:

Aveed® (testosterone undecanoate injection) [Prescribing Information], Malvern, PA. Endo Pharmaceuticals, Inc. May 2015. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/022219s005lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022219s005lbl.pdf). Accessed on June 28, 2017.

Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010; 95(6):2536-1559. Available at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-2354>. Accessed on June 27, 2017.

Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in adult men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2006; 91(6):1995-2010.

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](http://www.wpath.org/site_page.cfm?pk_association_webpage_menu=1351&pk_association_webpage=4655). Accessed on June 28, 2017.

Delatestryl® (testosterone enanthate injection, USP) [Prescribing Information], Malvern, PA Endo Pharmaceuticals, Inc. May 2015. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/009165s033lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/009165s033lbl.pdf). Accessed on June 26, 2017.

Department of Health and Human Services (HHS). Proposed Rule on Nondiscrimination in Health Programs and Activities. §1557 of Affordable Care Act (ACA); Proposed 45 C.F.R. §92.206; 80 Fed. Reg. 54176-54177. RIN 0945-AA02. The Kaiser Commission on Medicaid and the Uninsured. Issue Brief. October 2015. Final Rule. Published May 18, 2016. Effective July 18, 2016. Available at: <https://www.federalregister.gov/articles/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities>. Accessed on June 28, 2017.

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Depo®-Testosterone (testosterone cypionate injection, USP) [Prescribing Information], New York, NY. Pharmacia & Upjohn Company, division of Pfizer, Inc. April 2015. Available at: [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/085635s030lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/085635s030lbl.pdf). Accessed on June 26, 2017.

Dimopoulou C, Ceausu I, Depypere H, et al. European Menopause and Andropause Society (EMAS) position statement: Testosterone replacement therapy in the aging male. *Maturitas*. 2016; 84:94-99.

Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2009; 94(9):3132-3154. Available at: <http://press.endocrine.org/doi/pdf/10.1210/jc.2009-0345>. Accessed on June 28, 2017.

Morales A, Bebb RA, Manjoo P, et al. Diagnosis and management of testosterone deficiency syndrome in men: clinical practice guideline. *CMAJ*. 2015; 187(18):1369-1377.

Petak SM, Nankin HR, Spark RF, et al. American Association of Clinical Endocrinologists (AACE) Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients. 2002 update. Available at: <https://www.aace.com/files/hypo-gonadism.pdf>. Accessed on June 26, 2017.

Seftel AD, Kathrins M, Niederberger C. Critical update of the 2010 Endocrine Society clinical practice guidelines for male hypogonadism: a systematic analysis. *Mayo Clin Proc*. 2015; 90(8):1104-1115.

Testosterone enanthate injection, USP (Delatestry®) In: DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated December 19, 2015. Available at: <http://www.micromedexsolutions.com>. Accessed on June 28, 2017.

Testosterone undecanoate injection, USP (Aveed®) In: DrugPoints® System [electronic version]. Truven health Analytics, Greenwood Village, CO. Updated January 26, 2016. Available at: <http://www.micromedexsolutions.com>. Accessed on June 27, 2017.

Testosterone cypionate injection, USP (Depo®-Testosterone) In: DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated March 18, 2016. Available at: <http://www.micromedexsolutions.com>. Accessed on June 27, 2017.

U.S. Food and Drug Administration (FDA). Safety alerts. Testosterone and Other Anabolic Androgenic Steroids (AAS): FDA Statement - Risks Associated With Abuse and Dependence. October 25, 2016. Available at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm526151.htm>. Accessed on June 28, 2017.

U.S. Food and Drug Administration (FDA). FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products. Drug Safety Communications 2014. Available at: <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM383909.pdf>. Accessed on June 27, 2017.

Wang C, Nieschlag E, Swerdloff R, et al. International Society for the Study of Aging Male, the International Society of Andrology, the European Association of Urology, the European Academy of Andrology, and the American Society of Andrology (ISSAM/ISA/EAU/EAA/ASA). Investigation, treatment, and monitoring of late-onset hypogonadism in males: recommendations. *Eur Urol*. 2009; 55(1):121-130.

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