



Original Effective Date: 04/12/2018
Current Effective Date: 08/23/2023
Last P&T Approval/Version: 07/26/2023
Next Review Due By: 07/2024
Policy Number: C2270-A

Testosterone

PRODUCTS AFFECTED

ANDROID (methyltestosterone), ANDRODERM (testosterone topical), ANDROGEL (testosterone topical), AVEED (testosterone undecanoate), AXIRON (testosterone solution), DELATESTRYL (testosterone enanthate), DEPO-TESTOSTERONE (testosterone cypionate), FORTESTA (testosterone topical), JATENZO (testosterone undecanoate), METHITEST (methyltestosterone), NATESTO (testosterone nasal gel), TESTIM* (testosterone topical), TESTOPEL (testosterone implant), TESTRED* (methyltestosterone), TLANDO (testosterone undecanoate), VOGELXO* (testosterone topical), XYOSTED (testosterone enanthate), KYZATREX (testosterone undecanoate), STRIANT (testosterone buccal)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Hypogonadism, Delayed Puberty

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

Drug and Biologic Coverage Criteria

A. HYPOGONADISM:

1. (a) Documentation of diagnosis for a male member with congenital or acquired hypogonadotropic hypogonadism (i.e., gonadotropin or luteinizing hormone-releasing hormone [LHRH] deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation)
OR
(b) Documentation of a diagnosis for a male member with congenital or acquired primary hypogonadism (i.e., testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy)
AND
2. Documentation of at least two morning (before 10am) total testosterone baseline levels done on separate days within the past 6 months that are considered low per laboratory testing reference values. NOTE: The diagnosis of hypogonadism requires unequivocally and consistently low testosterone levels on at least 2 separate mornings (The Endocrine Society, 2018). The lower limit of normal for testosterone can vary depending on the laboratory used, clinical trials for a number of testosterone agents defined it as < 300 ng/dL. The American Urological Association suggests < 300 ng/dL as a reasonable cut-off in support of low testosterone diagnosis (2018). [DOCUMENTATION REQUIRED]
AND
3. Documentation of a trial and failure of at least 1 generic injectable product AND at least 1 generic topical product
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to testosterone include: Breast cancer (males); prostate cancer (known or suspected), pregnancy; Natesto, Striant, transdermal solution: Additional contraindications: Breastfeeding patients, patients who may become pregnant; Aved: Additional contraindications: Hypersensitivity to testosterone undecanoate, castor oil, benzyl benzoate; Depo-Testosterone: Additional contraindications: Hypersensitivity to testosterone cypionate, serious cardiac, hepatic, or renal disease; Testosterone enanthate (IM injection): Additional contraindications: Hypersensitivity to any component of the formulation; patients who may become pregnant, Testosterone enanthate (SUBQ injection): Additional contraindications: Hypersensitivity to any component of the formulation; males with hypogonadal conditions that are not associated with structural or genetic etiologies (eg, age-related hypogonadism); patients who may become pregnant; Testosterone undecanoate (oral): Additional contraindications: Hypersensitivity to any component of the formulation; males with hypogonadal conditions that are not associated with structural or genetic etiologies (eg, age-related hypogonadism). Contraindications to methyltestosterone include: Men with breast cancer or with known or suspected prostate cancer, women who are or may become pregnant.]

B. CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY

1. Documented diagnosis of constitutional delay of growth and puberty
AND
2. Documentation of random measurements of serum LH, FSH and testosterone that support diagnosis.
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to testosterone include: Breast cancer (males); prostate cancer (known or suspected), pregnancy; Natesto, Striant, transdermal solution: Additional contraindications: Breastfeeding patients, patients who may become pregnant; Aved: Additional contraindications: Hypersensitivity to testosterone undecanoate, castor oil, benzyl benzoate; Depo-Testosterone: Additional contraindications: Hypersensitivity

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to testosterone cypionate, serious cardiac, hepatic, or renal disease; Testosterone enanthate (IM injection): Additional contraindications: Hypersensitivity to any component of the formulation; patients who may become pregnant, Testosterone enanthate (SUBQ injection): Additional contraindications: Hypersensitivity to any component of the formulation; males with hypogonadal conditions that are not associated with structural or genetic etiologies (e.g., age-related hypogonadism); patients who may become pregnant; Testosterone undecanoate (oral): Additional contraindications: Hypersensitivity to any component of the formulation; males with hypogonadal conditions that are not associated with structural or genetic etiologies (e.g., age-related hypogonadism). Contraindications to methyltestosterone include: Men with breast cancer or with known or suspected prostate cancer, women who are or may become pregnant.]

C. METASTATIC BREAST CANCER: Refer to Molina Standard Oncology Criteria

D. TRANSGENDER HEALTH: See Molina Gender Dysphoria Hormone Therapy

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of clinical benefit specific to indication being treated

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months.

PRESCRIBER REQUIREMENTS:

HYPOGONADISM: None

CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY: Prescribed by or in consultation with a pediatric endocrinologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

HYPOGONADISM: 18 years of age or older

CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY: 14 years of age or older

QUANTITY:

No requirements

PLACE OF ADMINISTRATION:

The recommendation is that oral and topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intramuscular injectable products administered in a place of service that is a non-hospital facility-based location.

Testopel Implant: The recommendation is that injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Injectable, topical, oral, subcutaneous implant

DRUG CLASS:

Androgens

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FDA-APPROVED USES:

Primary or Hypogonadotropic Hypogonadism (congenital or acquired), Constitutional Delay Of Growth And Puberty, Metastatic Breast Cancer

Limitations of use: Safety and efficacy in men with age-related hypogonadism (or late-onset hypogonadism) has not been established (manufacturer's labeling). However, the Endocrine Society recommends offering testosterone therapy to patients with symptoms of testosterone deficiency and consistently and unequivocally low morning testosterone concentrations. In men >65 years of age, treatment should only be initiated on an individual basis and after consultation with the patient regarding risks and benefits (Endocrine Society [Bhasin2018]).

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Endogenous androgens are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. Some of these effects include alterations in body musculature and maturation of prostate, seminal vesicles, penis and scrotum. Androgens are also responsible for the growth spurt of adolescence and for the eventual termination of linear growth. Exogenous androgens in children can accelerate linear growth rates but may also cause a disproportionate advancement in bone maturation.

Testosterone replacement regimens supply exogenous testosterone and restore serum testosterone levels in the normal range (300 to 1,000 ng/dL). The International Society of Andrology (ISA), International Society for the Study of the Aging Male (ISSAM), European Association of Urology (EAU), European Academy of Andrology (EAA), and the American Society of Andrology (ASA) propose 230 ng/dL as the lower limit of serum testosterone at which members will benefit from testosterone replacement therapy.

The Endocrine Society recommends 300 ng/dL, and the American Association of Clinical Endocrinologists (AACE) suggests 200 ng/dL as the lower limit for initiating testosterone replacement. Testosterone level increases in males until 17 years of age and stabilizes to a serum level in the range of 300 to 1,000 ng/dL, until about 40 years of age. After this, the levels begin to decline at 1.2% to 2% per year.

About 20% of men > 60 years of age and 50% of men > 80 years of age are estimated to have serum testosterone levels that are subnormal compared with younger men. Given this inherent variability in testosterone levels in men based on age, it is also prudent to consider other variables that could affect a laboratory drawn testosterone level (e.g., time of day when the level is drawn, laboratory specific normal values for testosterone, total vs. free testosterone levels) before initiating replacement therapy. Male hypogonadism is characterized by low serum levels of testosterone and is classified according to the level of the hypothalamus-pituitary-testis axis involvement. It is classified as primary hypogonadism when the main problem involves the testes (elevated luteinizing hormone [LH] and follicle stimulating hormone [FSH]). It is secondary hypogonadism (hypogonadotropic hypogonadism) if the hypothalamus/pituitary axis are involved; low testosterone levels in this case are associated with low or inadequately normal levels of LH and FSH. The diagnosis of male hypogonadism is based on both a clinical suspicion and low testosterone levels. By restoring normal levels of testosterone, the replacement regimens correct symptoms of hypogonadism, which can include malaise, loss of muscle strength, depressed mood, and decreased libido. Testosterone regimens can be administered orally, parenterally, or transdermally. Injectable testosterone replacement products include testosterone cypionate, testosterone enanthate, and Aveed injections, and Testopel, which is implanted subcutaneously. These agents are all indicated for congenital or acquired primary hypogonadism and hypogonadotropic

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hypogonadism (secondary hypogonadism). Testopel and testosterone enanthate are also indicated for delayed puberty. Testosterone enanthate may also be used secondarily in women with advanced inoperable metastatic mammary cancer that are 1 to 5 years postmenopausal. The primary goal of this therapy is to ablate the ovaries. It can also be used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone responsive tumor. The prescribing information notes that the judgment regarding the use of androgen therapy in females should be made by an oncologist with expertise in the area. Compared with the other two intramuscular injections, Aveed has a longer duration between dosing after it reaches steady state levels. After the first injection, a second injection is administered after 4 weeks. After this second dosing, subsequent administration is once every 10 weeks. Dose titration is not necessary. The safety and efficacy of Aveed in males < 18 years of age have not been established.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of testosterone are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

Injectable testosterone (e.g., testosterone cypionate, testosterone enanthate, Aveed, Testopel) has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following condition. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. *To Enhance Athletic Performance.* Injectable testosterone products are not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

Contraindications:

Contraindications to testosterone include: Breast cancer (males); prostate cancer (known or suspected), pregnancy; Natesto, Striant, transdermal solution: Additional contraindications: Breastfeeding patients, patients who may become pregnant; Aveed: Additional contraindications: Hypersensitivity to testosterone undecanoate, castor oil, benzyl benzoate; Depo-Testosterone: Additional contraindications: Hypersensitivity to testosterone cypionate, serious cardiac, hepatic, or renal disease; Testosterone enanthate (IM injection): Additional contraindications: Hypersensitivity to any component of the formulation; patients who may become pregnant, Testosterone enanthate (SUBQ injection): Additional contraindications: Hypersensitivity to any component of the formulation; males with hypogonadal conditions that are not associated with structural or genetic etiologies (eg, age-related hypogonadism); patients who may become pregnant; Testosterone undecanoate (oral): Additional contraindications: Hypersensitivity to any component of the formulation; males with hypogonadal conditions that are not associated with structural or genetic etiologies (eg, age-related hypogonadism). Contraindications to methyltestosterone include: Men with breast cancer or with known or suspected prostate cancer, women who are or may become pregnant.

Documentation of allergenic cross-reactivity for androgens is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.

There is low quality evidence for efficacy of testosterone therapy in hypogonadism associated with aging. Data from five randomized, placebo-controlled trials including over 500 older men [20-26] during the 1990s showed some beneficial effects of testosterone treatment of older men, but the results were not consistent, possibly because of enrolling men who were not clearly hypogonadal, not increasing the serum testosterone to normal, insufficient duration of treatment, and/or not choosing clinically important outcomes. A committee of the Institute of Medicine (now the National Academy of Medicine) reviewed these and other trials and concluded that there was insufficient evidence to conclude that testosterone treatment of older men has any well-established benefit. The committee recommended that a coordinated set of randomized, placebo-controlled clinical trials should be performed to determine if testosterone does have any benefit. The Testosterone Trials (TTrials) were designed to implement this recommendation. The TTrials, demonstrated that testosterone treatment of symptomatic older men with unequivocally low testosterone levels is efficacious in improving sexual function, walking, mood,

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depressive symptoms, anemia, and bone density, all to modest degrees. Testosterone treatment, however, did not improve vitality or cognitive function and was associated with an increase in noncalcified coronary artery plaque volume. Although testosterone treatment was not associated with increased risks of clinical cardiac events or prostate cancer, a much larger and longer trial would be needed to assess these risks with greater certainty. There are theoretical and other reasons to think that testosterone treatment of older men with low testosterone might exacerbate certain diseases. For example, the prostate gland is testosterone dependent, so it is reasonable to wonder if raising the serum testosterone concentration will increase the risk of prostate cancer or benign prostatic hyperplasia. Erythropoiesis is also testosterone dependent, so raising the testosterone level, especially to supraphysiologic levels, can cause erythrocytosis.

No trial yet has been large enough or long enough to determine if testosterone increases the risk of prostate cancer or benign prostatic enlargement. If a digital rectal examination shows a prostate nodule or the prostate-specific antigen (PSA) is >4 ng/mL or >3 ng/mL in men at increased risk of prostate cancer (e.g., African American men or those who have a first-degree relative with diagnosed prostate cancer), the member should be referred for urologic evaluation before prescribing testosterone

Testosterone increases red blood cell production, which could cause an elevated hematocrit. Hematocrit should be measured before beginning treatment and evaluated if it is above 48 percent in a hypogonadal man. The measurement should be repeated after three to six months of treatment and at least once a year thereafter.

No clinical trial of testosterone has been large enough or long enough to determine its cardiovascular risk, but the US Food and Drug Administration (FDA) has not approved testosterone treatment for older men who have low testosterone but no known pituitary or testicular disease.

OTHER SPECIAL CONSIDERATIONS:

Boxed warning(s): Jatenzo, Tlando, Xyosted: increases in blood pressure; Androgel, Fortesta, Testim, Vogelxo, Axiron: Virilization has been reported in children who were secondarily exposed to testosterone gel. Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel; Aveed: Serious pulmonary oil microembolism (POME) reactions, involving urge to cough, dyspnea, throat tightening, chest pain, dizziness, and syncope; and episodes of anaphylaxis, including life-threatening reactions, have been reported to occur during or immediately after the administration of testosterone undecanoate injection. These reactions can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3121	Injection, testosterone enanthate, 1 mg
J1071	Injection, testosterone cypionate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
S0189	Testosterone pellet, 75 mg

AVAILABLE DOSAGE FORMS:

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Androderm PT24 2MG/24HR, 4MG/24HR
AndroGel GEL 20.25 MG/1.25GM(1.62%), 40.5 MG/2.5GM(1.62%)
AndroGel GEL 25 MG/2.5GM(1%), 50 MG/5GM(1%)
AndroGel Pump GEL 20.25 MG/ACT(1.62%)
Aveed SOLN 750MG/3ML
Depo-Testosterone SOLN 100MG/ML, 200MG/ML
EC-RX Testosterone CREA 0.2%, 0.4%, 10%, 20%
Fortesta GEL 10 MG/ACT(2%)
Jatenzo CAPS 158MG, 198MG, 237MG
Kyzatrex CAPS 100MG, 150MG, 200MG
Methitest TABS 10MG
7ethyltestosterone CAPS 10MG
Natesto GEL 5.5MG/ACT
Striant MISC 30MG
Testim GEL 50 MG/5GM(1%)
Testone CIK KIT 200MG/ML
Testopel PLLT 75MG
Testosterone Compounding Kit CREA 20%
Testosterone Cypionate SOLN 50MG/ML, 100MG/ML, 150MG/ML, 200MG/ML
Testosterone Enanthate SOLN 200MG/ML
Testosterone GEL 1.62%
Testosterone GEL 10 MG/ACT(2%)
Testosterone GEL 12.5 MG/ACT(1%)
Testosterone GEL 20.25 MG/1.25GM(1.62%), 40.5 MG/2.5GM(1.62%)
Testosterone GEL 20.25 MG/ACT(1.62%)
Testosterone GEL 25 MG/2.5GM(1%), 50 MG/5GM(1%)
Testosterone PLLT 25MG, 50MG, 100MG, 200MG
Testosterone Propionate SOLN 100MG/ML
Testosterone SOLN 30MG/ACT
Tlando CAPS 112.5MG
Vogelxo GEL 50 MG/5GM(1%)
Vogelxo Pump GEL 12.5 MG/ACT(1%)
Xyosted SOAJ 50MG/0.5ML, 75MG/0.5ML, 100MG/0.5ML

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4. Axiron (testosterone) topical solution. Prescribing Information. Indianapolis, IN: Lilly USA, LLC. July 2017.
5. Fortesta (testosterone) 2% gel. Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc. January 2022.
6. Testim (testosterone) 1% gel. Prescribing information. Malvern, PA: Auxilium Pharmaceuticals, Inc; August 2021.
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8. Vogelxo (testosterone) gel. Prescribing information. Maple Grove, MN: Upsher-Smith Laboratories, April 2020.
9. Jatenzo (testosterone) [prescribing information]. Northbrook, IL: Clarus Therapeutics Inc; June 2019.
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12. Aveed (testosterone undecanoate) injection, for intramuscular use [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2021.
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28. Exogenous testosterone or testosterone with finasteride increases bone mineral density in older men with low serum testosterone. Amory JK, Watts NB, Easley KA, Sutton PR, Anawalt BD, Matsumoto AM, BremnerWJ, Tenover JL *J Clin Endocrinol Metab.* 2004;89(2):503
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Prescriber Requirements Age Restrictions FDA-Approved Uses Coding/Billing Information Available Dosage Forms References	Q3 2023
REVISION- Notable revisions: Products Affected Required Medical Information Duration of Approval Background Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file