Original Effective Date: 04/12/2018
Current Effective Date: 09/28/2022
Last P&T Approval/Version: 07/27/2022
Next Review Due By: 07/2023
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)

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.

A. HYPOGONADISM:
   1. (a) Documentation of diagnosis for a male member with congenital or acquired

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

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; 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.]

B. DELAYED PUBERTY

1. Documentation of random measurements of serum LH, FSH and testosterone that support diagnosis.
AND
2. 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; 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

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

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

DELAYED 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

DELAYED 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

FDA-APPROVED USES:

Primary or Hypogonadotropic Hypogonadism (congenital or acquired), Delayed Puberty, Metastatic Breast Cancer

Limitations of use: Safety and efficacy in men with age-related hypogonadism (or late-onset

Molina Healthcare, Inc. confidential and proprietary © 2022

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

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 lutenizing 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 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

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

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.

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.

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

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

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, 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:
None

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	Inj, testosterone enan, 1mg
J1071	Inj, testosterone cyp, 1mg
J3145	Inj, testosterone undec, 1mg
S0189	Testosterone pellet, 75 mg

AVAILABLE DOSAGE FORMS:
Androderm transdermal patch 2mg, 4mg
AndroGel gel packet (1.25g) 1.62%, gel packet (2.5g) 1.62%, gel pump 1.62%
Aveed SOLN 750MG/3ML

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

AndroGel gel packet (2.5g) 1%, gel packet (5g)1%, gel pump 1%
Axiron topical solution 30mg
Depo-Testosterone (cypionate) injectable solution 100mg/ml, 200mg/mL
Delatestryl (enanthate) injectable solution 200mg/mL
Fortesta gel 2%
Jatenzo CAPS 158mg, 198mg, 237mg
Methitest (methyltestosterone) oral 10mg
Android (methyltestosterone) oral 10mg
Testred (methyltestosterone) oral 10mg
MethylTESTOSTERone CAPS 10mg
Natesto GEL 5.5mg/ACT
Testim gel 1%
Testopel PLLT 75mg
Testosterone GEL 1.62%, 10 MG/ACT(2%), 12.5 MG/ACT(1%), 20.25 MG/1.25GM(1.62%), 20.25 MG/ACT(1.62%), 25 MG/2.5GM(1%), 40.5 MG/2.5GM(1.62%), 50 MG/5GM(1%)
Testosterone PLLT 25mg, 50mg, 100mg, 200mg
Testosterone SOLN 30MG/ACT
Tlando CAPS 112.5MG
Vogelxo gel packet 1%, gel pump 1%
Xyosted SOAJ 50MG/0.5ML, 75MG/0.5ML, 100MG/0.5ML

REFERENCES

1. AACE Hypogonadism Task Force. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Members – 2002 Update. Endocr Pract.2002; 8(No. 6): 439-456
2. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version.
3. Cook, David M, et al. "American Association of Clinical Endocrinologists medical Guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition members - 2009 update: executive summary of recommendations." Endocrine practice 15.6(2009):580-586.
4. Gibney, James, et al. "Growth hormone and testosterone interact positively to enhance protein and energy metabolism in hypopituitary men." American journal of physiology: endocrinology and metabolism 289.2 (2005): E266-E271
5. Bhasin, S, et al. "Testosterone replacement and resistance exercise in HIV-infected men with weight loss low testosterone levels." JAMA. 2000. 283. (6) 763-770.
6. Isidori, Andrea M, et al. Effects of testosterone on sexual function in men: results of a meta-analysis.Clinical endocrinology. 2005 63(4):381-394. Kenny, A M, et al. Effects of transdermal testosterone on bone and muscle in older men with low bioavailable testosterone levels. The journals of gerontology. 2001. 56(5)M266-M272.
7. Tracz, Michal J, et al. Testosterone use in men and its effects on bone health. A systematic review and meta-analysis of randomized placebo-controlled trials. The Journal of clinical endocrinology and metabolism. 2006. 91(6):2011-2016.
8. Bolona, Enrique R, et al. Testosterone use in men with sexual dysfunction: a systematic review and meta-analysis of randomized placebo-controlled trials. Mayo Clinicproceedings.2007. 82(1):20-28.
9. The Endocrine Society. Testosterone therapy in Adult Men with Androgen Deficiency Syndromes. JClini Endocrinol Metab. 2010; 95(6): 2546-59.
10. Androderm (testosterone) [prescribing information]. Madison, NJ: Allergen USA, Inc; May 2020
11. Androgel (testosterone) 1.62% gel. Prescribing information. Abbvie Inc. Chicago, IL. November 2020
12. Androgel (testosterone) 1% gel. Prescribing information. Abbvie Inc. Chicago, IL. October 2016. AndroGel1% Prescribing Information North Chicago, IL: AbbVie Inc.; May 2019
13. Axiron (testosterone) topical solution. Prescribing Information. Indianapolis, IN: Lilly USA,LLC. July 2017.

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

14. Fortesta (testosterone) 2% gel. Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc. June 2020.
15. Testim (testosterone) 1% gel. Prescribing information. Malvern, PA: Auxilium Pharmaceuticals, Inc;November 2020.
16. Natesto (testosterone) nasal gel [prescribing information]. Englewood, CO: Aytu BioScience, Inc; October 2016.
17. Vogelxo (testosterone) gel. Prescribing information. Maple Grove, MN: Upsher-Smith Laboratories,September 2016. April 2020.
18. Hembree, Wylie C, et al. Endocrine treatment of transsexual persons: An Endocrine Society clinical practice guideline. The Journal of clinical endocrinology and metabolism94.9 (2009):3132-3154.
19. Effect of testosterone treatment on bone mineral density in men over 65 years of age.Snyder PJ, PeacheyH, Hannoush P, Berlin JA, Loh L, Holmes JH, Dlewati A, Staley J, Santanna J, Kapoor SC, AttieMF, HaddadJG Jr, Strom BL J Clin Endocrinol Metab. 1999;84(6):1966
20. Effect of testosterone treatment on body composition and muscle strength in men over 65 years of age. Snyder PJ, Peachey H, Hannoush P, Berlin JA, Loh L, Lenrow DA, Holmes JH, Dlewati A, Santanna J, Rosen CJ, Strom BL J Clin Endocrinol Metab. 1999;84(8):2647
21. Effects of transdermal testosterone on bone and muscle in older men with low bioavailable testosterone levels.Kenny AM, Prestwood KM, Gruman CA, Marcello KM, Raisz LG J Gerontol A Biol Sci Med Sci.2001;56(5):M266
22. 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
23. Exogenous testosterone (T) alone or with finasteride increases physical performance, grip strength, and lean body mass in older men with low serum T.Page ST, Amory JK, Bowman FD, Anawalt BD, MatsumotoAM, Bremner WJ, Tenover JL J Clin Endocrinol Metab. 2005;90(3):1502. Epub 2004 Nov 30.
24. DHEA in elderly women and DHEA or testosterone in elderly men.Nair KS, Rizza RA, O'Brien P, Dhatariya K, Short KR, Nehra A, Vittone JL, Klee GG, Basu A, Basu R, Cobelli C, Toffolo G, Dalla ManC, Tindall DJ,Melton LJ 3rd, Smith GE, Khosla S, Jensen MD N Engl J Med. 2006;355(16):1647
25. Effect of testosterone supplementation on functional mobility, cognition, and other parameters in older men:a randomized controlled trial.Emmelot-Vonk MH, Verhaar HJ, Nakhai Pour HR, Aleman A, Lock TM, BoschJL, Grobbee DE, van der Schouw YT. JAMA. 2008;299(1):39
26. Jatenzo (testosterone) [prescribing information]. Northbrook, IL: Clarus Therapeutics Inc; March 2019.
27. Xyosted (testosterone) [prescribing information]. Ewing, NJ: Antares Pharma, Inc; November 2019
28. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency AUA guideline. American Urological Association. Published 2018. Available at: https://www.auanet.org/guidelines/testosterone-deficiency-guideline
29. Tlando (testosterone undecanoate) capsules [prescribing information]. Ewing, NJ: Antares Pharma, Inc; March 2022.
30. Aveed (testosterone undecanoate) injection, for intramuscular use [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2021.
31. Testopel (testosterone pellets) [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2018.

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

SUMMARY OF REVIEW/REVISIONS	DATE
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

Molina Healthcare, Inc. confidential and proprietary © 2022
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.