Effective Date 05/15/2025
Coverage Policy Number IP0350

Testosterone (Oral, Topical, and Nasal)

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following testosterone oral, topical, and nasal products:

Oral Testosterone Products

- Jatenzo® (testosterone undecanoate capsules)
- Kyzatrex™ (testosterone undecanoate capsules)
- Tlando® (testosterone undecanoate capsules)

Transdermal Gel Testosterone Products

- AndroGel® (testosterone gel) and generics
- Fortesta™ (testosterone gel) and generics
- Testim® (testosterone gel) and generics
- Vogelxo™ (testosterone gel) and generics

Transdermal Patch Testosterone Product

- Androderm® (testosterone transdermal system)

Transdermal Testosterone Solution Product

- Axiron™ (testosterone topical solution – generics only available)

Nasal Testosterone Product

- Natesto™ (testosterone nasal gel)

This coverage policy addresses the uses of oral, topical, and nasal testosterone products. The use of injectable testosterone products, including implantable pellets, is addressed in a separate coverage policy. Please refer to the related coverage policy link above (Testosterone - Injectables and Implantable Pellets).

Coverage for treatment of gender dysphoria varies across plans. Coverage of drugs for hormonal therapy, as well as whether the drug is covered as a medical or a pharmacy benefit, varies across plans. Refer to the customer's benefit plan document for coverage details. In addition, coverage for treatment of gender dysphoria, including gender reassignment surgery and related services may be governed by state and/or federal mandates.[1]

Medical Necessity Criteria

Testosterone oral, topical, and nasal products are considered medically necessary when ONE of the following is met.

1. **Hypogonadism in Males (Testicular Hypofunction/Low Testosterone with Symptoms).** Individual meets **ALL** of the following criteria:
    A. Age 18 years or older
    B. Documentation of **ONE** of the following:
        i. Initial Therapy. **ALL** of the following are met:
            a. Has had persistent pre-treatment signs and symptoms of androgen deficiency (for example depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, and loss of libido)
            b. Has had **TWO** pre-treatment serum testosterone (total or free) measurements, each taken in the early morning, on two separate days (free testosterone levels are to be measured by equilibrium dialysis assay)
            c. The **TWO** serum testosterone levels (total or free) are **BOTH** low, as defined by the normal laboratory reference values.
        ii. Currently Receiving Testosterone Therapy and Records are Available. **BOTH** of the following are met:
            a. Has had persistent pre-treatment signs and symptoms of androgen deficiency (for example depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, and loss of libido)

b. Has had at least **ONE** pre-treatment serum testosterone (total or free) measurement taken in the early morning, which was low, as defined by the normal laboratory reference values (free testosterone levels are to be measured by equilibrium dialysis assay)

iii. Currently Receiving Testosterone Therapy and There is a Loss of Records or an Inability to Provide Pre-treatment Clinical Information. The individual has a recent serum testosterone (total or free) measurement which indicates appropriate treatment (testosterone level within the normal laboratory reference values) while receiving testosterone replacement therapy (free testosterone levels are to be measured by equilibrium dialysis assay)

C. No concurrent use with other testosterone products
D. Preferred product criteria is met for products listed in the below table(s)

2. **Gender-Dysphoric/Gender-Incongruent Persons; Persons Undergoing Female-To-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).** Individual meets **BOTH** of the following criteria:
   A. The medication is prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of transgender individuals.
   B. Preferred product criteria is met for products listed in the below table(s)

For Employer Plans:

Product	Criteria
Androgel (testosterone gel)	**EFFECTIVE 7/1/2025** The patient has tried **testosterone gel** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.
Fortesta (testosterone topical gel)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **THREE** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump) 3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Jatenzo (testosterone undecanoate capsules)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans** Documentation of failure, contraindication, or intolerance to **TWO** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump) 3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/ actuation pump (generic for Vogelxo)

Product	Criteria
Kyzatrex (testosterone undecanoate capsules)	**Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans** Documentation of failure, contraindication, or intolerance to **TWO** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump) 3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/ actuation pump (generic for Vogelxo)
Natesto (testosterone nasal gel)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **THREE** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump) 3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Testim (testosterone topical gel)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **THREE** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump) 3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Tlando (testosterone undecanoate capsules)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans** Documentation of failure, contraindication, or intolerance to **TWO** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump) 3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/ actuation pump (generic for Vogelxo)
Vogelxo (testosterone topical gel)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **THREE** of the following: [may require prior authorization] 1. Androgel 1% or its generic (2.5gm, 5gm gel packets) 2. Androgel 1.62% or its generic (1.25gm, 2.5gm gel packet or pump)

Product	Criteria
	3. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) 4. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 5. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) 6. Testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)

For Individual and Family Plans:

Product	Criteria
Androderm (testosterone transdermal system)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Androgel (testosterone topical gel)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Fortesta (testosterone topical gel)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Jatenzo (testosterone undecanoate capsules)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Kyzatrex (testosterone undecanoate capsules)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim)

Product	Criteria
	5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Natesto (testosterone nasal gel)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Testim (testosterone topical gel)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
testosterone 30mg/1.5ml (2%) solution (generic for Axiron)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Tlando (testosterone undecanoate capsules)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)
Vogelxo (testosterone topical gel)	Documentation of failure, contraindication, or intolerance to **ONE** of the following: 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of testosterone oral, topical, and nasal products is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered not medically necessary, including the following (this list may not be all inclusive):

1. **To Enhance Athletic Performance**

Background

OVERVIEW
The oral, topical, and nasal testosterone replacement products are all indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.[1-10,15,16] The labels for the FDA-approved products define those patients and/or conditions for which use of testosterone replacement products is indicated:

- **Primary hypogonadism (congenital or acquired):** Testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and above-normal gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]).
- **Hypogonadotropic hypogonadism (congenital or acquired):** Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

The diagnosis of male hypogonadism is based on both signs/symptoms 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.[12]

All of the oral, topical, and nasal testosterone replacement product labeling states that due to the lack of controlled evaluations in women and potential virilizing effects, the products are not indicated for use in women.[1-10,15]

Guidelines

- **Hypogonadism:** Guidelines from the American Urological Association (2018) note that clinicians should use a total testosterone level below 300 ng/dL as a reasonable cutoff in support of the diagnosis of low testosterone.[13] A clinical diagnosis requires low testosterone levels (two separate levels, both conducted in the early morning) combined with signs and symptoms. The Endocrine Society guidelines on testosterone therapy in men with hypogonadism (2018) recommend diagnosing hypogonadism in men with symptoms and signs of testosterone deficiency and unequivocally and consistently low serum total testosterone and/or free testosterone concentrations (when indicated).[11]
- **Gender-Dysphoric/Gender-Incongruent Persons; Persons Undergoing Female-To-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization):** A clinical practice guideline published by the Endocrine Society (2017) recommends that, prior to initiation of hormonal therapy, the treating

endocrinologist should confirm the diagnostic criteria of gender dysphoria/gender incongruence and the criteria for the endocrine phase of gender transition.[14] The clinician should also evaluate and address medical conditions that can be exacerbated by hormone depletion and treatment with sex hormones of the affirmed gender before beginning treatment. Guidelines mention that clinicians can use either parenteral or transdermal preparations to achieve appropriate testosterone values.

References

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3. Testosterone topical 1% gel [prescribing information]. Chestnut Ridge, NY: Par; January 2022.
4. AndroGel® topical 1.62% gel [prescribing information]. North Chicago, IL: AbbVie; November 2020.
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6. Testosterone topical solution [prescribing information]. Parsippany, NJ: Actavis; February 2019.
7. Testosterone topical 10mg gel pump [prescribing information]. Parsippany, NJ: Actavis; June 2020.
8. Vogelxo™ topical gel [prescribing information]. Maple Grove, MN: Upsher-Smith; April 2020.
9. Natesto™ nasal gel [prescribing information]. Englewood, CO: Acerus; December 2021.
10. Jatenzo® capsules [prescribing information]. Fort Collins, CO: Tolmar; August 2023.
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12. Lee M. Erectile dysfunction. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, eds. Pharmacotherapy: a pathophysiologic approach. 7th ed. New York, NY: McGraw-Hill; 2008:1369-1385.
13. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency. American Urological Association. 2018. Available at: Non-Oncology Guidelines - American Urological Association (auanet.org). Accessed on November 19, 2024.
14. Hembree WC, Cohen-Kettenis P, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.
15. Tlando® capsules [prescribing information]. Ewing, NJ: Verity; February 2024.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	05/01/2025
Selected Revision	**Preferred Product Requirement Table.** **Added** preferred product criteria for Androgel on Employer Plans, effective 7/1/2025.	05/15/2025

The policy effective date is in force until updated or retired.