Drug Coverage Policy

Effective Date.....06/15/2026
Coverage Policy Number.....IP0350
Policy Title.....Testosterone (Oral, Topical, and Nasal) Products

Testosterone (Oral, Topical, and Nasal) Products

Oral Testosterone Products
- Jatenzo® (testosterone undecanoate capsules - Clarus/Tolmar)
- Kyzatrex™ (testosterone undecanoate capsules - Marius)
- Tlando® (testosterone undecanoate capsules - Verity)

Transdermal Patch
- Androderm® (testosterone transdermal system [2,4 mg/day] - Allergan) [obsolete]

Transdermal Gels
- AndroGel® (testosterone 1% gel (generics only), 1.62% gel - Ascend, generic)
- Testim® (testosterone 1% gel - Endo, generic)
- testosterone 2% gel - Endo, generic only
- Vogelxo™ (testosterone 1% gel - Upsher-Smith, generic)

Transdermal Solution
- testosterone 2% solution - Actavis, generics only

Nasal Gel
- Natesto™ (testosterone nasal gel - Acerus)

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

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:

1. **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 patients usually have low serum testosterone concentrations and above-normal gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]).
2. **Hypogonadotropic hypogonadism (congenital or acquired):** Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These patients 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 females and potential virilizing effects, the products are not indicated for use in females.[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 males with hypogonadism (2018) recommend diagnosing hypogonadism in males 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.

Coverage Policy

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.

POLICY STATEMENT

Prior Authorization is required for benefit coverage of oral, topical, and nasal testosterone products. All approvals are provided for the duration noted below. In the approval indications, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a male, regardless of the individual's gender identity or gender expression. Because of the specialized skills required for evaluation and diagnosis of some patients treated with testosterone, certain approval conditions require testosterone to be prescribed by or in consultation with a physician who specializes in the conditions being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, prescription receipts and/or other information. All documentation must include patient-specific identifying information.

Oral, topical, and nasal testosterone products are considered medically necessary when ONE of the following is met (1 or 2):

FDA-Approved Indication

1. **Hypogonadism (Primary or Secondary) in Males* [Testicular Hypofunction/Low Testosterone with Symptoms].** Approve for 1 year if the patient meets ONE of the following (A or B):
   Note: The pretreatment timeframe refers to signs and symptoms of androgen deficiency and serum testosterone levels prior to the initiation of any testosterone therapy.
   A) Initial Therapy. Patient with hypogonadism as confirmed by ALL of the following (i, ii, iii, and iv):
      i. Patient has had persistent signs and symptoms of androgen deficiency (pretreatment); AND
      Note: Signs and symptoms of androgen deficiency include depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, and loss of libido.

ii. Patient has had two pretreatment serum testosterone (total or bioavailable) measurements, each taken in the early morning, on two separate days **[documentation required]**; AND

iii. The two serum testosterone levels are both low, as defined by the normal laboratory reference values **[documentation required]**; AND

iv. Preferred product criteria is met for product(s) listed in the below table(s); OR

B) Patient is Currently Receiving Testosterone Therapy. Approve if the patient meets BOTH of the following (i and ii):

i. Patient has had persistent signs and symptoms of androgen deficiency (pretreatment); AND
Note: Signs and symptoms of androgen deficiency include depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, and loss of libido

ii. Patient has had at least one pretreatment serum testosterone (total or bioavailable) level taken which was low, as defined by the normal laboratory reference value.

*Refer to the Policy Statement.

Other Uses with Supportive Evidence

2. Gender-Dysphoric/Gender-Incongruent Persons; Persons Undergoing Female-To-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization). Approve for 1 year if the patient meets BOTH of the following (A and B):

A) The medication is prescribed by, or in consultation with, an endocrinologist or a physician who specializes in the treatment of transgender individuals; AND

B) Preferred product criteria is met for product(s) listed in the below table(s)
Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.

For Employer Plans:

Product	Criteria
AndroGel (testosterone gel)	The patient has tried **testosterone topical 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.
Jatenzo (testosterone undecanoate capsules)	**Value/Advantage/Total Savings Drug List Plans** Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **TWO** of the following (1, 2, 3, 4): 1. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) [requires prior authorization] 2. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 3. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 4. Testosterone 50mg/5gm gel packet or tube or 12.5gm/ actuation pump (generic for Vogelxo) [requires prior authorization]

Product	Criteria
Kyzatrex (testosterone undecanoate capsules)	**<u>Value/Advantage/Total Savings Drug List Plans</u>** Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **TWO** of the following (1, 2, 3, 4): 1. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) [requires prior authorization] 2. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 3. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 4. Testosterone 50mg/5gm gel packet or tube or 12.5gm/ actuation pump (generic for Vogelxo) [requires prior authorization] **<u>Standard/Performance/Legacy Drug List Plans:</u>** Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to Jatenzo (testosterone undecanoate capsules)
Natesto (testosterone nasal gel)	**<u>Standard/Performance/Value/Advantage/Total Savings Drug List Plans:</u>** Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **THREE** of the following (1, 2, 3, 4): 1. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) [requires prior authorization] 2. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 3. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 4. Testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
Testim (testosterone topical gel)	**<u>Standard/Performance/Value/Advantage/Total Savings Drug List Plans:</u>** The patient has tried **<u>testosterone topical gel</u>** (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.
Tlando (testosterone undecanoate capsules)	**<u>Value/Advantage/Total Savings Drug List Plans</u>** Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **TWO** of the following (1, 2, 3, 4): 1. Testosterone 30mg/1.5ml (2%) solution (generic for Axiron) [requires prior authorization]

Product	Criteria
	2. Testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 3. Testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 4. Testosterone 50mg/5gm gel packet or tube or 12.5gm/ actuation pump (generic for Vogelxo) [requires prior authorization] **Standard/Performance Drug List Plans:** Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to Jatenzo (testosterone undecanoate capsules)
Vogelxo (testosterone topical gel)	**Standard/Performance/Value/Advantage/Total Savings Drug List Plans:** The patient has tried **testosterone topical 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.

For Individual and Family Plans:

Product	Criteria
Androderm (testosterone transdermal system)	Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **ONE** of the following (1, 2, 3, 4, 5): 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) [requires prior authorization] 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) [requires prior authorization] 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
AndroGel (testosterone topical gel)	The patient has tried **testosterone topical 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.
Jatenzo (testosterone undecanoate capsules)	Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **ONE** of the following (1, 2, 3, 4, 5): 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) [requires prior authorization]

Product	Criteria
	2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) [requires prior authorization] 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
Kyzatrex (testosterone undecanoate capsules)	Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **ONE** of the following (1, 2, 3, 4, 5): 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) [requires prior authorization] 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) [requires prior authorization] 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
Natesto (testosterone nasal gel)	Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **ONE** of the following (1, 2, 3, 4, 5): 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) [requires prior authorization] 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) [requires prior authorization] 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
Testim (testosterone topical gel)	The patient has tried **testosterone topical 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.
testosterone 30mg/1.5ml (2%) solution (generic for Axiron)	Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **ONE** of the following (1, 2, 3, 4, 5): 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) [requires prior authorization] 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) [requires prior authorization]

Product	Criteria
	3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
Tlando (testosterone undecanoate capsules)	Patient has tried and, according to the prescriber, the patient has had inadequate efficacy or significant intolerance to **ONE** of the following (1, 2, 3, 4, 5): 1. testosterone 1% (generic for Androgel 1% - 2.5gm, 5gm gel packets) [requires prior authorization] 2. testosterone 1.62% (generic for Androgel 1.62% - 1.25gm, 2.5gm gel packet or pump) [requires prior authorization] 3. testosterone 10mg/0.5gm (2%) gel pump (generic for Fortesta) [requires prior authorization] 4. testosterone 50mg/5gm tube (1%) gel (generic for Testim) [requires prior authorization] 5. testosterone 50mg/5gm gel packet or tube or 12.5gm/actuation pump (generic for Vogelxo) [requires prior authorization]
Vogelxo (testosterone topical gel)	The patient has tried **testosterone topical 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.

Conditions Not Covered

Oral, topical, and nasal testosterone products for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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

References

1. Androderm® transdermal patch [prescribing information]. Madison, NJ: Allergan; May 2020.
2. Testim® topical gel [prescribing information]. Malvern, PA: Endo; July 2025.
3. Testosterone topical 1% gel [prescribing information]. Durham, NC: Encube; January 2025.
4. AndroGel® topical 1.62% gel [prescribing information]. Bridgewater, NJ: Ascend; July 2025.
5. Kyzatrex® capsules [prescribing information]. Raleigh, NC: Marius; September 2025
6. Testosterone topical solution [prescribing information]. Parsippany, NJ: Actavis; March 2025.
7. Testosterone topical 10mg gel pump [prescribing information]. Parsippany, NJ: Actavis; August 2025.
8. Vogelxo™ topical gel [prescribing information]. Maple Grove, MN: Upsher-Smith; April 2020.
9. Natesto™ nasal gel [prescribing information]. Toronto, ON: Acerus; July 2025.

10. Jatenzo® capsules [prescribing information]. Fort Collins, CO: Tolmar; September 2025.
11. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(5):1715-1744.
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. Reaffirmed 2024. Available at: Non-Oncology Guidelines - American Urological Association (auanet.org). Accessed on November 14, 2025.
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; July 2025.
16. Undecatrex™ capsules [prescribing information]. San Antonio, TX: Trifluent; September 2022.

Revision Details

Summary of Changes	Review Date	Effective Date
No criteria changes.	02/27/2026	05/01/2025
Preferred Product Requirement Table. **Added** preferred product criteria for Androgel on Employer Plans, effective 7/1/2025.	03/13/2025	05/15/2025
Updated the policy title from "Testosterone (Oral, Topical, and Nasal)" to "Testosterone (Oral, Topical, and Nasal) Products" **Added** a policy statement. **Added** a documentation statement. **Hypogonadism (Primary or Secondary) in Males* [Testicular Hypofunction/Low Testosterone with Symptoms]. Initial Therapy** **Added** a note defining the pretreatment timeframe. **Hypogonadism (Primary or Secondary) in Males* [Testicular Hypofunction/Low Testosterone with Symptoms]. Patient Currently Receiving Testosterone Therapy** **Removed** the no concurrent use with other testosterone products statement**.** **Removed** the "Loss of records" criteria. **Employer Plans Preferred Product Requirements** **Fortesta:** Removed from the preferred product table. **Jatenzo:** Removed Androgel 1% and 1.62% as alternative options. **Kyzatrex:** Removed Androgel 1% and 1.62% as alternative options. **Natesto:** Removed Androgel 1% and 1.62% as alternative options. **Testim:** Updated the criteria to multi-source brand criteria.	12/18/2025	02/15/2026

Tlando: Removed Androgel 1% and 1.62% as alternative options. **Vogelxo:** Updated the criteria to multi-source brand criteria. **Individual and Family Plans Preferred Product Requirements** **Androgel:** Updated the criteria to multi-source brand criteria. **Fortesta:** Removed from the preferred product table. **Testim:** Updated the criteria to multi-source brand criteria. **Vogelxo:** Updated the criteria to multi-source brand criteria. **Removed** the Reauthorization Criteria and Authorization Duration sections. **Updated** the conditions not covered statement.		
Updated the Jatenzo, Kyzatrex and Tlando Employer Plans preferred product requirements.	04/23/2026	06/15/2026

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

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