CVS Caremark®

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| Reference number(s) |
| 1370-A |

# Initial Prior Authorization Testosterone – Topical and Nasal

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Androgel | testosterone | topical gel |
| Fortesta | testosterone | topical gel |
| Natesto | testosterone | nasal gel |
| Testim | testosterone | topical gel |
| testosterone (all brands) | testosterone | topical solution |
| Vogelxo | testosterone | topical gel |

## Indications

### FDA-approved Indications

#### Androgel, Fortesta, Natesto, Testim, Testosterone Topical Gel, Testosterone Topical Solution, Vogelxo

Topical and nasal testosterone products are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

* 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 gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
* 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 testosterone serum concentrations but have gonadotropins in the normal or low range.

##### Limitations of Use:

* Safety and efficacy of topical and nasal testosterone products in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.
* Safety and efficacy of topical and nasal testosterone products in males less than 18 years old have not been established.
* Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

### Compendial Uses

#### Androgel, Fortesta, Natesto, Testim, Testosterone Topical Gel, Testosterone Topical Solution, Vogelxo

Gender dysphoria9,11-13 (also known as transgender and gender diverse (TGD) persons)

## Coverage Criteria

### Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

* The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
* The patient’s comorbid conditions are reasonably controlled.
* The patient has been educated on ANY contraindications AND side effects to therapy.
* Before the start of therapy, the patient has been informed of fertility preservation options.
* If the patient is less than 18 years of age, then ALL of the following criteria are met:
  + The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.
  + The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

### Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

* The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
* Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

## Continuation of Therapy

### Gender Dysphoria

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

### Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

* The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
* Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

## Duration of Approval (DOA)

* 1370-A: DOA: 12 months

## References

1. Androgel 1.62% [package insert]. Morristown, NJ: Ascend Therapeutics US, LLC; November 2020.
2. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; January 2022.
3. Natesto Nasal Gel [package insert]. Mississauga, ON: Acerus Pharmaceutical Corporation; December 2021.
4. Testim [package insert]. Malvern, PA: Endo USA,; August 2021.
5. Testosterone Gel 1% [package insert]. Durham, NC: Encube Ethicals, Inc.; July 2024.
6. Testosterone Topical Solution [package insert]. Bedminster, NJ: Alembic Pharmaceuticals, Inc.; December 2023.
7. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; April 2020.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 3, 2025.
9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/03/2025).
10. 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.
11. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
12. Hembree WC, Cohen-Kettenis PT, 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.
13. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.