Reference number(s)
229-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.

Coverage Criteria

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

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)

- 229-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.

Document History

Created: UM Development (AH)

Date: 07/2003

Revised: NB) 01/2005; (MG) 02/2006; (NB) 02/2007(2); (AM) 01/2008, 12/2008; (MS) 11/2009, 12/2010; (TM) 11/2011; (PL) 10/2012 (created MDC-2 due to extended commercial duration), 11/2012; (CS) 08/2013; (PL) 11/2013; (SE) 04/2014 (rephrased diagnosis question); (RP) 06/2014 (Add Natesto); (PL) 06/2014 (Add Vogelxo); (CF/JH) 11/2014, 02/2015 (updated testosterone level question); (LN) 04/2015 (added denial reasons); (CF/JH) 11/2015; (SE) 06/2016 (created separate Med D); (CF/JH) 11/2016; (KC) 11/2017, 10/2018 (no clinical changes), 08/2019 (removed “male” from lab questions), 10/2019 (removed MDC-2 from title), 02/2020 (no clinical changes), 02/2021 (added age-related hypogonadism question); (VLS) 02/2022

(removed Striant); (SS) 02/2023 (no clinical changes); (MRS) 02/2024 (no clinical changes); (DMH) 02/2025 (removed Androderm)

Reviewed: CDPR/Medical Affairs (MM): 01/2005, 02/2006; (WF): 02/2007, 01/2008, 12/2008, 11/2009; (KP) 11/2010, 11/2011, 03/2012, 10/2012; (DNC) 11/2012; (LCB) 11/2013; (SES) 11/2014; (KRU) 02/2015; (LCB) 11/2015; (MC) 12/2016; (DNC) 02/2017; (ME) 11/2017; (EPA) 08/2019; (CHART) 10/31/19, 02/27/20, 02/25/21, 02/24/2022, 02/23/2023, 02/29/2024, 02/27/2025

External Review: 08/2005, 04/2006, 06/2007, 04/2008, 04/2009, 02/2010, 02/2011, 03/2012, 02/2013, 08/2013, 02/2014, 06/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 10/2019 (FYI), 02/2020, 06/2020, 06/2021, 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)? [Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.] [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the requested drug being prescribed for primary or hypogonadotropic hypogonadism? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is this request for continuation of therapy? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Before the patient started testosterone therapy, did the patient have a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values? [No further questions]	Yes	No
5	Does the patient have at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values, before the start of testosterone therapy? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Deny	Go to 2	We have denied your request because your plan does not cover this drug for age-related hypogonadism, also referred to as late-

			onset hypogonadism . We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exclusion, age-related hypogonadism]
2.	Go to 3	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are primary hypogonadism and hypogonadotropic hypogonadism. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
3.	Go to 4	Go to 5	
4.	Approve, 12 Months	Deny	Your plan only covers this drug when you had a morning testosterone test before you started testosterone treatment and your test results were in a certain range (low). We denied your request because: A) You did not have a morning testosterone test before you started treatment, or B) Your results were not in the approvable range. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation, lab/test]

5.	Approve, 12 Months	Deny	Your plan only covers this drug when you have had two morning testosterone tests before starting treatment and your test results are in a certain range (low). We denied your request because: A) You did not have two morning testosterone tests before starting treatment, or B) Your results were not in the approvable range. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Lab/test]