

Title: Testosterone Topical Products (only)

Origination: 02/02/99	Revised: 11/11/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Medication Summary

- Testosterone is the primary androgen found in the body and is endogenously synthesized by cells in the testis, ovary, and adrenal cortex;
- Testosterone is used in the management of hypogonadism, either congenital or acquired;
- Topical products include Androgel, Testim 1% topical gel, Fortesta, Axiron, and Androderm transdermal system;
- Testosterone is indicated for replacement therapy in **males** for conditions associated with a deficiency or absence of endogenous testosterone and includes the following diagnoses:
 - **Primary hypogonadism** (congenital or acquired):
Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and above normal gonadotropin levels (Follicle Stimulating Hormone, Luteinizing Hormone).
 - **Hypogonadotropic hypogonadism** (congenital or acquired):
Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone levels, but have gonadotropins in the normal or low range.

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Background Information, continued:

Exclusions

- For the use in the treatment of sexual dysfunction due to the prescription benefit exclusion:
Exception: Testosterone will be covered for sexual dysfunction only for those Members with such coverage;
- Males less than 18 years of age;
- Female;
- A male with prostate carcinoma **or** breast carcinoma (contraindicated for use).

Procedure (per Catalyst question/answer format):

1. Is the request for initial coverage, or for continuation of coverage?
 Initial, continue to 2.
 Continuation, continue to 5.
2. Is the member a male, and at least 18 years of age?
 Yes = continue to question 3
 No = deny. The plan only allows for use in members that are male, and age 18 or greater based on FDA-approved indications. Based on the information provided, this member does not meet coverage criteria.
3. Is there documentation from the Member's medical records verifying the diagnosis of **primary or secondary hypogonadism/hypogonadotropic hypogonadism** (congenital or acquired)?
 Yes, continue to 4
 Other = Deny, the patients plan does not cover this medication for the diagnosis provided.
4. Is there clinical documentation (laboratory value) supporting at least one low **total** testosterone level < 300 ng/dl, **OR** low **free** testosterone level < 50 pg/ml (baseline level)?
 Yes = Approve indefinitely, within standard dosing guidelines.
 No = Deny, the plan requires a baseline testosterone level below the normal range. Based on the information provided, this member does not meet coverage criteria.
5. For continuation (i.e. new AvMed member who have been on medication with previous insurance provider), is there clinical documentation of a **baseline** (prior to starting therapy) low **total** testosterone level < 300 ng/dl, **OR** low **free** testosterone level < 50 pg/ml?
 Yes = Approve indefinitely, within standard dosing guidelines.
 No = Deny, the plan requires baseline testosterone levels below normal range. Based on the information provided, this member does not meet coverage criteria.

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References:

1. Androgel (testosterone) Prescribing Information. Solvay Pharmaceuticals, Inc. Marietta, GA. Revised September 2009.
2. Androderm (testosterone) Prescribing Information. Watson Pharma, Inc. Corona, CA. Revised November 1999.
3. Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2006 Jun;91(6):1995-20.
4. Winters SJ. Current status of testosterone replacement therapy in men. *Arch Fam Med.* 1999 May-Jun;8(3):257-63.
5. Beg S, Al-Khoury L, Cunningham GR. Testosterone replacement in men. *Curr Opin Endocrinol Diabetes Obes.* 2008 Aug;15(4):364-70.
6. Bassil N, Alkaade S, Morley JE. The benefits and risks of testosterone replacement therapy: a review. *Ther Clin Risk Manag.* 2009 Jun;5(3):427-48.
7. Wu, FCW. Commentary: Guideline for Male Testosterone Therapy: A European Perspective. *The Journal of Clinical Endocrinology & Metabolism*, February 2007, 92(2):418–419
8. Leichtnam, ML et al. Testosterone Hormone Replacement Therapy: State-of-the-Art and Emerging Technologies. [Pharm Res.](#) 2006 Jun;23(6):1117-32. Epub 2006 Jun 9.
9. Fortesta (testosterone) Gel Prescribing Information. Endo Pharmaceuticals Inc., Chadds Ford, PA. Revised April 2011.
10. Axiron (testosterone) Topical Solution Prescribing Information. Lilly USA, LLC Indianapolis, IN. Revised July 2011.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.