

Horizon BCBSNJ
 Medical Necessity Guideline

Section	Drugs
Policy Number	
Effective Date	6-25-04
Review Date	5-27-05; 10-27-06, 11-19-07, 9-26-08, 9-8-09

Subject:

**DRUG CLASS: TESTOSTERONE PRODUCTS TOPICAL-BUCCAL
 (ANDROGEL, TESTIM, ANDRODERM, STRIANT)**

IMPORTANT NOTE:

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

FDA-APPROVED INDICATION

Androgens are indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:

Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation.

Medical Necessity Guideline:

1. The following questionnaire may be used to determine medical necessity of Testosterone topical and buccal products.

REVIEW CRITERIA

1. Is the patient male?	Yes	No
2. Does the patient have confirmed or suspected carcinoma of the prostate or breast?	Yes	No
3. Is the patient being treated for primary hypogonadism (congenital or acquired)? [If the answer to this question is yes, then skip to question 5.]	Yes	No
4. Is the patient being treated for secondary (i.e. hypogonadotropic) hypogonadism (e.g., idiopathic gonadotropin or LHRH deficiency)? [If the answer to this question is no, then no further questions are required.]	Yes	No

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|---|-----------|
| 5. Before the start of testosterone therapy did the patient (or does the patient currently) have a confirmed low testosterone level (i.e. morning total testosterone < 300 ng/dL, morning free or bioavailable testosterone < 5 ng/dL) or absence of endogenous testosterone? | Yes No |
| 6. Is the request for MORE THAN the following dispensing limits:
Androderm - 1 patch per day
Androgel - 10 grams per day
Testim - 10 grams per day
Striant - 2 units per day | Yes No |

Guideline for Approval

Dispensing Limit:

- **Androderm (all strengths) 30 patches per 25 days supply**
- **Androgel (all strengths) 300 grams per 25 days supply**
- **Testim (all strengths) 300 grams per 25 days supply**
- **Striant (all strengths) 60 buccals per 25 days supply**

The duration of 25 days is used for 30-day fill period to allow time for refill processing. The duration of 75 days is used for 90-day fill period to allow time for refill processing.

Guideline for Approval

Duration of Approval		12 months	
Set 1 - primary hypogonadism		Set 2 - secondary hypogonadism	
Yes to Question(s)	No to Question(s)	Yes to Question(s)	No to Question(s)
1	2	1	2
3	6	4	3
5		5	6

Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

BLACK BOX WARNINGS

None

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and to decrease the potential for use to enhance athletic performance. Topical and buccal testosterone products are indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone such as primary hypogonadism or hypogonadotropic hypogonadism.¹⁻⁴ Hypogonadism is defined as a morning total serum testosterone concentration < 300 nanograms per deciliter, or a morning free or bioavailable testosterone concentration < 5 nanograms per deciliter.^{6,8,9} Androgens are contraindicated in men with known or suspected carcinoma of the breast or prostate.¹⁻⁸ Topical and buccal testosterone products are not indicated for use in women, have not been evaluated for use in women, and are contraindicated for use in women.^{1,3-4}

Horizon BCBSNJ has the following dispensing limits:

- Androderm – one patch per day
- Androgel – less than or equal to 10 grams per day
- Testim – less than or equal to 10 grams per day
- Striant – less than or equal to 2 units per day

REFERENCES

1. USPDI Drug Information for Healthcare Professionals. MICROMEDEX Thomson Healthcare. Greenwood, CO. 2003.
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3. Androderm product information. Watson Pharma, Inc. Corona, CA. November 2005.
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5. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients-2002 Update. AACE Hypogonadism Task Force. Endocrine Practice 2002. Nov-Dec;8(6):439-456.
6. Testoderm/Testoderm TTS product information. Alza Pharmaceuticals. January 1998.
7. Testim product information. Auxilium Pharmaceuticals, Inc. Morristown, PA. September 2003.
8. Rhoden EL, Morgentaler A. Risks of Testosterone-Replacement Therapy and Recommendations for Monitoring. *N Engl J Med* 2004; 350: 482-492.
9. Cunningham GR, Swerdloff RS. Summary from the Second Annual Andropause Consensus Meeting. Clinical Affairs Committee of the Endocrine Society. 2001.
10. Androgen deficiency syndromes in Men Guideline Task Force. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. The Endocrine Society; 2006. Available at: <http://www.endo-society.org/quickcontent/clinicalpractice/clinical-guidelines/upload/AndrogensMenGuideline053006.pdf>
11. McEvoy, Gerald K, ed. 2007. AHFS Drug Information. Bethesda, MD: American Society of Health-System Pharmacists, Inc.
12. Bhasin S, Cunningham GR, Hayes FJ. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2006. 91:1995-2010.

Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

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