Topical and Nasal Testosterone Products

Policy # 00335
Original Effective Date: 01/09/2013
Current Effective Date: 10/17/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on a review of the available data, branded and generic topical and nasal testosterone products, including, but not limited to Androderm®‡ (testosterone transdermal system), AndroGel®‡ (testosterone gel), Axiron®‡ (testosterone topical solution), Fortesta®‡ (testosterone topical gel), Striant®‡ (testosterone buccal system, mucoadhesive), Natesto™‡ (testosterone nasal gel), branded topical Testosterone, Vogelxo (testosterone gel), and Testim®‡ (testosterone gel) may be considered **eligible for coverage** when the below patient selection criteria are met:

Patient Selection Criteria:
Coverage eligibility will be considered for branded or generic topical and nasal testosterone products when the following criteria are met:

- The patient must be prescribed Androgel 1.62% or generic topical testosterone products, unless there is clinical evidence or patient history that suggests the use of Androgel 1.62% or generic topical testosterone products will be/was ineffective or will/did cause an adverse reaction to the patient; AND
- The patient is a male with hypogonadism (primary or secondary) as confirmed by a low for age serum testosterone level defined by the normal laboratory reference value.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of branded or generic topical and nasal testosterone products for 1.) indications such as athletic enhancement, 2.) contraindicated situations (e.g. male with carcinoma of the breast OR known or suspected carcinoma of the prostate (excluding males with treated and cured prostate cancer), or 3.) for usage not included in the above patient selection criteria to be **investigational.***

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of branded or generic topical and nasal testosterone products in male patients when the patient does not have a low for age serum testosterone level (based on normal laboratory reference levels) when treating hypogonadism (primary or secondary) to be **not medically necessary**.**

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Based on review of available data, the Company considers the use of branded topical and nasal testosterone products (other than Androgel 1.62%), unless there is clinical evidence or patient history that suggests the use of Androgel 1.62% or generic topical testosterone products will be/was ineffective or will/did cause an adverse reaction to the patient, to be **not medically necessary**.**

Background/Overview

Transdermal, nasal, and buccal testosterone replacement products are indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The prescribing information for these drugs defines those patients and/or conditions for which they are indicated:

- 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. These men usually have low serum testosterone concentrations accompanied by gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Secondary hypogonadism (i.e., 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 concentrations without associated elevations in gonadotropins. Appropriate adrenal cortical and thyroid hormone replacement therapy may be necessary in patients with multiple pituitary or hypothalamic abnormalities.

Rationale/Source

Multiple topical testosterone products and a nasal testosterone product are U.S. Food and Drug Administration (FDA)-approved for the treatment of primary or secondary hypogonadism in males. These products are contraindicated in women. They are also contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate (excluding males with treated and cured prostate cancer).

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests Androgel 1.62% or generic topical testosterone products will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using topical or nasal testosterone products other than Androgel 1.62% or generic topical testosterone products for testosterone replacement.

References

1. Express Scripts Prior Authorization Policy. topical testosterone products.8/1/2012
2. Androderm [package insert]. Corona, CA: Watson Pharma, Inc.; August 2010.
3. Testim [package insert]. Norristown, PA: Auxilium Pharmaceuticals, Inc.; September 2009.
4. AndroGel 1% gel [package insert]. North Chicago, IL: Abbott Laboratories; March 2011.
5. Striant buccal system [package insert]. Livingston, NJ: Columbia Laboratories, Inc.; 2003.
6. Axiron solution [package insert]. Indianapolis, IN: Lilly USA; November 2010.
7. Foresta gel for topical use [package insert]. Chadds Ford, PA: Endo Pharmaceuticals; April 2011
8. AndroGel 1.62% gel [package insert]. North Chicago, IL: Abbott Laboratories; April 2011

9. Delemarre EM, Felius B, Delemarre-van de Wall HA. Inducing puberty. Eur J Endocrinol. 2008;159:S9-S15.
10. Ambler GR. Androgen therapy for delayed male puberty. Curr Opin Endocrinol Diabetes Obes. 2009;16(3):232-239.
11. Richmond EJ, Rogol AD. Male pubertal development and the role of androgen therapy. Nat Clin Pract Endocrinol Metab. 2007;3(4):338-344.
12. Natesto [package insert]. Malvern, PA. Endo Pharmaceuticals Inc

Policy History

Original Effective Date: 01/09/2013
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01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. New Policy
02/19/2013	Format revision. Coding section removed.
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Added the statement that Axiron or Androgel should be used unless there is clinical evidence or patient history that suggests the use of Axiron or Androgel will be/was ineffective or will/did cause an adverse reaction to the patient.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Added Nasal products to the policy. Title change.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. No change to coverage.
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Criteria changed to prefer Androgel 1.62% or generic products. Removed the indication of delayed puberty.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2019

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.