



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Topical Testosterone Products

Policy # 00335

Original Effective Date: 01/09/2013

Current Effective Date: 01/15/2014

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, topical 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), and Testim[®] ‡ (testosterone gel) may be considered **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria:

Coverage eligibility will be considered for topical testosterone products when one of the following criteria is met:

- 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 values; or
- The patient is a male of at least 12 years of age and the patient has delayed puberty or requires induction of puberty.

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 topical 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 topical 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) or if the male patient is not at least 12 years of age when using these drugs to induce puberty or treat delayed puberty to be **not medically necessary**.**

Background/Overview

Transdermal 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.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 1 of 3



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Topical Testosterone Products

Policy # 00335

Original Effective Date: 01/09/2013

Current Effective Date: 01/15/2014

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.

There is also evidence for usage in delayed puberty or for the induction of puberty in males aged 12 years of age or older.

Rationale/Source

Multiple topical testosterone products are FDA approved for the treatment of primary or secondary hypogonadism in males. There is evidence for usage in delayed puberty or for the induction of puberty in males aged 12 years of age or older. 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). Patient selection criteria are based on information collected in a review of the available data.

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. Fortesta 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, Feliuss 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.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Topical Testosterone Products

Policy # 00335

Original Effective Date: 01/09/2013

Current Effective Date: 01/15/2014

Policy History

Original Effective Date: 01/09/2013

Current Effective Date: 01/15/2014

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.

Next Scheduled Review Date: 01/2015

*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.