

## Pharmacy Policy Bulletin

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<b>Title:</b>	Androgens
<b>Policy #:</b>	Rx.01.4

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▶ **Intent:**

The intent of this policy is to communicate the medical necessity criteria for Androgel, Axiron, Androderm, Fortesta, Natesto, Striant, Testim, Vogelxo and generic testosterone products as provided under the member's pharmacy benefit.

### ▶ **Description:**

Male hypogonadism is characterized by low testosterone levels. Primary hypogonadism is characterized by low testosterone levels in the setting of elevated luteinizing hormone (LH) and follicle-stimulating hormone (FSH) concentrations. Examples of primary hypogonadism include, but are not limited to, Klinefelter syndrome, castration (physical or chemical), and trauma. Secondary hypogonadism, also referred to as hypogonadotropic hypogonadism, is characterized by low testosterone levels in the setting of normal or low LH and FSH. In this type of hypogonadism, dysfunction of the hypothalamus or pituitary is the underlying etiology. Examples of hypogonadotropic hypogonadism include, but are not limited to, idiopathic hypogonadotropic hypogonadism, Kallman syndrome, and pituitary tumors, surgery, or destruction.

The active ingredient in all products listed is testosterone. Exogenous testosterone serves to replace testosterone in individuals who are deficient. Testosterone therapy is indicated for replacement therapy in patients with low testosterone levels due to primary hypogonadism or hypogonadotropic hypogonadism.

### ▶ **Policy:**

Androgel, Axiron, generic transdermal testosterone products, Androderm, Fortesta, Natesto, Striant, Testim, and Vogelxo are approved when ALL of the following are met:

1. Diagnosis of primary or secondary hypogonadism
2. Documentation of ONE of the following:
  - a. Negative history of prostate and breast cancer; OR
  - b. History of prostate cancer status post prostatectomy and documentation that the risk versus benefit has been assessed
3. Inadequate response or inability to tolerate AndroGel (applies to requests for Androderm, Axiron, Fortesta, Natesto, Striant, Testim, and Vogelxo)
4. New users only, BOTH of the following
  - a. Normal prolactin level; and
  - b. Low (morning) testosterone level

▸ **Black Box Warning:**

Transdermal testosterone (AndroGel, Axiron, Fortesta, Testim, Vogelxo)

Secondary exposure: Virilization has been reported in children who were secondarily exposed to transdermal testosterone. Ensure that children avoid contact with unwashed or unclothed application sites in men using transdermal testosterone. Advise patients to strictly adhere to recommended instructions for use.

▸ **Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## **BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▸ **References:**

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**Applicable Drugs:**

**i** Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Androgel	Testosterone
Androderm	Testosterone
Axiron	Testosterone
Fortesta	Testosterone
Natesto	Testosterone
Striant	Testosterone
Testim	Testosterone
Vogelxo	Testosterone

**Cross References:**

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<b>Policy Version Number:</b>	13.00
<b>P&amp;T Approval Date:</b>	January 12, 2017
<b>Policy Effective Date:</b>	April 1, 2017
<b>Next Required Review Date:</b>	July 14, 2017

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