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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	April 11, 2014
Subject:	Testosterone Topical	**Page:**	1 of 8

Last Review Date: September 6, 2024

Testosterone topical

Description

Androderm patch, AndroGel packets and pump, Axiron solution, Fortesta gel, Testim gel, Vogelxo

Background
Endogenous androgens, including testosterone and dihydrotestosterone (DHT), are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics (1).

Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations. Symptoms associated with male hypogonadism include the following: impotence and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics, and osteoporosis (1).

Regulatory Status
FDA-approved indications: For testosterone replacement therapy in men for conditions associated with a deficiency or absence of endogenous testosterone for the following (2-9):

1. Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.

2. 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 testosterone serum concentrations but have gonadotropins in the normal or low range.

Off-Label Use:
Testosterone can be used in the treatment of Gender Dysphoria (GD) and should only be started once a diagnosis of GD or transsexualism has been made per the DSM V or ICD-10 criteria (11).

Topical testosterone includes a boxed warning of secondary exposure. Virilization has been reported in children who were secondarily exposed to transdermal testosterone. Children should avoid contact with unwashed or unclothed application sites in men using transdermal testosterone. Patients should be advised to strictly adhere to recommended instructions for use (2-9).

Male patients, with benign prostatic hyperplasia (BPH), must be monitored for worsening of signs and symptoms of BPH. Physicians should evaluate male patients for the presence of prostate cancer prior to the initiation of therapy. A normal prostate cancer risk is a PSA level that is less than 4 ng/ml. High prostate cancer risk patients, such as African American men and men whose father or brother had prostate cancer, should have a PSA less than 3 ng/ml. Patients should be re-evaluated 12 months after initiation of treatment, and then in accordance with prostate cancer screening practices (2-9).

Two total testosterone levels are required to determine medical necessity of testosterone replacement. Two morning samples drawn between 8:00 a.m. and 10:00 a.m. obtained on different days are required. Total testosterone levels need to below 300 ng/dL on both days in order to be considered for therapy (12).

Hematocrit levels must be less than 54% prior to initiation of testosterone therapy and reevaluated annually thereafter (2-9).

Patients with severe obstructive sleep apnea and severe lower urinary tract symptoms are recommended not to use androgen therapy due to possible worsening of symptoms and/or even death (2).

Extreme caution should be used in patients with history of cardiovascular disease (2).

Safety and efficacy of transdermal testosterone in patients younger than 18 years have not been established. Improper use may result in acceleration of bone age and premature closure of epiphyses (2-9).

Related policies
Testosterone injectable / implant, Testosterone oral / buccal / nasal, Testosterone powder

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Androderm patch, AndroGel gel, AndroGel pump, Axiron solution, Fortesta gel, Testim gel, or Vogelxo gel may be considered **medically necessary** if the conditions indicated below are met.

Androderm patch, AndroGel gel, AndroGel pump, Axiron solution, Fortesta gel, Testim gel or Vogelxo gel may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older
Gender Male

Diagnosis

Patient must have the following:

Deficiency of testosterone (hypogonadism)

AND ALL of the following:

1. Two morning total testosterone levels less than 300 ng/dL on different days
2. Patients over 40 years of age must have baseline prostate specific antigen (PSA) less than 4 ng/ml
    a. Prostatectomy patients excluded from this requirement
3. Absence of current prostate cancer / palpable prostate nodules
4. Hematocrit less than 54%
5. If concurrent diagnosis of benign prostatic hypertrophy (BPH), then patient will be monitored for worsening symptoms
6. Evaluation of cardiovascular risk for MI (myocardial infarction), angina, stroke

7. Absence of un-treated sleep apnea
8. **NO** dual therapy with another testosterone product

Diagnosis

Patient must have the following:

Gender Dysphoria (GD)

1. Female to male transition
2. **NO** dual therapy with another testosterone product

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Gender Male

Diagnosis

Patient must have the following:

Deficiency of testosterone (hypogonadism)

AND ALL of the following:

1. Total testosterone levels of 800 ng/dL or less
2. Absence of worsening effects of benign prostatic hypertrophy (BPH), if present
3. Re-evaluation of cardiovascular risk for MI (myocardial infarction), angina, stroke
4. **NO** dual therapy with another testosterone product

AND confirmation that the following will be monitored every 12 months:

1. Serum testosterone concentrations
2. Prostate specific antigen (PSA) for patients over 40 years of age
    a. Prostatectomy patients excluded from the requirement
3. Hematocrit levels

Diagnosis

Patient must have the following:

Gender Dysphoria (GD)

1. Female to male transition
2. **NO** dual therapy with another testosterone product

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Testosterone Product	Quantity	Days Supply
Androderm 2mg patches	180	90
Androderm 4mg patches	180	90
Any combination of Androderm that does not exceed 8 mg/day		
Androgel 1% 25mg packets	360 (12 boxes)	90
Androgel 1% 50mg packets	180 (6 boxes)	90
Androgel 1.62% 20.25mg packets	360 (12 boxes)	90
Androgel 1.62% 40.5mg packets	180 (6 boxes)	90
Androgel 1% pump	12 bottles	90
Androgel 1.62% pump	6 bottles	90
Axiron 30mg/1.5mL solution	6 bottles	90
Fortesta pump	6 bottles	90
Testim	180 tubes (6 cartons)	90
Vogelxo 1% 50mg packets	180 (6 boxes)	90
Vogelxo 1% 50mg tubes	180 (6 boxes)	90
Vogelxo 1% 1.25g pump	12 bottles	90

Duration 6 months for all diagnoses except GD
2 years for GD

Prior – Approval *Renewal* Limits

Quantity

Testosterone Product	Quantity	Days Supply
Androderm 2mg patches	180	90
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Any combination of Androderm that does not exceed 8 mg/day		
Androgel 1% 25mg packets	360 (12 boxes)	90
Androgel 1% 50mg packets	180 (6 boxes)	90
Androgel 1.62% 20.25mg packets	360 (12 boxes)	90
Androgel 1.62% 40.5mg packets	180 (6 boxes)	90
Androgel 1% pump	12 bottles	90
Androgel 1.62% pump	6 bottles	90
Axiron 30mg/1.5mL solution	6 bottles	90
Fortesta pump	6 bottles	90
Testim	180 tubes (6 cartons)	90
Vogelxo 1% 50mg packets	180 (6 boxes)	90
Vogelxo 1% 50mg tubes	180 (6 boxes)	90
Vogelxo 1% 1.25g pump	12 bottles	90

Duration 12 months for all diagnoses except GD
2 years for GD

Rationale

Summary

Topical testosterone is approved for testosterone replacement therapy in men for conditions associated with a deficiency of testosterone such as: hypogonadotropic hypogonadism (congenital or acquired), and primary hypogonadism (congenital or acquired). The following should be monitored: prostate-specific antigen (PSA) levels, serum testosterone concentrations, hematocrit, presence of prostate cancer, and worsening effects of benign prostatic hypertrophy (BPH), if present and been assessed for their cardiovascular risk. Safety and efficacy of testosterone transdermal in patients younger than 18 years have not been established (2-12).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of the topical testosterone products Androderm patch, AndroGel packets and pump, Axiron solution, Fortesta gel, Testim gel, and Vogelxo gel while maintaining optimal therapeutic outcomes.

References

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Policy History

Date	Action
March 2014	Addition to PA
March 2014	Annual Review
June 2014	Revision of testosterone levels for continuation and addition of Vogelxo to PA program. Removal of absence of severe sleep apnea, severe lower urinary tract symptoms and addition of hematocrit level of 54%
August 2014	Revision of diagnosis for male patients 18 years or older to deficiency of testosterone/hypogonadism. Revision of renewal duration to 12 months.
December 2014	Change for patients over 40 years of age must have baseline PSA less than 4 ng/ml and prostatectomy patients excluded from the requirement
March 2015	Annual review and reference update.
April 2015	Addition of assessment of cardiovascular risk to criteria and Androderm quantity change from 90/90 to 180/90

June 2015	Annual review Addition of the evaluation of cardiovascular risk for MI, angina, stroke and absence of un-treated sleep apnea and no dual therapy with another testosterone product. Also clarify Androderm so any combination that does not exceed 8 mg /day
December 2015	Annual review Addition of Gender Dysphoria (GD) and duration
May 2016	Addition of transgender specialist to GD prescriber requirement Policy number change from 5.08.31 to 5.30.31
June 2016	Annual review
September 2016	Annual editorial review and reference update
January 2017	Removal of First Testosterone and First Testosterone MC and removal of GD age requirements
March 2017	Annual Review
December 2017	Annual editorial review and reference update Addition of age and gender requirement in continuation section
November 2018	Annual editorial review and reference update
March 2019	Annual review and reference update
July 2019	Changed approval duration for gender dysphoria from lifetime to 2 years
September 2019	Annual review
December 2020	Annual review and reference update
December 2021	Annual editorial review and reference update
September 2022	Annual review
December 2022	Annual review. Removed GD requirements of meeting DSM criteria and being prescribed by an endocrinologist or transgender specialist
September 2023	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.