

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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## Androgens

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Varies upon diagnosis

Medication	Strengths	Quantity Limit	Comments
Androderm (testosterone patch)	2 mg patch	1 patch per day	Non-Preferred
	2.5 mg patch	2 patches per day	
	4 mg patch	1 patch per day	
	5 mg patch	1 patch per day	
AndroGel (testosterone gel)	1% (2.5 g) packet	2 packets per day	Non-Preferred
	1% (5 g) packet	1 packet per day	Non-Preferred
	1% pump	2 pump bottles per 30 days	Non-Preferred
	1.62% pump	1 pump bottle per 30 days	Non-Preferred
	1.62% (1.25 g) packet	1 packet per day	Non-Preferred
	1.62% (2.5 g) packet	1 packet per day	Non-Preferred
Generic Androgel (testosterone gel 1%)	1% (2.5 g) packet	2 packets per day	Preferred
	1% (5 g) packet	1 packet per day	Preferred
Androxy (fluoxymesterone)	10mg tablets	N/A	N/A
Axiron (testosterone solution)	Topical solution (30 mg per actuation)	1 bottle per 30 days	Non-Preferred

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Fortesta (testosterone gel)	Gel pump (10 mg per actuation)	1 pump bottle per 30 days	Non-Preferred
Methyltestosterone (Android, Methitest, Testred)	10mg capsules and tablets	N/A	N/A
Natesto (testosterone nasal gel)	5.5mg/0.122g (60 actuations per bottle)	3 metered dose pumps per 30 days	Non-Preferred
Striant (testosterone buccal)	30 mg mucoadhesive (buccal system)	2 buccal systems per day	Non-Preferred
Testim (testosterone gel)	1% gel	1 tube per day	Non-Preferred
Testosterone gel	25 mg/2.5 g packet	2 packets per day	Preferred
	50 mg/5 g packet	1 packet per day	
	50 mg/5 g tube	1 tube per day	
Testosterone 1% gel	12.5 mg/1.25 g pump	2 pump bottles per 30 days	Preferred
Testosterone gel pump	Gel Pump (10 mg per actuation) 120 pumps per bottle	1 pump bottle per 30 days	Non-Preferred
Testosterone solution (generic Axiron)	Topical solution (30 mg per actuation)	1 bottle per 30 days	Non-Preferred
Vogelxo gel	50 mg/5 g packet	1 packet per day	Non-Preferred

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	50 mg/5 g tube	1 tube per day	
	1 % (12.5 mg/1.25 g) pump (60 pumps per bottle)	2 pump bottles per 30 days	

## APPROVAL CRITERIA

Requests for non-preferred topical testosterone agents may be approved based on the following criteria, in addition to the prior authorization criteria below:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response to one preferred topical testosterone agent.

Preferred topical testosterone agents: AB1-rated testosterone gel 1% (generic AndroGel 1%, for example Actavis Pharma, Par Pharmaceutical, Perrigo Pharmaceuticals, Prasco Labs, Upsher-Smith LA), non-AB1-rated testosterone gel 1% (Single Source Brand testosterone 1% gel).

Non-preferred topical testosterone agents: Androderm, AndroGel 1% (brand), AndroGel 1.62% (brand and generic), Axiron, testosterone solution (generic Axiron), Fortesta, Natesto, Striant, Testim, testosterone 10 mg gel pump, Vogelxo.

## Prior Authorization

Requests for all topical testosterone agents (preferred and non-preferred) must meet the following criteria:

- I. Initial requests for androgen agents for replacement therapy in the treatment of hypogonadism may be approved if the following criteria are met:
  - A. Individual is male; **AND**
  - B. Individual is 18 years of age or older; **AND**
  - C. Individual has a diagnosis of one of the following:
    1. Primary hypogonadism (defined in males as low testosterone due to primary

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testicular failure [originating from a problem in the testicles]; congenital or acquired), (for example, bilateral torsion, cryptorchidism, chemotherapy, Klienfelter Syndrome, orchitis, orchiectomy, toxic damage from alcohol or heavy metals, vanishing testis syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]);

**OR**

2. Hypogonadotropic hypogonadism, also called secondary hypogonadism (defined in males as low testosterone originating from a problem in the hypothalamus or pituitary gland; congenital or acquired), (for example, idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, pituitary-hypothalamic injury);

**AND**

- D. Prior to starting therapy ,an initial and a repeat (at least 24 hours apart) morning total testosterone level is provided to confirm a low testosterone serum level indicating the following:
  1. Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; **OR**
  2. Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL;

**AND**

- E. Individual presents with symptoms associated with hypogonadism, such as but not limited to the following:
  1. Reduced sexual desire (libido) and activity; **OR**
  2. Decreased spontaneous erections; **OR**
  3. Breast discomfort/gynecomastia; **OR**
  4. Loss of body (axillary and pubic) hair, reduced shaving; **OR**
  5. Very small (especially less than 5 mL) or shrinking testes; **OR**
  6. Inability to father children or low/zero sperm count; **OR**
  7. Height loss, low trauma fracture, low bone mineral density; **OR**
  8. Hot flushes, sweats; **OR**
  9. Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.

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Requests for continuation of therapy with androgen agents for replacement therapy in the treatment of hypogonadism may be approved if the following criteria are met:

- I. Individual met all diagnostic criteria for initial therapy; **AND**
- II. Individual has had serum testosterone level measured in the previous 180 days; **AND**
- III. Individual has obtained clinical benefits as noted by symptom improvement.

Androgens agents for the treatment of hypogonadism may **not** be approved for the following:

- I. Untreated obstructive sleep apnea (OSA); **OR**
- II. Polycythemia as defined by hematocrit greater than 48% and 50% for men living at higher altitudes (Bhasin et al, 2018); **OR**
- III. Severe congestive heart failure (CHF); **OR**
- IV. Known, suspected, or history of prostate cancer unless individual has undergone radical prostatectomy, prostate cancer was organ-confined, has been disease free for two (2) years and has an undetectable prostate-specific antigen (PSA) level (such as <0.1 ng/dL).

**Coverage duration:** 1 year

FDA-approved products: fluoxymesterone (Androxy), methyltestosterone (Android, Methitest, Testred), testosterone gel (AndroGel/AndroGel Pump, Fortesta, Testim, Testosterone Gel tube/packet, Testosterone Pump, Vogelxo), transdermal testosterone (Androderm), testosterone buccal tablets (Striant), testosterone solution (Axiron), testosterone nasal gel (Natesto).

Requests for testosterone agents for transgender individuals may be approved if the following criteria are met:

- I. Individual is 16 years of age or older; **AND**
- II. Individual has a diagnosis of gender dysphoria or gender identity disorder; **AND**
- III. The goal of treatment is female-to-male gender reassignment.

**Coverage duration:** 1 year

Appropriate agents: Testosterone gel (AndroGel/AndroGel Pump, Fortesta, Testim, Vogelxo, Testosterone Gel tube/packet, Testosterone Pump), transdermal testosterone (Androderm),

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testosterone buccal tablets (Striant), testosterone solution (Axiron), testosterone nasal gel (Natesto) (Endocrine Society, 2009).

Requests for androgen agents for the treatment of breast cancer may be approved if the following criteria are met:

- I. Individual is a female who is 1-5 years post-menopausal; **AND**
- II. Individual is using secondarily for advancing inoperable metastatic (skeletal) breast cancer;

**OR**

- III. Individual is a postmenopausal woman with breast cancer who has benefited from oophorectomy and is considered to have a hormone responsive tumor

**Coverage duration:** 1 year

FDA-approved products: fluoxymesterone (Androxy), methyltestosterone (Android/Methitest/Testred)

Requests androgen agents for the treatment of delayed puberty may be approved if the following criteria are met:

- I. Individual is a male age 14 years of age or older; **AND**
- II. Individual is using to stimulate puberty; **AND**
- III. Documentation is provided indicating few to no signs of puberty.

**Coverage duration:** 6 months; for continuation of therapy documentation of bone age and effects of treatment on epiphyseal growth centers must be provided at time of request.

FDA-approved products: fluoxymesterone (Androxy), methyltestosterone (Android/Methitest/Testred). (see **NOTES** 1 and 2)

**Notes:**

1. Testosterone gel and transdermal testosterone have not been evaluated clinically in males younger than 18 years of age
2. Androgens may be used to stimulate puberty in carefully selected males. In males with clearly delayed puberty, brief treatment with conservative doses of testosterone may occasionally be justified.

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3. Testosterone topical gel (AndroGel, Axiron, Fortesta, Testosterone gel, Vogelxo, and Testim) has a black box warning for secondary exposure to testosterone due to direct skin contact. Virilization has been reported in children who were secondarily exposed to testosterone gel. Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel.

Requests for quantities greater than the allowed limits may be approvable under the following criteria for each medication:

I. **Natesto (testosterone nasal gel)**

A. 5.5 mg/0.122 g

1. Other diagnoses or greater quantities will be sent for physician review.

II. **Testosterone (testosterone gel)**

A. 1% 25 mg/2.5 g packet

1. #90 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 2 packets per day.
2. Renewal of #90 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

A.

B. 50 mg/5 g packet

1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

C. 50 mg/5 g tube

1. #60 of the tubes per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 tube per day.
2. Renewal of #60 tubes per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

D. 1% Pump

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1. Up to #8 pumps per day (4 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
  2. Renewal of #8 pumps per day (4 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.
- E. 10 mg/actuation Pump
1. #120 g (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
  2. Renewal of #120 g (2 bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.

### III. Testosterone (Testosterone solution)

#### A. 30 mg/actuation solution

1. #180 mL (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #2 pumps per day.
2. Renewal of #180 mL (2 bottles) per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

### IV. Vogelxo (testosterone gel)

#### A. 50 mg/5 g packet

1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

#### B. 50 mg/5 g tube

1. #60 of the tubes per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 tube per day.

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2. Renewal of #60 tubes per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

C. 1% Pump

1. Up to #8 pumps per day (4 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
2. Renewal of #8 pumps per day (4 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

V. **Androderm (testosterone transdermal system)**

A. 2 mg and 4 mg

1. #30 of the 2mg **AND** #30 of the 4mg patches per 30 days may be approved for a total of 6 mg daily, if the serum testosterone is below normal range after at least 30 days of therapy on lower dose.
2. Renewal of #30 of the 2mg **AND** #30 of the 4mg patches per 30 days may be approved for a total of 6 mg daily may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

B. 2.5 mg

1. #90 transdermal patches per 30 days may be approved if the serum testosterone is below normal range while on 5mg daily.
2. Renewal of #90 transdermal patches per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

VI. **AndroGel (testosterone gel)**

A. 1% 2.5 gm – Includes Generic Androgel (AB1-rated testosterone gel 1%) as well

1. #90 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 2 packets per day.
2. Renewal of #90 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.

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3. Other diagnoses or greater quantities will be sent for physician review.
- B. 1% 5 gm – Includes Generic Androgel (AB1-rated testosterone gel 1%) as well
  1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
  2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.
- C. 1% Pump
  1. Up to #8 pumps per day (4 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
  2. Renewal of #8 pumps per day (4 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.
- D. 1.62% 1.25 gm
  1. #90 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
  2. Renewal of #90 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.
- E. 1.62% 2.5 gm
  1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
  2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.
- F. 1.62% Pump
  1. Up to #4 pumps per day (2 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #2 pumps per day.
  2. Renewal of #4 pumps per day (2 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
  3. Other diagnoses or greater quantities will be sent for physician review.

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**VII. Testim (testosterone gel)**

A. 5 gm

- #60 tubes per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 tube per day.
- Renewal of #60 tubes per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
- Other diagnoses or greater quantities will be sent for physician review.

**VIII. Axiron (testosterone solution)**

A. 30 mg/actuation solution

- #180 mL (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #2 pumps per day.
- Renewal of #180 mL (2 bottles) per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
- Other diagnoses or greater quantities will be sent for physician review.

**IX. Fortesta (testosterone gel)**

A. 10 mg/actuation gel

- #120 g (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
- Renewal of #120 g (2 bottles) per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
- Other diagnoses or greater quantities will be sent for physician review.

**X. Striant (testosterone buccal)**

A. 30 mg buccal system

- Other diagnoses or greater quantities will be sent for physician review

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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