### Market Applicability/Effective Date

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## Androgens

### Override(s)
- Prior Authorization
- Quantity Limit

<table>
<thead>
<tr>
<th>Approval Duration</th>
<th>Varies upon diagnosis</th>
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### Medication

<table>
<thead>
<tr>
<th>Medication</th>
<th>Strengths</th>
<th>Quantity Limit</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Androderm (testosterone patch)</td>
<td>2 mg patch</td>
<td>1 patch per day</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td></td>
<td>2.5 mg patch</td>
<td>2 patches per day</td>
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<tr>
<td></td>
<td>4 mg patch</td>
<td>1 patch per day</td>
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<tr>
<td></td>
<td>5 mg patch</td>
<td>1 patch per day</td>
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</tr>
<tr>
<td>AndroGel (testosterone gel)</td>
<td>1% (2.5 g) packet</td>
<td>2 packets per day</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td></td>
<td>1% (5 g) packet</td>
<td>1 packet per day</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td></td>
<td>1% pump</td>
<td>2 pump bottles per 30 days</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td></td>
<td>1.62% pump</td>
<td>1 pump bottle per 30 days</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td></td>
<td>1.62% (1.25 g) packet</td>
<td>1 packet per day</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td></td>
<td>1.62% (2.5 g) packet</td>
<td>1 packet per day</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td>Generic Androgel (testosterone gel 1%)</td>
<td>1% (2.5 g) packet</td>
<td>2 packets per day</td>
<td>Preferred</td>
</tr>
<tr>
<td></td>
<td>1% (5 g) packet</td>
<td>1 packet per day</td>
<td>Preferred</td>
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<tr>
<td>Androxy (fluoxymesterone)</td>
<td>10mg tablets</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Axiron (testosterone solution)</td>
<td>Topical solution (30 mg per actuation)</td>
<td>1 bottle per 30 days</td>
<td>Non-Preferred</td>
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<tr>
<td>First-Testosterone (testosterone ointment)</td>
<td>2% compounding kit</td>
<td>N/A</td>
<td>N/A</td>
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<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Description</th>
<th>Dosage</th>
<th>Formulation</th>
<th>Applicable Markets</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>First-Testosterone MC (testosterone cream)</td>
<td>2% compounding kit</td>
<td>N/A</td>
<td>N/A</td>
<td>FL, GA, KS, KY, LA, MD, NJ</td>
<td>N/A</td>
</tr>
<tr>
<td>Fortesta (testosterone gel)</td>
<td>Gel pump (10 mg per actuation)</td>
<td>1 pump bottle per 30 days</td>
<td>Non-Preferred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methyltestosterone (Android, Methitest, Testred)</td>
<td>10mg capsules and tablets</td>
<td>N/A</td>
<td>N/A</td>
<td>FL, GA, KS, KY, LA, MD, NJ, NY</td>
<td>Non-Preferred</td>
</tr>
<tr>
<td>Natesto (testosterone nasal gel)</td>
<td>5.5mg/0.122g (60 actuations per bottle)</td>
<td>3 metered dose pumps per 30 days</td>
<td>Non-Preferred</td>
<td></td>
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<tr>
<td>Striant (testosterone buccal)</td>
<td>30 mg mucoadhesive (buccal system)</td>
<td>2 buccal systems per day</td>
<td>Non-Preferred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testim (testosterone gel)</td>
<td>1% gel</td>
<td>1 tube per day</td>
<td>Non-Preferred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testosterone gel</td>
<td>25 mg/2.5 g packet</td>
<td>2 packets per day</td>
<td>Preferred</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>50 mg/5 g packet</td>
<td>1 packet per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>50 mg/5 g tube</td>
<td>1 tube per day</td>
<td></td>
<td></td>
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<tr>
<td>Testosterone 1% gel</td>
<td>12.5 mg/1.25 g pump</td>
<td>2 pump bottles per 30 days</td>
<td>Preferred</td>
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<tr>
<td>Testosterone gel pump</td>
<td>Gel Pump (10 mg per actuation) 120 pumps per bottle</td>
<td>1 pump bottle per 30 days</td>
<td>Preferred</td>
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<tr>
<td>Vogelxo gel Non-Preferred</td>
<td>50 mg/5 g packet</td>
<td>1 packet per day</td>
<td>Non-Preferred</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>50 mg/5 g tube</td>
<td>1 tube per day</td>
<td></td>
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**APPROVAL CRITERIA**

Requests for non-preferred topical testosterone agents may be approved based on the following criteria:

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 Par Pharmaceutical, Actavis Pharma, Perrigo Pharmaceuticals), non-AB1-rated testosterone gel 1% (Single Source Brand testosterone 1% gel)

Non-preferred topical testosterone agents: AndroGel 1% (brand), Fortesta, Natesto, Axiron, Testim, Androderm, Striant, AndroGel 1.62%, Vogelxo

**AND**

Initial requests for androgen agents for replacement therapy in the treatment of hypogonadism may be approved if the following criteria are met:

I. Individual is male; **AND**

II. Individual is 18 years of age or older; **AND**

III. Individual has a diagnosis of one of the following:

1. Primary hypogonadism (congenital or acquired), such as but not limited to:
   a. Cryptorchidism; **OR**
   b. Bilateral torsion; **OR**
   c. Orchitis; **OR**
   d. Vanishing testis syndrome; **OR**
   e. Orchiectomy; **OR**
   f. Klinefelter Syndrome; **OR**
   g. Chemotherapy; **OR**
   h. Toxic damage from alcohol or heavy metals; **OR**
   i. Idiopathic primary hypogonadism;

   **OR**

2. Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to:
   a. Idiopathic luteinizing hormone-releasing hormone (LHRH) deficiency; **OR**
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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 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 50% (Bhasin et al, 2010); OR
III. Severe congestive heart failure (CHF); OR

b. Pituitary-hypothalamic injury;

AND

IV. For individuals beginning treatment:
   1. 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;
      a. Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; OR
      b. Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL;

   AND

   2. Individual presents with symptoms associated with hypogonadism, such as but not limited to the following:
      a. Reduced sexual desire (libido) and activity; OR
      b. Decreased spontaneous erections; OR
      c. Breast discomfort/gynecomastia; OR
      d. Loss of body (axillary and pubic) hair, reduced shaving; OR
      e. Very small (especially less than 5 mL) or shrinking testes; OR
      f. Inability to father children or low/zero sperm count; OR
      g. Height loss, low trauma fracture, low bone mineral density; OR
      h. Hot flushes, sweats; OR
      i. Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.
**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 ointment (First-Testosterone), testosterone cream (First-Testosterone MC), 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), 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

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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
      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. **Vogelxo (testosterone gel)**

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V. **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.
      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

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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.

### VI. Testim (testosterone gel)

a. 5 gm
   1. #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.
   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.

### VII. Axiron (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.

### VIII. Fortesta (testosterone gel)

a. 10 mg/actuation gel
   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.

### IX. Striant (testosterone buccal)

a. 30 mg buccal system
   1. Other diagnoses or greater quantities will be sent for physician review
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