<table>
<thead>
<tr>
<th>Medication</th>
<th>Strengths</th>
<th>Quantity Limit</th>
<th>Comments</th>
</tr>
</thead>
<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>
<td></td>
</tr>
<tr>
<td></td>
<td>4 mg patch</td>
<td>1 patch per day</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 mg patch</td>
<td>1 patch per day</td>
<td></td>
</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>
</tr>
<tr>
<td>Androxy (fluoxymesterone)</td>
<td>10mg tablets</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<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>
</tr>
<tr>
<td>First-Testosterone (testosterone ointment)</td>
<td>2% compounding kit</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>First-Testosterone MC (testosterone cream)</td>
<td>2% compounding kit</td>
<td>N/A</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>
</tr>
<tr>
<td>Methyltestosterone (Android, Methitest, Testred)</td>
<td>10mg capsules and tablets</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
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:
   A. Primary hypogonadism (congenital or acquired), such as but not limited to:
      1. Cryptorchidism; **OR**
      2. Bilateral torsion; **OR**
      3. Orchitis; **OR**
      4. Vanishing testis syndrome; **OR**
      5. Orchiectomy; **OR**
      6. Klinefelter Syndrome; **OR**
      7. Chemotherapy; **OR**
      8. Toxic damage from alcohol or heavy metals; **OR**
      9. Idiopathic primary hypogonadism;

   **OR**

   B. Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to:
      1. Idiopathic luteinizing hormone-releasing hormone (LHRH) deficiency; **OR**
      2. Pituitary-hypothalamic injury;

**AND**

IV. For individuals beginning treatment:
   A. 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**

   B. 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 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**
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 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**

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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.
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)

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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.
      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.
### Market Applicability/Effective Date

| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|---------|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | X |

*FHK- Florida Healthy Kids

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| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|--------|---------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | N/A | N/A | X | N/A | X | X | X | X | X | X | N/A | N/A | X |

*FHK- Florida Healthy Kids

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.

VII. 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.

VIII. 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.

IX. 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.

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