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.
CRX-ALL-0226-18
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.
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.
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:

1. Individual is 16 years of age or older; **AND**
2. Individual has a diagnosis of gender dysphoria or gender identity disorder; **AND**
3. 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:

1. Individual is a female who is 1-5 years post-menopausal; **AND**
2. Individual is using secondarily for advancing inoperable metastatic (skeletal) breast cancer; **OR**
3. 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:

1. Individual is a male age 14 years of age or older; **AND**
2. Individual is using to stimulate puberty; **AND**

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.
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.

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
I. Testosterone gel and transdermal testosterone have not been evaluated clinically in males younger than 18 years of age
II. 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.
III. 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 that 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.
   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

---

**Market Applicability/Effective Date**

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

*FHK- Florida Healthy Kids*
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.
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.
### Market Applicability/Effective Date

<table>
<thead>
<tr>
<th>Market</th>
<th>DC</th>
<th>FL &amp; FHK</th>
<th>FL MMA</th>
<th>FL LTC</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
<th>LA</th>
<th>MD</th>
<th>NJ</th>
<th>NV</th>
<th>NY</th>
<th>TN</th>
<th>TX</th>
<th>WA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
<td>X</td>
<td>N/A</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
<td>NA</td>
</tr>
</tbody>
</table>

*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.

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.

### VII. Testim (testosterone gel)

A. 5 gm

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.
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.

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.

X. **Striant (testosterone buccal)**
   A. 30 mg buccal system
   1. Other diagnoses or greater quantities will be sent for physician review

---

**State Specific Mandates**

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Key References:**


DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.