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### Market Applicability

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<td><strong>Applicable</strong></td>
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- **Jatenzo (oral testosterone undecanoate)**
  - Dosage: 158 mg, 198 mg capsules
  - Quantity: 4 capsules per day
  - Form: Non-Preferred

- **Methyltestosterone (Android, Methitest, Testred)**
  - Dosage: 237 mg capsules
  - Quantity: 2 capsules per day
  - Form: Non-Preferred

- **Natesto (testosterone nasal gel)**
  - Dosage: 5.5mg/0.122g (60 actuations per bottle)
  - Quantity: 3 metered dose pumps per 30 days
  - Form: Non-Preferred

- **Striant (testosterone buccal)**
  - Dosage: 30 mg mucoadhesive (buccal system)
  - Quantity: 2 buccal systems per day
  - Form: Non-Preferred

- **Testim (testosterone gel)**
  - Dosage: 1% gel
  - Quantity: 1 tube per day
  - Form: Non-Preferred

- **Testosterone gel**
  - Dosage: 25 mg/2.5 g packet
  - Quantity: 2 packets per day
  - Form: Preferred

  - Dosage: 50 mg/5 g packet
  - Quantity: 1 packet per day

  - Dosage: 50 mg/5 g tube
  - Quantity: 1 tube per day

- **Testosterone 1% gel**
  - Dosage: 12.5 mg/1.25 g pump
  - Quantity: 2 pump bottles per 30 days
  - Form: Preferred

- **Testosterone gel pump (generic Fortesta)**
  - Dosage: Gel Pump (10 mg per actuation) 120 pumps per bottle
  - Quantity: 1 pump bottle per 30 days
  - Form: Non-Preferred

- **Testosterone solution (generic Axiron)**
  - Dosage: Topical solution (30 mg per actuation)
  - Quantity: 1 bottle per 30 days
  - Form: Non-Preferred

- **Vogelxo gel**
  - Dosage: 50 mg/5 g packet
  - Quantity: 1 packet per day

  - Dosage: 50 mg/5 g tube
  - Quantity: 1 tube per day

  - Dosage: 1% (12.5 mg/1.25 g) pump (60 pumps per bottle)
  - Quantity: 2 pump bottles per 30 days
  - Form: Non-Preferred

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*Product discontinued

§Limited to 30 days’ supply per benefit

†Non-preferred but not subject to step therapy through preferred oral/topical testosterone agent

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**Limitations indicates FDA recommended maximum daily dose of 396mg (two 198 mg capsules) twice daily for treatment of hypogonadism.**

**APPROVAL CRITERIA**

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

1. 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:** testosterone gel 1% (generic AndroGel 1%)

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

**Prior Authorization**

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

1. 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 testicular failure [originating from a problem in the testicles]; congenital or acquired), (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefelter 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. Hypogonadotrophic 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);

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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. Confirmation is provided indicating few to no signs of puberty.

**Coverage duration**: 6 months; for continuation of therapy confirmation 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).

**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.
4. Jatenzo has a black box warning regarding possible blood pressure increases that can lead to major adverse cardiovascular events (MACE). Prior to initiation, baseline cardiovascular risk should be assessed and blood pressure should be adequately controlled. New onset hypertension or exacerbation of existing hypertension should be cause for re-evaluation of risk versus benefit for continuation of therapy. Due to this risk, Jatenzo should only be used for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.

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.

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. **Testosterone** (Testosterone solution)

A. 30 mg/actuation solution

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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.
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.
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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.

X. Striant (testosterone buccal)
A. 30 mg buccal system
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