Testosterone Injectable

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
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Medications

<table>
<thead>
<tr>
<th>Medication</th>
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</thead>
<tbody>
<tr>
<td>Aveed Injection (testosterone undecanoate) 750mg/3mL</td>
</tr>
<tr>
<td>Delatestryl Injection (testosterone enanthate) 200mg/mL</td>
</tr>
<tr>
<td>Depo-Testosterone Injection (testosterone cypionate) 100mg/mL, 200mg/mL</td>
</tr>
<tr>
<td>Xyosted Injection (testosterone enanthate) 50mg/0.5mL, 75mg/0.5mL, 100mg/0.5mL</td>
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APPROVAL CRITERIA

Testosterone injections for Symptomatic Hypogonadism (Primary or Secondary) in Adults:

I. Requests for testosterone injections for initiation of replacement therapy may be approved if the following criteria are met:
   A. Individual is a male; **AND**
   B. Individual is 18 years or older; **AND**
   C. Prior to starting testosterone therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level confirms a low testosterone serum level indicating one of the following (1 or 2):
      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**
   D. Individual has a diagnosis of one of the following (1 or 2):
      A. Primary hypogonadism (congenital or acquired) (for example, bilateral torsion, cryptorchidism, chemotherapy, Klinefelter Syndrome, orchitis, orchietomy, toxic damage from alcohol or heavy metals, Vanishing Testis Syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]); **OR**
### Market Applicability

<table>
<thead>
<tr>
<th>Market</th>
<th>DC</th>
<th>GA</th>
<th>KY</th>
<th>MD</th>
<th>NJ</th>
<th>NY</th>
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<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</table>

B. Hypogonadotropic hypogonadism (congenital or acquired) (for example, idiopathic gonadotropic or luteinizing hormone-releasing hormone (LHRH) deficiency, pituitary- hypothalamic injury); **AND**

E. Individual presents with symptoms associated with hypogonadism, such as, but not limited, to at least **one** of the following (1 through 9):
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 need for 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.

II. Requests for testosterone injections for **continuation of replacement therapy** may be approved if the following criteria are met:
   A. Individual met all diagnostic criteria for initial therapy; **AND**
   B. Individual has had serum testosterone level measured in the previous 180 days; **AND**
   C. Individual has obtained clinical benefits as noted by symptom improvement.

Testosterone injections for **replacement therapy** 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).

**Testosterone injections for delayed puberty:**

I. Requests for **testosterone enanthate** (Delatestryl) injections for treatment of delayed puberty may be approved if the following criteria are met:
   A. Individual is a male 14 years of age or older; **AND**
   B. Individual is using to stimulate puberty; **AND**
   C. Individual has few to no signs of puberty.
Testosterone injections for breast cancer:

I. Requests for **testosterone enanthate** (Delatestryl) **injections for treatment of breast cancer** may be approved for treatment if the following criteria are met:
   A. Female 1-5 years post-menopause; **AND**
   B. Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer;
      **OR**
   C. Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor.

Testosterone injections for HIV-associated weight loss and wasting:

I. Requests for **testosterone enanthate** (Delatestryl) **OR testosterone cypionate** (Depo-Testosterone) **injections for treatment of HIV-associated weight loss and wasting** may be approved if the following criteria are met:
   A. Individual has been diagnosed with low testosterone; **AND**
   B. Individual has HIV-associated weight loss and wasting.

Testosterone injections for transgender individuals:

I. Requests for **testosterone injections for transgender individuals** may be approved if the following criteria are met:
   A. Individual is 16 years of age or older; **AND**
   B. Individual has a diagnosis of gender dysphoria/incongruence or gender identity disorder (DrugDex B, IIa); **AND**
   C. The goal of treatment is female-to-male gender reassignment.

### State Specific Mandates

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

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.

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