PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>TESTOSTERONE PRODUCTS (BRAND AND GENERIC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GENERIC NAME</td>
<td><strong>TESTOSTERONE</strong></td>
</tr>
<tr>
<td>dosage form</td>
<td>enanthate injection</td>
</tr>
<tr>
<td></td>
<td>cypionate injection</td>
</tr>
<tr>
<td></td>
<td>topical gel</td>
</tr>
<tr>
<td></td>
<td>topical cream</td>
</tr>
<tr>
<td></td>
<td>topical ointment</td>
</tr>
<tr>
<td></td>
<td>topical solution</td>
</tr>
<tr>
<td></td>
<td>transdermal patch</td>
</tr>
<tr>
<td></td>
<td>nasal gel</td>
</tr>
<tr>
<td></td>
<td>mucosal gel</td>
</tr>
<tr>
<td></td>
<td>mucoadhesive buccal system</td>
</tr>
<tr>
<td></td>
<td>propionate implant pellets</td>
</tr>
<tr>
<td></td>
<td>powder</td>
</tr>
</tbody>
</table>

**Status:** CVS Caremark Criteria  
**Type:** Initial Prior Authorization

**POLICY**

**FDA-APPROVED INDICATIONS**

Topical, buccal, nasal, implant, and injectable testosterone products are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- **Primary hypogonadism** (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter Syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
- **Hypogonadotropic hypogonadism** (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Safety and efficacy of topical, buccal, nasal, implant, and injectable testosterone products in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Safety and efficacy of topical, buccal, nasal, implant, and injectable testosterone products in males less than 18 years old have not been established.

Topical testosterone products may have different doses, strengths or application instructions that may result in different systemic exposure.

**Delatestryl**  
**Males**

Delatestryl is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

- **Primary hypogonadism** (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.
- **Hypogonadotropic hypogonadism** (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.
Safety and efficacy of Delatestryl in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Delayed puberty - Delatestryl may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Females
Metastatic Mammary Cancer - Delatestryl may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of countering estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in pre-menopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Depo-Testosterone
Depo-Testosterone is indicated for replacement therapy in the male in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome: or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotrophic or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation.

Safety and efficacy of Depo-Testosterone in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Compendial Uses
Gender Dysphoria in Female-to-Male transgender13-14, 17-20

Testopel
Males
Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome: or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotrophic or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testopel (testosterone pellets) in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

COVERAGE CRITERIA
- Testosterone products will be covered with prior authorization when the following criteria are met:
  - The drug is being prescribed for a male patient with congenital or acquired primary hypogonadism (i.e., testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy) OR
  - The drug is being prescribed for a male patient with congenital or acquired hypogonadotropic hypogonadism (i.e., gonadotropin or luteinizing hormone-releasing hormone [LHRH] deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation)

AND
• The patient had or currently has at least two confirmed low testosterone levels according to current practice guidelines or your standard lab reference values

**OR**

- Delatestryl (testosterone enanthate injection) is being prescribed for inoperable metastatic breast cancer in a female patient who is 1 to 5 years postmenopausal AND the patient had an incomplete response to other therapy for metastatic breast cancer

**OR**

- Delatestryl (testosterone enanthate injection) is being prescribed for a pre-menopausal female patient with breast cancer who has benefited from oophorectomy and is considered to have a hormone-responsive tumor

**OR**

- Delatestryl (testosterone enanthate injection) or Testopel (testosterone propionate implant pellets) is being prescribed for delayed puberty in a male patient

**OR**

- The drug is being prescribed for female-to-male gender reassignment in a patient who is 14 years of age or older and able to make an informed, mature decision to engage in therapy

**REFERENCES**