Subcutaneous Hormonal Implants
[Testopel (testosterone pellets)]

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
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<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
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**Medications**
- Testopel (testosterone pellets) for subcutaneous implantation
- Estrogen and estrogen containing combination subcutaneous implanted agents*

**APPROVAL CRITERIA**

Requests for Testopel (subcutaneous testosterone implants) for hormone replacement therapy may be approved if the following criteria are met:

I. Individual is male; **AND**

II. Individual is 18 years of age or older; **AND**

III. 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:
   A. Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; **OR**
   B. Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL;

**AND**

IV. Individual has a diagnosis of one of the following conditions:
   A. Primary hypogonadism (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**
   B. Hypogonadotropic hypogonadism (also called secondary hypogonadism) (congenital or acquired), (for example, idiopathic gonadotropic or luteinizing hormone-releasing hormone [LMRH] deficiency, pituitary-hypothalamic injury);

**AND**

V. Individual presents with symptoms associated with hypogonadism, such as, but not limited to at least one of the following:
   A. Reduced sexual desire (libido) and activity; **OR**
   B. Decreased spontaneous erections; **OR**

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-0462-19
### Market Applicability

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<th>Market</th>
<th>DC</th>
<th>GA</th>
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<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
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C. Breast discomfort/gynecomastia; OR
D. Loss of body (axillary and pubic) hair, reduced need for shaving; OR
E. Very small (especially less than 5 mL) or shrinking testes; OR
F. Inability to father children or low/zero sperm count; OR
G. Height loss, low trauma fracture, low bone mineral density; OR
H. Hot flushes, sweats; OR
I. Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.

Requests for Testopel (subcutaneous testosterone implants) for **continuation of hormone replacement therapy** 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 the value is below or within therapeutic range based on laboratory reference range; AND
III. Individual has obtained clinical benefits as noted by symptom improvement.

Requests for Testopel (subcutaneous testosterone implants) for **delayed puberty** may be approved if the following criteria are met:

I. Individual is a male 14 years of age or older; AND
II. Individual is using hormone to stimulate puberty; AND
III. Confirmation individual has few to no signs of puberty.

Requests for Testopel (subcutaneous testosterone implants) 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/incongruence or gender identity disorder; AND
III. The goal of treatment is female-to-male gender reassignment.

Requests for Testopel (subcutaneous testosterone implants) may **not** be approved for the following criteria:

I. Hormone replacement therapy (HRT) for female menopause; OR

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CRX-ALL-0462-19
II. Delayed puberty in females.

Requests for Testopel (subcutaneous testosterone implants) may not be approved when the above criteria are not met and for all other indications.

*Estrogen and estrogen containing combination subcutaneous implanted agents

Requests for estrogen and estrogen containing combination subcutaneous implanted agents will not be approved. These agents are not FDA approved.

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<th>State Specific Mandates</th>
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<tbody>
<tr>
<td>State name</td>
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<td>N/A</td>
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Key References:

1. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.