Clinical Policy: Testosterone (Testopel)
Reference Number: LA.PHAR.354
Effective Date: 01.21
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Testosterone pellet (Testopel®) is an implantable androgen.

FDA Approved Indication(s)
Testopel is indicated for:
• Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:
  o Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, or orchiectomy
  o Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary - hypothalamic injury from tumors, trauma, or radiation
• Treatment of delayed puberty in carefully selected males

Limitation(s) of use:
• Testopel: Safety and efficacy of Testopel in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Policy/Criteria
Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Testopel is medically necessary when the following criteria are met:

I. Initial Approval Criteria
  A. Hypogonadism (must meet all):
     1. Diagnosis of primary hypogonadism or hypogonadotropic hypogonadism;
     2. Documentation of serum testosterone level < 300 ng/dL on at least 2 separate days within the last 6 months;
     3. Medical justification supports inability to use transdermal (e.g., patch, gel) and injectable testosterone;
4. **Dose does not exceed 450 mg (6 pellets) every 3 months (Testopel).**
   Approval duration: 6 months

B. **Delayed Puberty (must meet all):**
   1. Request is for Testopel;
   2. Diagnosis of delayed puberty;
   3. Prescribed by or in consultation with an endocrinologist;
   4. Documentation supports inability to use injectable testosterone;
   5. Dose does not exceed 450 mg (6 pellets) every 3 months.
   Approval duration: 6 months

C. **Other diagnoses/indications**
   1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

II. **Continued Therapy**
   A. **Hypogonadism (must meet all):**
      1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 450 mg (6 pellets) every 3 months (Testopel).
      Approval duration: 12 months

   B. **Delayed Puberty:**
      1. Re-authorization is not permitted. Members must meet the initial approval criteria.
      Approval duration: Not applicable

   C. **Other diagnoses/indications (must meet 1 or 2):**
      1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.
      Approval duration: Duration of request or 12 months (whichever is less); or
      2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

III. **Diagnoses/Indications for which coverage is NOT authorized:**
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –LA.PMN.53 for Medicaid, or evidence of coverage documents;
   B. Age-related hypogonadism or late-onset hypogonadism.

IV. **Appendices/General Information**
   *Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration  
LHRH: luteinizing hormone-releasing hormone

**Appendix B: Therapeutic Alternatives**
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.*

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>testosterone cypionate</td>
<td>Male hypogonadism: 50 to 400 mg IM once every 2 to 4 weeks</td>
<td></td>
</tr>
<tr>
<td>injection</td>
<td></td>
<td>400 mg every 2 to 4 weeks</td>
</tr>
<tr>
<td>testosterone enanthate</td>
<td>Male hypogonadism: 50 to 400 mg IM once every 2 to 4 weeks</td>
<td></td>
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<tr>
<td>injection</td>
<td>Males with delayed puberty: 50 to 200 mg every 2 to 4 weeks for a limited duration, for example, 4 to 6 months.</td>
<td>400 mg every 2 to 4 weeks</td>
</tr>
<tr>
<td>testosterone 1% gel</td>
<td>Male hypogonadism: Starting dose: 50 mg applied topically QD. Dose may be</td>
<td>100 mg/day</td>
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<tr>
<td>(AndroGel®)</td>
<td>titrated to a maximum of 100 mg QD based on serum testosterone level.</td>
<td></td>
</tr>
<tr>
<td>testosterone 1.62% gel</td>
<td>Male hypogonadism: Starting dose: 40.5 mg applied topically QD. Dose may be</td>
<td>81 mg/day</td>
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<tr>
<td>(AndroGel®)</td>
<td>titrated to a maximum of 81 mg QD based on serum testosterone level.</td>
<td></td>
</tr>
<tr>
<td>testosterone 2% gel</td>
<td>Male hypogonadism: 40 mg (4 pump actuations) applied topically QD to the</td>
<td>70 mg/day</td>
</tr>
<tr>
<td>(Fortesta®)</td>
<td>thighs. Dose may be titrated to a maximum of 70 mg (4 pump actuations on one thigh and 3 pump actuations on the other thigh) QD based on serum testosterone level. Dose should be titrated to maintain serum testosterone in the range of 500-1250 ng/dL.</td>
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<tr>
<td>testosterone transdermal</td>
<td>Male hypogonadism: 1 patch topically nightly for 24 hours</td>
<td>1 patch/day</td>
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<tr>
<td>patch (Androderm®)</td>
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</tbody>
</table>

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

**Appendix C: Contraindications/Boxed Warnings**

- **Contraindication(s):**
  - Men with known carcinoma of the breast or known or suspected carcinoma of the prostate
  - Pregnant women
**Appendix D: General Information**

- Per the Endocrine Society (2018), the diagnosis of hypogonadism requires unequivocally and consistently low testosterone levels on at least 2 separate mornings. Although the lower limit of normal for testosterone can vary depending on the laboratory used, clinical trials for a number of testosterone agents defined it as < 300 ng/dL. Additionally, the American Urological Association suggests < 300 ng/dL as a reasonable cut-off in support of low testosterone diagnosis (2018).

- Patients with primary hypogonadism usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone and luteinizing hormone) above the normal range. Patients with hypogonadotropic hypogonadism have low serum testosterone concentrations but have gonadotropins in the normal or low range.

- Androgens may be used cautiously to stimulate puberty in carefully selected patients with clearly delayed puberty. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support.

- Testopel implantation has much less flexibility for dosage adjustment than oral administration or intramuscular injections of oil solutions or aqueous suspensions, requires surgical removal if testosterone should be discontinued, and carries a risk of sloughing out of the skin.

### V. Dosage and Administration

<table>
<thead>
<tr>
<th><strong>Drug Name</strong></th>
<th><strong>Dosing Regimen</strong></th>
<th><strong>Maximum Dose</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Testopel</td>
<td>150 to 450 mg (2 to 6 pellets) SC every 3 to 6 months</td>
<td>450 mg (6 pellets) every 3 months</td>
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<tr>
<td></td>
<td>For every 25 mg/week of testosterone propionate, 150 mg (2 pellets) should be</td>
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<tr>
<td></td>
<td>implanted every 3 to 6 months.</td>
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<tr>
<td></td>
<td>If testosterone therapy needs to be discontinued (e.g., for severe adverse reactions), the pellets may need to be removed by a health care professional.</td>
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<tr>
<td></td>
<td>Dosages in delayed puberty generally are in the lower range of that listed above and, for a limited duration, for example 4 to 6 months.</td>
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</tbody>
</table>

### VI. Product Availability

Testopel pellet for implantation: 75 mg

### VII. References


Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>S0189</td>
<td>Testosterone pellet, 75 mg</td>
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</tbody>
</table>

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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