Clinical Policy: Testosterone for Topical Use (Axiron, Fortesta, Testim, Vogelxo)
Reference Number: ERX.NPA.52
Effective Date: 01.11.17
Last Review Date: 11.17

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

Description
Testosterone (Axiron®, Fortesta®, Testim®, Vogelxo®) is an androgen.

FDA Approved Indication(s)
Axiron, Fortesta, Testim, and Vogelxo are indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchietomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone, luteinizing hormone) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone 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.

Limitation(s) of use:
- Safety and efficacy of Axiron, Fortesta, Testim, and Vogelxo in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.
- Safety and efficacy of Axiron, Fortesta, Testim, and Vogelxo in males <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.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Axiron, Fortesta, Testim, and Vogelxo are 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. Age ≥ 18 years;
      4. Dose does not exceed:
         a. Axiron: 120 mg (4 pump actuations) daily;
         b. Fortesta: 70 mg (7 pump actuations) once daily;
         c. Testim: 100 mg (two tubes) once daily;
         d. Vogelxo: 100 mg (two tubes, two packets, or 8 pump actuations) once daily.

   Approval duration: 12 months

   B. Other diagnoses/indications
      1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).
II. Continued Therapy
   A. Hypogonadism (must meet all):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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:
         a. Axiron: 120 mg (4 pump actuations) daily;
         b. Fortesta: 70 mg (7 pump actuations) once daily;
         c. Testim: 100 mg (two tubes) once daily;
         d. Vogelxo: 100 mg (two tubes, two packets, or 8 pump actuations) once daily.
   
   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions
         and documentation supports positive response to therapy.
         Approval duration: Duration of request or 12 months (whichever is less); or
      2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III
         (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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

   Appendix B: Therapeutic Alternatives
   N/A

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone</td>
<td>Starting dose is 60 mg of testosterone (1 pump or 1 twist actuation of 30 mg of testosterone to each axilla), applied once daily, at the same time each morning. The dose of testosterone may be decreased from 60 mg (2 pump or 2 twist actuations) to 30 mg (1 pump or 1 twist actuation) or increased from 60 mg to 90 mg (3 pump or twist actuations) or from 90 mg to 120 mg (4 pump or 4 twist actuations) based on the serum testosterone concentration from a single blood draw 2 – 8 hours after applying Axiron and at least 14 days after starting treatment or following dose adjustment.</td>
<td>120 mg/day</td>
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<tr>
<td>(Axiron)</td>
<td></td>
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</tr>
<tr>
<td>Testosterone</td>
<td>The recommended starting dose is 40 mg of testosterone (4 pump actuations) applied once daily to the thighs in the morning. The dose can be adjusted between a minimum of 10 mg of testosterone and a maximum of 70 mg of testosterone.</td>
<td>70 mg/day</td>
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<tr>
<td>(Fortesta)</td>
<td></td>
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<tr>
<td>Testosterone</td>
<td>The recommended starting dose is 50 mg of testosterone (one tube) applied once daily (preferably in the morning) to clean, dry intact skin of the shoulders and/or upper arms. If the serum testosterone concentration is below the normal range (300 ng/dL to 1,000 ng/dL), the daily Testim dose may be increased from 50 mg testosterone (one tube) to 100 mg testosterone (two tubes) once daily.</td>
<td>100 mg/day</td>
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<tr>
<td>(Testim)</td>
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<td></td>
</tr>
</tbody>
</table>
**Testosterone for Topical Use**

### Drug Name | Dosing Regimen | Maximum Dose
---|---|---
Testosterone (Vogelxo) | The recommended starting dose is 50 mg of testosterone (one tube, one packet, or 4 pump actuations) applied topically once daily at approximately the same time each day to clean, dry intact skin of the shoulders and/or upper arms. If the serum testosterone concentration is below the normal range (300 ng/dL to 1,000 ng/dL), the daily Vogelxo dose may be increased from 50 mg testosterone (one tube, one packet, or 4 pump actuations) to 100 mg of testosterone (two tubes, two packets, or 8 pump actuations) once daily. | 100 mg/day

**VI. Product Availability**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone (Axiron)</td>
<td>Topical solution (metered-dose pump): 30 mg of testosterone per pump or twist</td>
</tr>
<tr>
<td>Testosterone (Fortesta)</td>
<td>Topical gel (metered-dose pump): 10 mg of testosterone per pump</td>
</tr>
<tr>
<td>Testosterone (Testim)</td>
<td>Topical gel (unit-dose tube): 50 mg of testosterone</td>
</tr>
<tr>
<td>Testosterone (Vogelxo)</td>
<td>Topical gel (unit-dose tube): 50 mg of testosterone&lt;br&gt;Topical gel (unit-dose packet): 50 mg of testosterone&lt;br&gt;Topical gel (metered-dose pump): 12.5 mg of testosterone per pump</td>
</tr>
</tbody>
</table>

**VII. References**


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created.</td>
<td>12.16</td>
<td>01.17</td>
</tr>
<tr>
<td>4Q17 Annual Review Converted to new template. Specified concentration of testosterone that is below the normal range per PI within the last 6 months. Added age restriction as safety and efficacy in pediatric patients &lt; 18 years have not been established. Increased initial approval duration from 3 to 12 months. Added max dose requirement on re-auth. Added age-related hypogonadism or late-onset hypogonadism as indications for which coverage is not authorized as safety and efficacy have not been established per PI.</td>
<td>09.12.17</td>
<td>11.17</td>
</tr>
</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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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