Clinical Pharmacy Program Guidelines for Testosterone

1. **Background:**

Testosterone products are approved by the Food and Drug Administration (FDA) for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadotropic hypogonadism (congenital or acquired). Primary hypogonadism originates from a deficiency or disorder in the testicles. Secondary hypogonadism indicates a problem in the hypothalamus or the pituitary gland. Testosterone use has been strongly linked to improvements in muscle mass, bone density, and libido.

The purpose of this program is to provide coverage for androgens and anabolic steroid therapy for the treatment of conditions for which they have shown to be effective and are within the scope of the plan’s pharmacy benefit. Coverage for the enhancement of athletic performance or body building will not be provided.

Black boxed warnings may include but may not be limited to secondary exposure to testosterone. Please see full prescribing information for additional details.

2. **Coverage Criteria:**
A. **Initial Authorization for Hypogonadism**

1. **One** of the following:

   a. **Two** pre-treatment serum total testosterone levels less than 300 ng/dL (<10.4 nmol/L) or less than the reference range for the lab, taken at separate times (This may require treatment to be temporarily held. Document lab value and date for both levels)

   -OR-

   b. **Both** of the following:

      (1) Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

      (2) **One** pre-treatment calculated free or bioavailable testosterone level less than 50 pg/mL (<5 ng/dL or < 0.17 nmol/L) or less than the reference range for the lab (This may require treatment to be temporarily held. Document lab value and date)

   -OR-

   c. Patient has a history of **one** of the following:

      (1) Bilateral orchiectomy

      (2) Panhypopituitarism

      (3) A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter’s syndrome)

   -AND-

2. Patient is **not** taking any of the following:

   a. One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen

   b. Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

   -AND-

3. Patient was male at birth

   -AND-
4. Diagnosis of hypogonadism

-AND-

5. **One** of the following:
   a. Significant reduction in weight (less than 90% ideal body weight) (e.g., AIDS wasting syndrome)
   b. Osteopenia
   c. Osteoporosis
   d. Decreased bone density
   e. Decreased libido
   f. Organic cause of testosterone deficiency (e.g., injury, tumor, infection, or genetic defects)

-AND-

6. **One of** the following:
   a. If the request is for a non-preferred **topical testosterone** (gel, solution) or **testosterone transdermal systems** (patches), the patient has a history of failure, contraindication, or intolerance to generic testosterone 1% topical gel

-AND-

   b. If the request is for **Xyosted**, **both** of the following:
      i. The patient has a history of failure, contraindication, or intolerance to testosterone cypionate injection (generic Depo-Testosterone)

-AND-

      ii. The patient has a history of failure or rationale for not being able to use intramuscular testosterone enanthate injection (generic Delatestryl)

-AND-

7. If the request is for Jatenzo, the patient has a history of failure, contraindication, or intolerance to **all** of the following:
   a. testosterone cypionate vials
   b. testosterone enanthate vials
   c. testosterone gel- tube, pack or pump bottle

**Authorization will be issued for 12 months.**
B. **Initial Authorization for Gender Dysphoria**

1. Using hormones to change physical characteristics

   -AND-

2. The covered person must be diagnosed with gender dysphoria, as defined by the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM)

   -AND-

3. Patient is not taking any of the following:
   a. One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
   b. Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

   -AND-

4. One of the following:
   a. If the request is for a non-preferred **topical testosterone** (gel, solution) or **testosterone transdermal systems** (patches), the patient has a history of failure, contraindication, or intolerance to generic testosterone 1% topical gel

   -AND-

   b. If the request is for **Xyosted**, both of the following:
      i. The patient has a history of failure, contraindication, or intolerance to testosterone cypionate injection (generic Depo-Testosterone)

      -AND-

      ii. The patient has a history of failure or rationale for not being able to use intramuscular testosterone enanthate injection (generic Delatestryl)

      -AND-

5. If the request is for Jatenzo, the patient has a history of failure or rationale for not being able to use **all** of the following:
a. testosterone cypionate  
b. testosterone enanthate vials  
c. testosterone gel- tube, pack or pump bottle

Authorization will be issued for 12 months.

C. Reauthorization for both Non-Gender Dysphoria and Gender Dysphoria

1. Reauthorization will be approved based on both of the following:

   a. **One** of the following:

      (1) Follow-up total serum testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document value and date)

      -OR-

      (2) Follow-up total serum testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted (document value and date)

      -OR-

   (3) **Both** of the following:

      (a) Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

      -AND-

      (b) **One** of the following:

      i. Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal male limits of the reporting lab (document lab value and date)

      -OR-

      ii. Follow-up calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper male limits of normal for the reporting lab and the dose is adjusted
-AND-

b. Patient is not taking any of the following:

(1) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Nutropin AQ, Omnitrope, Saizen
(2) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane])

Authorization will be issued for 12 months.

3. Additional Clinical Rules:
Coverage for patient population may be dependent upon benefit design

4. References:

2. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version.


<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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</thead>
<tbody>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>9/2009</td>
<td>Criteria taken from previously approved AmeriChoice policy. Policy was reformatted.</td>
</tr>
<tr>
<td>12/2010</td>
<td>Annual Review</td>
</tr>
<tr>
<td>3/2011</td>
<td>Annual Review. Added Axiron and Fortesta to non-preferred product list</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/2011</td>
<td>Annual Review. Added Androgel 1.62% to non-preferred product list</td>
</tr>
</tbody>
</table>
| 12/2011| Changed Androgel 1.62% from non-preferred product list to preferred product list.  
                           Changed Androgel 1% from preferred product list to non-preferred product list.  |
| 12/2012| Annual Review                                                          |
| 12/2014| Full updated made to clinical criteria.                                 |
|        | Serum testosterone requirement changed to two levels less than 280 ng/dL, previously required one level less or equal to 300 ng/dL.  
        | Added an alternative diagnostic option to serum testosterone testing: conditions that may cause altered sex-hormone binding globulin with one of the following (1) calculated free or bioavailable testosterone level less than 5 ng/dL or bilateral orchietomy, panhypopituitarism, or (2) a genetic disorder known to cause hypogonadism.  
        | Added all of the following new requirements:  
        | • Not used in combination with growth hormones or aromatase inhibitors  
        | • Patient is male                                                       
        | • Diagnosis of hypogonadism                                            
        | • One of the following: significant reduction in weight (less than 90% ideal body weight) (eg, AIDS wasting syndrome), osteopenia, osteoporosis, decreased bone density, decreased libido, organic cause of testosterone deficiency |
| 3/2015 | Gender Identity disorder initial criteria created for New Jersey and Washington plans due to plan requirement.  
<pre><code>    | Gender Identity disorder added to Male hypogonadism reauthorization criteria for New Jersey and Washington plans due to plan requirement. |
</code></pre>
<p>| 6/2015 | Changed products that the criteria applies to due to a PDL change.      |
| 11/2016| Updated clinical criteria to align with Employer and Individual’s policy, added trial/failure of generic testosterone 1% topical gel to section A and B |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>2/2017</td>
<td>Updated header to define preferred and non-preferred products.</td>
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<tr>
<td></td>
<td>Clarified that reauthorization is for non-gender dysphoria indications.</td>
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<tr>
<td>3/2017</td>
<td>Changed authorization durations to 12 months.</td>
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<tr>
<td>4/2017</td>
<td>In the female to male transition section, removed language requiring documented real life experience living as the other gender or a period of psychotherapy as this is not supported by WPATH guidelines.</td>
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<tr>
<td>5/2017</td>
<td>In the female to male transition section, removed language requiring demonstrable knowledge of what hormones medically can and cannot do and their social benefits and risks, and the requirement that if significant medical or mental health concerns are present, they are reasonably well controlled. Changed “transsexual” to “transgender”. Updated references. Updated reauthorization header to clarify that it applies to all conditions.</td>
</tr>
<tr>
<td>6/2018</td>
<td>Updated required testosterone level to less than 300 ng/dL based on 2018 American Urological Society treatment guidelines.</td>
</tr>
<tr>
<td>2/2019</td>
<td>Program name change from Topical Androgens to Testosterone. Xyosted added to program.</td>
</tr>
<tr>
<td>6/2019</td>
<td>Added Jatenzo to the program.</td>
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</tbody>
</table>