1. **Background:**

The topical testosterone products are approved by the Food and Drug Administration (FDA) for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadotrophic 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. When hypogonadism develops before the age of puberty some of the signs and symptoms of hypogonadism include: small testes, phallus, or prostate, impaired body hair growth, gynecomastia, persistent high pitched voice, and disproportionate growth of arms and legs in comparison to trunk of body. Signs and symptoms associated with later onset hypogonadism are loss of libido, erectile dysfunction, sarcopenia, low bone mass, decreases in muscle mass, depressive thoughts, fatigue, loss of body hair, hot flushes, loss of vigour (1). Testosterone use has been strongly linked to improvements in muscle mass, bone density, and libido (2). Topical products include Axiron*, Androderm, Androgel*, Fortesta*, Testim and Striant*.

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 drug benefit. Coverage for the enhancement of athletic performance or body building will not be provided.

*Coverage for patient population may be dependent upon benefit design

2. **Coverage Criteria:**

A. **Initial Authorization for Male Patients**

1. Topical testosterone (gel, solution) or testosterone transdermal systems (patches) will be approved based on all of the following:

   a. **One** of the following:
1) **Two** pre-treatment serum total testosterone levels less than 280 ng/dL (<9.7 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) \(^{(1)}\)

-OR-

2) **Both** of the following: \(^{(25)}\)

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

3) Patient has a history of **one** of the following:

   a) Bilateral orchiectomy
   
   b) Panhypopituitarism
   
   c) A genetic disorder known to cause hypogonadism (eg, congenital anorchia, Klinefelter’s syndrome)

-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, Norditropin, Nordiflex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin \(^{(5)}\)

   2) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane]) \(^{(2,5)}\)

-AND-

   c. Male patient

-AND-

   d. Diagnosis of hypogonadism
-AND-

e. **One** of the following: (11-26)

1) Significant reduction in weight (less than 90% ideal body weight) (eg, AIDS wasting syndrome)
2) Osteopenia
3) Osteoporosis
4) Decreased bone density
5) Decreased libido
6) Organic cause of testosterone deficiency (eg, injury, tumor, infection, or genetic defects)

-AND-

f. History of failure to three-month trial of injectable testosterone defined by **one** of the following:

1) Contraindication or intolerance to a three-month trial of injectable testosterone

-OR-

2) Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria)

Patients new to any topical testosterone therapy: Authorization will be issued for 6 months. (25)

Patients continuing testosterone therapy: Authorization will be issued for 12 months.

B. **Initial Authorization for Female to Male Transsexual Persons** (34)

1. Topical testosterone (gel, solution) or testosterone transdermal systems (patches) will be approved based on **all** of the following:

   a) Age 18 years or older

   -AND-

   b) Using hormones to change physical characteristics
c) Demonstrable knowledge of what hormones medically can and cannot do and their social benefits and risks

-AND-

d) One of the following:

1) A documented real-life experience (living as the other gender) of at least three months prior to the administration of hormone.

-OR-

2) A period of psychotherapy of a duration specified by the mental health professional after the initial evaluation (usually a minimum of three months).

-AND-

e) The Covered person must meet the definition of Gender Identity Disorder (see definition below):

1) Gender Identity Disorder: A disorder characterized by the following diagnostic criteria:
   a. A strong and persistent cross-gender identification (not merely a desire for any perceived cultural advantages of being the other sex)
   b. Persistent discomfort with his or her sex or sense of inappropriateness in the gender role of that sex
   c. The disturbance is not concurrent with a physical intersex condition
   d. The disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
   e. The transsexual identity has been present persistently for at least two years;
   f. The disorder is not a symptom of another mental disorder or a chromosomal abnormality.

-AND-

f) Patient is not taking any of the following:

1) One of the following growth hormones, unless diagnosed with panhypopituitarism: Genotropin, Humatrope,
Norditropin FlexPro, Norditropin, NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin(5)

2) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane]) (2-5)

-AND-

 g) One of the following:

 1) History of failure to three-month trial of injectable testosterone defined by one of the following:
 2) Contraindication or intolerance to a three-month trial of injectable testosterone
 3) Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria)

Patients new to any topical testosterone therapy: Authorization will be issued for 6 months. (25)

Patients continuing testosterone therapy: Authorization will be issued for 12 months.

C. Reauthorization

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

a. One of the following:

 1) Total serum testosterone level drawn within the past 12 months which is within or below the normal limits of the reporting lab (document value and date)

-OR-

 2) Total serum testosterone level drawn within the past 12 months which is outside of upper 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) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

-AND-

b) **One** of the following:

(i) Calculated free or bioavailable testosterone level drawn within the past 12 months which is within or below the normal limits of the reporting lab (document lab value and date)

-OR-

(ii) Calculated free or bioavailable testosterone level drawn within the past 12 months which is outside of upper limits of normal for the reporting lab and the dose is adjusted (document value and date)

-AND-

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

1) One of the following growth hormones, unless diagnosed with panyhypopituitarism: Genotropin, Humatrope, Norditropin FlexPro, Norditropin NordiFlex, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin

2) Aromatase inhibitor (eg, Arimidex [anastrozole], Femara [letrozole], Aromasin [exemestane]) (2-5)

**Authorization will be issued for 12 months.**

3. **Additional Clinical Rules:**

- Supply limits may be in place.
- * May be excluded from coverage

4. **References:**


26. ISA, ISSAM, EAU, EAA and ASA recommendations: investigation, treatment and monitoring of late-onset hypogonadism in males. The Aging Male. 2009; 12(1) : 5-12


40. AMA Health Care Advocacy Agenda, 2005.

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Change Control</strong></td>
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<tr>
<td>8/2014</td>
<td>Adopted UHCP medical necessity program with Sierra addition of trial/failure/contraindication to injectable testosterone to initial authorization criteria. Addition of subsections for the male population and the female to male transsexual population, updated to include language from the gender identity disorder/gender dysphoria treatment medical coverage determination guideline, references updated.</td>
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<tr>
<td>8/2015</td>
<td>Updated to include UHCP 10/2014 updates to program. Modified criteria for total testosterone to consider reference range of the laboratory. Added criteria for when Free Testosterone level may be utilized. Added criteria for conditions that do not require testosterone levels. Extended initial authorization period for patients already on therapy. Clarified initial authorization periods. Clarified that levels for reauthorization should be within the past 12 months. Updated references.</td>
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