Androgens & Anabolic Steroids

**Covered Medications**

<table>
<thead>
<tr>
<th>Androgens, oral</th>
<th>Androgens, injectable</th>
<th>Anabolic Steroids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone buccal system (Striant®)</td>
<td>Testosterone aqueous injection (Tesamone®)</td>
<td>Oxymetholone tablets (Anadrol-50®)</td>
</tr>
<tr>
<td>Methyltestosterone tablets (Methitest®)</td>
<td>Testosterone cypionate injection (Depo-Testosterone®)</td>
<td>Stanozolol tablets (Winstrol®)</td>
</tr>
<tr>
<td>Methyltestosterone capsules (Testred®, Android®)</td>
<td>Testosterone enanthate injection (Delatestryl®)</td>
<td>Oxandrolone tablets (Oxandrin®)</td>
</tr>
<tr>
<td>Fluoxymesterone tablets (Andoxy®)</td>
<td>Testosterone propionate injection</td>
<td>Nandrolone decanoate injection</td>
</tr>
<tr>
<td></td>
<td>Testosterone pellets (Testopel®)</td>
<td></td>
</tr>
</tbody>
</table>

**What they do and how they are used**

- Testosterone is a hormone produced by the testes that is responsible for inducing and maintaining male secondary sex characteristics. The female ovaries also produce small amounts of testosterone.
- Testosterone products are used as hormone replacement therapy in males for conditions associated with deficiency or absence of testosterone, such as primary and secondary hypogonadism and delayed puberty.
- Testosterone may be used in women as palliative treatment of metastatic inoperable breast cancer.
- Primary hypogonadism is a condition that involves a decrease or an absence of testosterone directly due to a problem with the testes.
- Primary hypogonadism may be caused by conditions as cryptorchidism (where one or both testis fail to descend normally), orchitis (inflammation of the testis) or bilateral orchidectomy (surgical removal of testis).
- Since the pituitary stimulates the testes to release testosterone, conditions that interfere with this process cause secondary hypogonadism, and can include surgery, tumors, trauma or radiation.
- Typically, total serum testosterone levels < 300 ng/dL (< 10.4 nmol/L) signify a deficiency. However, it is not recommended to routinely screen for androgen deficiency or provide testosterone replacement therapy based on a sole lab value.
- A patient and/or physician will notice signs and symptoms, such as incomplete sexual development, low libido and erectile dysfunction, breast discomfort, loss of body hair/reduced shaving, inability to father children, hot flashes/sweats, or reduced muscle/strength and height. The diagnosis is confirmed based on the serum testosterone level.
- The Endocrine Society and The American Association of Clinical Endocrinologists recommend that only men who have low serum testosterone levels AND consistent signs and symptoms be diagnosed and treated for testosterone deficiency.
- An increased number of prescriptions are being written for testosterone products in older or elderly men for the treatment of “andropause”.
- Unlike the abrupt drop in estrogen during menopause for women, andropause is a term used to describe the gradual decrease in bioavailable serum testosterone as men age. A decrease in testosterone is associated with signs and symptoms such as loss of libido, erectile dysfunction, depression, lethargy, osteoporosis, and loss of muscle mass and strength.
- No benefit was shown in a recent randomized, double-blind, placebo-controlled, trial studying testosterone supplementation in healthy males over 60 years of age with serum testosterone levels on the lower end of normal. Lean body mass increased and fat decreased, but functional mobility or muscle strength did not improve. Additionally, there were no benefits to cognition or bone mineral density and a greater percentage of patients treated with testosterone had metabolic syndrome after 6 months compared to placebo due to decreases in HDL (Emmelot-Vonk, 2008).
- Anabolic steroids are synthetic agents derived from testosterone. As testosterone derivatives, anabolic steroids display both androgenic and anabolic properties. When used with a high protein and calorie diet, anabolic steroids promote positive nitrogen balance, which may improve utilization of dietary proteins in promoting growth of skeletal muscle (the anabolic effect).
- Their anabolic activity may be used to promote weight gain in patients with cachexia who have lost weight due to chronic infection, surgery, prolonged corticosteroid use or severe trauma. Less common uses include treatment for anemia and hereditary angioedema.
- Anabolic steroids have the potential to be used to enhance physical appearance (bodybuilding) and/or athletic performance at doses 10 to 100 times the therapeutic dose. These particular uses are typically outside the scope of most drug benefit plans.

**Rationale for prior authorization**

To provide coverage for testosterone replacement 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 (e.g. conditions other than enhancement of athletic performance or bodybuilding).

**Benefit design**

Coverage is determined through prior authorization process for every claim.

Medco Health Solutions, Inc. May 2008
### Prior authorization criteria

Coverage for select androgens and anabolic steroids is provided in situations where the drug is not being used for the enhancement of athletic performance or bodybuilding in accord with the following criteria:

**Testosterone Products:**
1. Coverage is provided for males for the treatment of hypogonadism in patients with pre-treatment serum testosterone levels of $< 300$ ng/dL ($< 10.4$ nmol/L) – **coverage duration: 5 years.**
2. Coverage is provided for males for the treatment of delayed puberty – **coverage duration 6 months.**
3. Coverage is provided for females for the palliative treatment of metastatic inoperable breast cancer – **coverage duration is 5 years.**

**Anabolic steroids:**
1. Coverage is provided for the treatment of hereditary angioedema - **coverage duration is 5 years.**
2. Coverage is provided to promote weight gain - **coverage duration is 5 years.**
3. Coverage is provided for the treatment of anemia/stimulation of erythropoiesis - **coverage duration is 5 years.**

### References

- Available from URL: [http://www.nap.edu/books/0309090636/html/](http://www.nap.edu/books/0309090636/html/)