

## Testosterone and Hypogonadism

### Overview of Testosterone:<sup>10, 11, 12</sup>

Testosterone is a naturally occurring steroid hormone that is made from cholesterol and is responsible for the development of male sexual characteristics. Females also produce testosterone, but in smaller amounts. Testosterone is produced by the testes in men and by the ovaries in women, although small quantities are also produced by the adrenal glands in both sexes. Testosterone plays an important role within the human body, including regulation of libido and sex drive, bone density, muscle mass, brain function, and mood. In some individuals, the body produces too little testosterone and testosterone replacement therapy is required. Testosterone replacement therapy can treat a variety of conditions such as delayed puberty in males, AIDS-associated wasting syndrome, menopausal symptoms, palliative treatment of breast cancer, and male hypogonadism.

### Testosterone Deficiency:<sup>10, 11, 14</sup>

Testosterone levels rise during male puberty, peak during the late teen years, and then level off. After age 30, it's normal for a man's testosterone levels to decrease slightly every year. If the body produces too little testosterone it can lead to a condition called hypogonadism. Male hypogonadism refers to a decrease in one or both of the two major functions of the testes: sperm production or testosterone production. These abnormalities can result from disease of the testes (primary hypogonadism) or disease of the hypothalamus or pituitary gland (secondary hypogonadism). In the brain, the hypothalamus tells the pituitary gland how much testosterone is needed, and the pituitary relays that information to the testicles. The clinical features of male hypogonadism depend upon the age of onset, severity of testosterone deficiency, and whether there is a decrease in one or both of the two major functions of the testes.

- What are the symptoms of low testosterone?
  - Low energy
  - Low libido
  - Low bone mineral density
  - Decrease in body hair
  - Difficulty gaining muscle mass despite vigorous exercise
  - Changes in cholesterol levels
  - Decrease in hemoglobin and mild anemia

### Testosterone Replacement Therapy:

When appropriate, male hypogonadism can be treated with testosterone replacement therapy. There are several testosterone delivery systems currently available in the prescription drug marketplace. Examples include:

- Transdermal patch: Androderm
- Topical gel: Androgel, Axiron, Fortesta, Testim
- Buccal tablet: Striant
- Implantable pellet: Testopel
- Intramuscular injections: Aveed, testosterone cypionate, testosterone enanthate, testosterone propionate

Table 1 – Testosterone Product Examples

Drug Name	Dosage Form	Cost per month (AWP)*
Androderm	Topical patch	\$615.00
Androgel	Topical gel	\$630.00
Axiron	Topical solution	\$690.00
Fortesta	Topical gel	\$500.00
Natesto	Nasal gel	\$260.00
Striant	Buccal tablets	\$720.00
Testim	Topical gel	\$600.00
Testosterone cypionate	Intramuscular injection	\$45.00

\*Note: Monthly costs are estimates reflecting typical doses and may vary based on patient-specific dosage regimens.

### MedTrakRx's Cost Management Strategy:<sup>13, 15, 16</sup>

As the table above illustrates, testosterone replacement products can be costly. Testosterone replacement therapy should be considered in adult males who have symptoms of hypogonadism as well as laboratory results demonstrating low serum testosterone concentrations. Serum testosterone concentrations should be measured in the morning (the time of day when testosterone levels are the highest). These treatment recommendations are supported by The American Association of Clinical Endocrinologists and The American College of Endocrinology. Based on these guidelines, MedTrakRx recommends that all plans administer a prior authorization (PA) process for testosterone replacement therapy. This utilization management strategy requires documentation of two pretreatment, low morning serum testosterone levels obtained within the past 12 months and at least two signs or symptoms of testosterone deficiency. Application of PA criteria ensures that benefit coverage for testosterone replacement therapy is provided in scenarios in which treatment is clinically appropriate.

## References

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