

Testosterone Replacement Therapy

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Testosterone is a type of hormone that the body naturally makes. Both men and women have testosterone with men normally having a much higher level. Testosterone helps the body with many things including supporting bone and muscle health. When the body's level of testosterone is lower than normal, it may lead to symptoms such as:

- Feeling depressed or tired
- Having little to no interest in sex, also known as having a low libido
- Low energy
- Weak muscles or bones

There are tests available to help health care providers decide whether testosterone replacement therapy is needed for people with low testosterone levels. After examination and learning about symptoms that a person may have, prescribers can order a blood test to check testosterone level. It is recommended to be done in the morning (before 10 am) for the most accurate results. If the test shows that a person has

low testosterone, the test will be repeated a second time for confirmation. Depending on the individual, other tests may be needed.

If testing confirms that a person has low testosterone, there are treatment options available. This includes non-drug treatment options such as losing weight (if overweight) or managing other medical conditions that may cause testosterone to be low (such as diabetes, high blood pressure, sleep apnea, or liver disease). Low testosterone can also be treated by testosterone replacement therapy, available in multiple different forms. As with all medications, there are benefits, but also risks or side effects with their use. **Table 1: Testosterone Products for Testosterone Replacement Therapy**, list out names of the commonly prescribed testosterone products that are used to treat people with low testosterone. These products are sometimes used for other reasons such as treating breast cancer in certain people.

Table 1: Testosterone Products for Testosterone Replacement Therapy

Route of Administration	Dosage Forms	Brand Names	Generic Name	FDA-approved age range
Nasal	Gel	Natesto	Testosterone	ages ≥18 years and adults
Oral	Capsule	Jatenzo	Testosterone Undecanoate	
		Tlando		
		Kyzatrex		
Parenteral	Implant, pellets for sub-Q injection	Testopel	Testosterone	adolescents and adults
	Solution, for sub-Q injection	Xyosted	Testosterone Enanthate	ages ≥18 years and adults
	Injection (in oil), for intramuscular injection	Delatestryl		adolescents and adults
		Depo-Testosterone	Testosterone Cypionate	ages ≥12 years and adults
		Aveed	Testosterone Undecanoate	ages ≥18 years and adults
Topical	Gel	Androgel 1%	Testosterone	
		Androgel 1.62%		

		Fortesta		
		Testim		
		Vogelxo		
	Solution	Axiron		
	Transdermal System	Androderm		

NOTE: The Plan requires that members be unable to use, or have tried and failed preferred product(s) first. Requests for non-formulary medications are subject to Medical Necessity Criteria for Non-Formulary Products (PG069).

Definitions

"Acquired" means developed or acquired after birth.

"AIDS or acquired immunodeficiency syndrome" is the medical term that is used to describe a stage of HIV infection when the immune system is at its weakest, causing a person to get infections (opportunistic diseases) that they normally would not get if their immune system was stronger.

"Carcinoma" is another word for cancer.

"Chemotherapy" refers to treatment involving the use of drugs to kill or slow the growth of cancer cells.

"Congenital" means present from birth.

"Cryptorchidism" is a condition in which one or both testicles fail to descend into the scrotum.

"HIV or human immunodeficiency virus" is the name of a virus that can infect a person, and weaken their immune system, leading to long-term problems, including decreasing their ability to fight off infections.

"Free Testosterone Levels" is the amount of unbound or biologically active testosterone in the blood.

"Hypogonadism" is a condition of having a level of testosterone that is lower than normal.

“Hypogonadotropic Hypogonadism” is a form of hypogonadism caused by the inadequate secretion of gonadotropin-releasing hormone (GnRH) or gonadotropins, hormones responsible for stimulating the production of testosterone.

“Idiopathic” means of unknown cause or origin.

“Oophorectomy” is the surgical removal of one or both ovaries.

“Orchiectomy” is the surgical removal of one or both testicles.

“Palliative treatment” is therapy that helps a person suffering from cancer or other life-threatening diseases to feel better or more comfortable, but does not cure the disease.

“Primary Hypogonadism” is a form of hypogonadism caused by testicular failure or abnormalities in the testes.

“Qualified Healthcare Professional” is a licensed and certified individual who is trained and authorized within the scope of their professional practice to diagnose health conditions and prescribe medications.

Examples of qualified healthcare professionals include:

1. Primary Care Physicians: General practitioners who serve as the patient's first point of contact and can diagnose a variety of health conditions.
2. Nurse Practitioners: Advanced practice registered nurses who can prescribe medications, including those that are controlled, in all U.S. states.
3. Physician Assistants: Medical professionals who can diagnose illness, develop and manage treatment plans, and prescribe medications.
4. Specialist Physicians: Such as endocrinologists who specialize in hormonal disorders, urologists who treat conditions of the urinary tract and male reproductive system, infectious disease specialists for conditions like HIV, and oncologists for cancer-related conditions.

The involvement of a specific healthcare professional in prescribing testosterone products should align with their expertise, the patient's specific condition, and the complexity of the care needed.

“Sex Hormone Binding Globulins” are proteins that bind to and transport sex hormones, such as testosterone, in the bloodstream.

“Testosterone” is a chemical, or hormone, that is made mainly in the testicles.

“**Total Serum Testosterone Concentrations**” is the amount of testosterone present in the blood.

Medical Necessity Criteria for Authorization

The Plan considers Testosterone Products medically necessary when ALL the following criteria are met for the applicable indication listed below:

For hormone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone; primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired):

Medical Necessity Criteria for Authorization

The Plan considers **Testosterone Products** medically necessary when **ALL** of the following criteria are met:

1. The member has a documented diagnosis of hypogonadism (primary or hypogonadotropic types); **AND**

Examples of congenital or acquired primary hypogonadism:

- orchiectomy, or testicular failure caused by cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals

Examples of congenital or acquired hypogonadotropic hypogonadism:

- idiopathic gonadotropin or gonadotropin-releasing hormone (luteinizing hormone releasing hormone) deficiency
- pituitary-hypothalamic injury caused by tumors, trauma, or radiation

2. The medication is prescribed by a qualified healthcare professional (see **Definitions**). If the situation requires specialized expertise for accurate diagnosis, prescription, assessment of treatment risks and benefits, proficiency in the preparation and administration of the specific testosterone product, monitoring of side effects, or coordination of care, the prescription should be provided by, or in consultation with, a specialist with relevant training, such as an endocrinologist or urologist; **AND**
3. The member has documented signs and/or symptoms of low testosterone levels (e.g., low sex drive, weak muscles or bones, or low energy); **AND**
4. Clinical chart documentation has been provided confirming **ONE** of the following:
 - a. Prior to treatment, total serum testosterone concentrations have been measured in the morning on at least two separate days and these total serum testosterone concentrations are below 300 ng/dL; **or**

- b. The member has elevated sex hormone binding globulins and has two low free testosterone levels that are at the lower limit of normal for the reference laboratory; **or**
- c. When already on treatment, a total serum testosterone concentration has been measured and is less than or within the normal reference range.

For hormone therapy for transgender males (female-to-male)

Medical Necessity Criteria for Authorization

The Plan considers **Testosterone Products** medically necessary when the following criteria is met:

1. The requested medication is being used for endocrine treatment of gender dysphoric/gender incongruent persons

For hypogonadism associated with HIV infection

Medical Necessity Criteria for Authorization

The Plan considers **Testosterone Products** medically necessary when **BOTH** of the following criteria are met:

1. The member has documented human immunodeficiency virus (HIV) infection; **AND**
2. The requested medication is being requested for the treatment of **ONE** of the following:
 - a. androgen deficiency (e.g., hypogonadism); **or**
 - b. AIDS wasting

For palliative treatment of breast cancer that is inoperable in women:

Medical Necessity Criteria for Authorization

The Plan considers **testosterone cypionate or testosterone enanthate** medically necessary when **ALL** of the following criteria is met:

1. The requested medication is prescribed by or in consultation with a qualified clinician (e.g., oncologist) experienced in the treatment of breast cancer; **AND**
2. The requested medication is being used for palliative treatment of inoperable carcinoma of the breast (androgen-responsive, advanced, inoperable, metastatic breast carcinoma); **AND**
3. The member is considered to have a hormone-responsive tumor; **AND**
4. The member is a female patient and meets **ONE** of the following:
 - a. is pre-menopausal **AND** has benefited from oophorectomy; **or**

- b. is one (1) to five (5) years post-menopausal **AND** is unable to use or has tried and failed other hormonal agents (e.g., tamoxifen, anastrozole, letrozole, exemestane)

For the treatment of delayed puberty in males

Medical Necessity Criteria for Authorization

The Plan considers **Testosterone Products** medically necessary when **ALL** of the following criteria are met:

1. The medication is prescribed by a qualified specialist (e.g., pediatric endocrinologist) experienced in treating carefully selected males with delayed puberty; **AND**
2. Safety and efficacy of the requested medication has been established for the member's age as evidenced by FDA-approved labeling (Use in Specific Populations); **AND**
3. Documentation of **BOTH** of the following:
 - a. prior to initiation of therapy, fully discussing the potential risk of therapy with the patient and his parents; **and**
 - b. radiographic examination of the hand and wrist at 6-month intervals to determine the rate of bone maturation and to assess the effect of therapy on the epiphyseal centers.

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Testosterone Products for any other indication are considered not medically necessary by the Plan, as they are deemed to be experimental, investigational, or unproven. These include but are not limited to:

- for men with late-onset hypogonadism (i.e., low testosterone concentrations related to aging), without a clinical diagnosis of hypogonadism
- for nonmedical use such as for cosmetic purposes to achieve bodies with lean muscle mass, or to enhance athletic performance or physique
- for the management of vasomotor symptoms associated with menopause
- for the prevention of postpartum breast pain and engorgement
- for the treatment of erectile dysfunction in men with normal serum testosterone concentrations
- for the treatment of hypoactive sexual desire disorder
- for the treatment of depression, fatigue, cognitive decline, or cardiovascular disease in men without documented hypogonadism
- any other uses not supported by robust clinical evidence and/or widely accepted clinical practice guidelines

Appendix

In the interest of promoting safe, effective, and evidence-based use of Testosterone Products, the Plan considers uses outside of established medical indications as not medically necessary. These uses are considered experimental, investigational, or lacking sufficient evidence to demonstrate clear health benefits that outweigh potential risks. The following provides examples of such uses, although this is not an exhaustive list:

It is important to note that such uses may also be considered non-covered benefits by the Plan.

1. For men with late-onset hypogonadism (i.e., low testosterone concentrations related to aging), without a clinical diagnosis of hypogonadism: Clinical evidence and guidelines have not sufficiently established that age-related decline in testosterone is detrimental or that replacement therapy is beneficial in men without a clinical diagnosis of hypogonadism.
2. For nonmedical use such as for cosmetic purposes to achieve bodies with lean muscle mass, or to enhance athletic performance or physique: Testosterone is not approved for use in nonmedical or performance-enhancement purposes due to potential adverse health effects and ethical considerations.

NOTE: These uses may also be considered a non-covered benefit by the Plan.

3. For the management of vasomotor symptoms associated with menopause: While testosterone may affect vasomotor symptoms, it's not approved for this indication due to lack of robust clinical evidence showing significant benefits outweighing potential risks.
4. For the prevention of postpartum breast pain and engorgement: Current clinical evidence does not support the use of testosterone for this indication, with other treatments showing more efficacy and safety.
5. For the treatment of erectile dysfunction in men with normal serum testosterone concentrations: Testosterone is not typically first-line therapy for erectile dysfunction, particularly in men with normal serum testosterone. Other treatments are typically more effective.
NOTE: This use may also be considered a non-covered benefit by the Plan.
6. For the treatment of hypoactive sexual desire disorder: The clinical evidence supporting testosterone use for this indication is not sufficiently robust, and the potential risks may outweigh benefits.
7. For the treatment of depression, fatigue, cognitive decline, or cardiovascular disease in men without documented hypogonadism: Clinical evidence and guidelines does not support the use of testosterone for these indications in the absence of hypogonadism.
NOTE: This use may also be considered a non-covered benefit by the Plan.
8. Any other uses not supported by robust clinical evidence and/or widely accepted clinical practice guidelines: The Plan aims to ensure treatments are used in a safe and effective manner.

Therefore, indications lacking robust clinical evidence or guideline support are deemed not medically necessary.

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