



MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 02/04/14
LAST REVIEW DATE: 09/16/14
LAST CRITERIA REVISION DATE: 04/21/14
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TESTOSTERONE REPLACEMENT THERAPY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Testosterone replacement therapy is the primary treatment for androgen deficiency in males when symptoms of hypogonadism are present. Testosterone therapy has been used in the absence or deficiency of endogenous testosterone. Testosterone therapy routes include oral, intramuscular injections, topical patch, topical gel, buccal tablets and subcutaneous pellets.

Testosterone is produced in males primarily by the testes in response to stimuli from the hypothalamic and pituitary glands. Low testosterone is caused by deficient production of the hormone, and is also known as androgen deficiency.

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Definitions:

Hypogonadism is the clinical syndrome associated with androgen deficiency. Symptoms are dependent upon age, severity of androgen deficiency, duration of androgen deficiency, individual sensitivity to androgen, and comorbid illness.

Chronic Steroid Treatment:

Men receiving ongoing treatment for manifestations of a chronic condition, as opposed to episodic treatment for an acute condition or acute flare of a chronic condition. The length of acute episodic steroid treatment may vary from several days to several months, but in most cases will be less than 4-6 weeks.

Criteria:

- Testosterone replacement therapy for the treatment of male androgen deficiency syndromes is considered **medically necessary** with documentation of **ALL** of the following:
 1. An established diagnosis of hypogonadism with persistently low testosterone levels defined as **ANY** of the following:
 - Total testosterone level less than the reference lab's normal value on two separate occasions
 - Serum free testosterone level and total testosterone less than reference lab normal value on the same date
 2. Clinical manifestations suggestive of androgen deficiency including **ANY** of the following:
 - Breast discomfort, gynecomastia
 - Decreased spontaneous erections
 - Height loss, low trauma fracture or low bone mineral density
 - Hot flushes, sweats
 - Incomplete or delayed sexual development, eunuchoidism
 - Loss of body hair (facial, axillary or pubic)
 - Low or zero sperm count
 - Reduced sexual desire (libido) and activity
 - Small (<5ml) or shrinking testes
 3. Androgen deficiency diagnosis is not made during an acute or subacute illness
 4. Complete physical examination, including a digital prostate examination, completed before initiating testosterone replacement therapy. A digital prostate examination should be done periodically during therapy.

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Criteria: (cont.)

- Testosterone replacement therapy is considered **medically necessary** with documentation of **ANY** of the following:
 1. HIV-infected individuals with documentation of **ALL** of the following:
 - Low testosterone levels
 - Weight loss
 2. Individuals on chronic steroid treatment with low testosterone levels
 3. Delayed male puberty with documentation of **ALL** of the following:
 - Age 14 years or older
 - Pre-pubertal testes
 - Serum testosterone < 100
- Testosterone replacement therapy for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Older men with low testosterone levels in the absence of clinical signs and symptoms of hypogonadism



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Resources:

1. 5.01.23 BCBS Association Medical Policy Reference Manual. Issue date 12/12/2013
Testosterone Replacement Therapies.
2. External Consultant Review. Pediatric Endocrinology and Diabetes. 05/15/2006.
3. External Consultant Review. SW Pediatric Endocrinology. 05/06/2006.
4. The Endocrine Society. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. 2010.
5. Vigen R, O'Donnell CI, Baron AE, et al. Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels. *JAMA*. Nov 6 2013;310(17):1829-1836.