

Treatment of Males with Low Testosterone

Noridian Healthcare Solutions, LLC

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Proposed

Please Note: This is a Proposed LCD.

Proposed LCDs are works in progress and not necessarily a reflection of the current policies or practices. Proposed LCDs in an approval status display on the CMS MCD for public review.

Contractor Information

Proposed

Contractor Name Noridian Healthcare Solutions, LLC

Contract Number 01112

Contract Type A and B MAC

(A and B MAC - 01111 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01211 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC -

Associated Contract Numbers 01311 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01911 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01182 - J - E)

Noridian Healthcare Solutions, LLC, (A and B MAC - 01212 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01312 - J - E) Noridian Healthcare Solutions, LLC

Proposed LCD Information

Proposed

Source LCD ID N/A

Proposed LCD ID DL36538

**Original ICD-9
LCD ID** N/A

**Proposed LCD
Version** 7

**Proposed LCD
Title** Treatment of Males with Low Testosterone

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Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

**CMS National
Coverage
Policy**

42 Code of Federal Regulations (CFR) §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS Internet Online Manual Pub. 100-02 (Medicare Benefit Policy Manual), Chapter 15, Section 80, “Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests”

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) “Reporting ICD Diagnosis and Procedure Codes”.

CMS Internet-Only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 12, §30-Correct Coding Policy

Jurisdiction California - Northern

**Super MAC
Jurisdiction** J - E

Coverage Guidance



**Coverage
Indications,
Limitations and/or
Medical Necessity**

Noridian has noted a rapid increase in the use of testosterone supplements that exceed the expected use in the Medicare population based on current published data. According to a Health Technology Assessment on Testosterone Testing from the Washington State Health Care Authority, the presence of low serum testosterone is 9.0% in men aged 45 to 54 years, 16.5% in men aged 55 to 64 years, and 18.3% in men aged 65 to 74 years. These estimates were derived from the National Health and Nutrition Examination Survey III (NHANESIII), which defined low testosterone levels as < 300 nanogram per deciliter (ng/dL) (10.4 nanomoles per liter [nmol/L]). The diagnosis of hypogonadism depends on measuring the total, free and/or biologically active testosterone; sex hormone binding globulin (SHBG) and the pituitary axis. Male hormone is bound to SHBG, and SHBG tends to rise with age, lowering the free testosterone level. Testosterone level accuracy varies among labs with different assays, and can be affected by chronic diseases, age, levels of binding, measurement variables, testing accuracy, etc. Estimates of the low end of testosterone depend on the method and accuracy of testing and can be as low as 160 ng/dl. Decisions on hypogonadism depend on both repeated hormone testing and a group of clinical symptoms. Neither alone is adequate for defining hypogonadism.

Testosterone levels are controlled by interaction of the testicular-pituitary-hypothalamic axis. Primary hypogonadism is failure of the testes to produce testosterone (for a number of reasons) and is usually accompanied by elevated LH and/or FSH. Secondary hypogonadism is disruption of the testicular-pituitary-hypothalamic pathway and may be due to pituitary or hypothalamic axis damage including systemic illness and genetic aberration. Age related hypogonadism (e.g. lower testosterone in the older male population) is not necessarily a disease and may be asymptomatic and / or may be related or associated with many chronic

illnesses. “Low T Syndrome” or “Low T” is not a syndrome and may be an incidental finding or lab error. Low serum testosterone alone does not constitute a diagnosis of androgen deficiency or clinical hypogonadism. Diagnosis of a clinical condition requires the presence of certain characteristic symptoms as well as an abnormally low serum testosterone.

Many of the symptoms are not specific to, and not directly correlated to specific levels of testosterone. Guidelines from the Endocrine Society suggest some of the following symptoms may be related to low serum testosterone but **may** also have many other causes in the elderly population:

More Specific Signs / Symptoms

- Incomplete or delayed sexual development; eunuchoidism
- Reduced sexual desire (libido) and activity
- Breast discomfort, gynecomastia
- Loss of body (axillary and pubic) hair, reduced shaving
- Very small (Especially < mL) or shrinking testes
- Inability to father children
- Low or zero sperm count
- Height loss, low-trauma fracture, low bone mineral density

- Hot flushes, sweats

Less Specific Signs/Symptoms

- Decreased energy, motivation, initiative and self confidence
- Feeling sad or blue, depressed mood, dysthymia
- Poor concentration and memory
- Sleep disturbance, increased sleepiness
- Mild anemia
- Reduced muscle bulk and strength
- Increased fat or increased body mass index
- Diminished physical or work performance

Noridian expects that the evaluation of primary hypogonadism be undertaken with at least 2 separate serum testosterone levels taken on two different days in the morning (when testosterone secretion is highest) , and / or two morning levels of “free” or bioavailable testosterone) **and**

LH or FSH levels. Elevated LH /FSH confirms primary hypogonadism and the potential need for replacement hormone. If the two testosterone determinations are low AND the LH/FSH levels are also low, pituitary disease (including a serum prolactin) or chronic diseases should be assessed before making a diagnosis of age related low testosterone. Only patients with low testosterone associated significant symptoms should be considered for treatment. A comprehensive examination is required to evaluate for medications or chronic diseases known to cause decreased energy, memory problems, impotence and mental health problems.

Noridian would consider the low testosterone related symptoms from the nonspecific and specific groups described above to be documented in the chart **along with two low testosterone levels drawn on two mornings and a single LH or FSH** to demonstrate the need for testosterone therapy in the age related group of symptomatic androgen deficiency. Documentation of the symptoms, signs, physical examination and lab tests must be available in the chart if requested.

Treatment of symptoms associated with low testosterone is controversial. It is not certain if low testosterone is the cause of the symptoms, a marker for underlying chronic diseases, or the effect of the symptoms-and there is a considerable placebo effect. Long term effects of testosterone on the geriatric population are mixed but are being studied by the NIH. Long term use of testosterone can damage the hypothalamic-pituitary-testicular axis and lead to permanent testicular failure.

Testosterone is **contraindicated** in patients with breast cancer and untreated prostate cancer. There are recent FDA listed warnings about thromboembolic disease, increase in erythrocythemia, and hypertension. The clinical records shall reflect that these issues were discussed with the patient before initiating therapy.

Where replacement is indicated, the dose of replacement therapy should be the least amount necessary to obtain a serum testosterone in the low normal range. Testosterone replacement can be administered by many routes. The current preferred routes are by transdermal preparations. Since topical or transdermal agents are administered daily in low dose, the risk of supraphysiological or subtherapeutic levels is minimized. The use of topical agents is thought to minimize adverse events. Indeed, in series examining the toxicity of topical agents, adverse events are nearly nonexistent when administered by these routes (Steidle et al., 2003). The main disadvantage of the topical agents are their high cost (\$100 to \$150 per month), substantially higher than self-administered injection therapy, and the potential risk of inadvertent transfer of hormone to women or children through skin contact. There is no evidence that unusually high doses-or higher than published frequencies of administration-are any

more effective than doses established by the FDA and could lead to increased side effects. Ongoing monitoring of hormone levels and side effects are necessary.

Proposed Process Information



Synopsis of Changes	Changes	Fields Changed
Associated Information	Not Applicable	
Sources of Information and Basis for Decision	<p>1. Bhasin, MD, S., Travison, PHD, T., & Jasuja, PhD, R. Testosterone and Aging. <i>Translational Endocrinology & Metabolism</i>, 2 (2), 39-72. 2011.</p> <p>2. Bhasin, MD, S., Cunningham, G., & Hayes, F. (2013). Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. http://dx.doi.org/10.1210/jc.2005-2847</p> <p>3. Brannigan, MD, R., Paduch, MD, PHD, D., & Fuchs, E., et al; The Laboratory Diagnosis of Testosterone Deficiency, 2013 AUA White Paper., (American Urological Association Education and Research, Inc.).</p> <p>4. FDA Safety Alert: Testosterone Products: Drug Safety Communication - FDA Cautions About Using Testosterone Products for Low Testosterone Due to Aging; Requires Labeling Change to Inform of Possible Increased Risk of Heart Attack and Stroke; UPDATE 04/15/2015.</p> <p>5. Handelsman, MBBS, PHD, D., & Perls MD, MPH, T. (n.d.). , Disease Mongering of Age-Associated Declines in Testosterone and Growth Hormone Levels. <i>Journal of the American Geriatrics Society</i>, 63(4), 809-811. April 2015.</p> <p>6. Huhtaniemi, I. (2014). Late-onset hypogonadism: Current concepts and controversies of pathogenesis, diagnosis and treatment. <i>Asian Journal of Andrology</i>, 16(2), 192-202.</p> <p>7. Paduch, D. et al "Testosterone Replacement in Androgen-Deficient Men With Ejaculatory Dysfunction: A Randomized Controlled Trial" <i>J Clin Endocrinol Metab</i>. 2014-4434. 2015.</p>	

8. Rishi Sharma, Olurinde A. Oni, Kamal Gupta, et.al. European Heart Journal, published online: 6 August 2015.

9. Steidle, C.P. MD, New Advances in the Treatment of Hypogonadism in the Aging Male, Rev Urol. 2003; 5 (Suppl 1): S34–S40.

10. Testosterone Testing, Health Technology Assessment Program (HTA) Washington State Health Care Authority (Draft Report) February 6, 2015.

	Meeting Date	Meeting Information	State
Open Meetings	02/04/2016	Four Points by Sheraton Hotel 1617 1st Avenue San Diego, CA 92101	American Samoa, California - Entire State, Guam, Hawaii, California - Northern, California - Southern
Part B MAC Contractor Advisory Committee (CAC) Meetings	Meeting Date	Meeting Information	State
	02/17/2016	Los Angeles, CA	California - Entire State
	02/12/2016	Honolulu, HI	American Samoa, Guam, Hawaii
	02/18/2016	Las Vegas, NV	Nevada
Comment Period Start Date	02/04/2016		
Comment Period End Date	04/10/2016		
Released to Final LCD Date	Not yet released.		
Reason for Proposed LCD	Aberrant Local Utilization Request for Coverage by a Practitioner (Part B) Other: Recent rapid increase in inappropriate and clinically dangerous drug utilization.		
Proposed LCD Contact	Contractor Medical Director (s) Noridian Healthcare Solutions, LLC JE Part A Attention: Draft LCD Comments PO Box 6782 Fargo, North Dakota 58103-6782 policy.drafts@noridian.com		

Coding Information



Bill Type Codes

Revenue Codes

Group 1: Paragraph

Group 1: Codes

	11980	SUBCUTANEOUS HORMONE PELLE T IMPLANTATION (IMPLANTATION OF ESTRADIOL AND/OR TESTOSTERONE PELLETS BENEATH THE SKIN)
CPT/HCPCS Codes	96372	THERAPEUTIC, PROPHYLACTIC, OR DIAGNOSTIC INJECTION (SPECIFY SUBSTANCE OR DRUG); SUBCUTANEOUS OR INTRAMUSCULAR
	J1071	INJECTION, TESTOSTERONE CYPIONATE, 1 MG
	J3121	INJECTION, TESTOSTERONE ENANTHATE, 1 MG
	J3145	INJECTION, TESTOSTERONE UNDECANOATE, 1 MG
	J3490	UNCLASSIFIED DRUGS

**Does the CPT 30%
Coding Rule Apply?**

No

Group 1: Paragraph

Group 1: Codes

ICD-10 Codes that Support Medical Necessity	D35.2	Benign neoplasm of pituitary gland
	E23.0	Hypopituitarism
	E23.1	Drug-induced hypopituitarism
	E23.3	Hypothalamic dysfunction, not elsewhere classified
Note: Performance is optimized by using code ranges.	E23.6	Other disorders of pituitary gland
	E23.7	Disorder of pituitary gland, unspecified
	E29.1	Testicular hypofunction
	E29.8	Other testicular dysfunction
	E89.5	Postprocedural testicular hypofunction

**ICD-10 Codes that DO
NOT Support Medical
Necessity**

Group 1: Paragraph

Group 1: Codes

**Note: Performance is
optimized by using
code ranges.**

**Additional ICD-10
Information**

Associated Documents



Attachments

There are no attachments for this LCD.

**Related Local Coverage
Documents**

This LCD version has no Related Local Coverage Documents.

**Related National Coverage
Documents**

This LCD version has no Related National Coverage Documents.