

Local Coverage Determination (LCD): Treatment of Males with Low Testosterone (L36538)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

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L36538

For services performed on or after 07/12/2016

LCD Title

Treatment of Males with Low Testosterone

Revision Effective Date

For services performed on or after 11/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL36538

Retirement Date

N/A

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Notice Period Start Date

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CMS National Coverage Policy

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.

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

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 <math>< \text{mL}</math>) 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 replacement therapy 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. Some physicians recommend obtaining baseline PSA testing and ongoing monitoring to test for prostate cancer.

Long term testosterone therapy will shrink testicular tissue and can lead to infertility, and therefore would be contraindicated in those interested in reproduction.

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 suprphysiological 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.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

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Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R5	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R4	<p>11/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage.</p> <p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To Code Removal
10/01/2017	R3	<p>8/21/2017: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in the policy.</p> <p>LCD is revised to add the following diagnoses effective 10/01/2017:</p> <p>D44.3: Neoplasm of uncertain behavior of pituitary gland.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
01/01/2017	R2	2017 CPT Coding update to include 84410.	<ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes
10/01/2016	R1	Added ICD-10 CM Code N50.89 per ICD-10 CM 2016-2017 Coding Updates.	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57615 - Billing and Coding: Treatment of Males with Low Testosterone

A55053 - Response to Comments: Treatment of Males with Low Testosterone

A55056 - Testopel Coverage

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 11/01/2019 - N/A

Updated on 10/24/2019 with effective dates 11/01/2019 - N/A

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Keywords

N/A