FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33412

Contractor Name
First Coast Service Options Inc.

Contractor Number
09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Testosterone pellets (Testopel®)

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Sections 10; 20; & 40
CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.1.3
Social Security Act Section 1861 (t) (2) (B)
Primary Geographic Jurisdiction
Florida
Puerto Rico/Virgin Islands

Oversight Region
Region I

Original Determination Effective Date
10/01/2015

Original Determination Ending Date
N/A

Revision Effective Date
N/A

Revision Ending Date
N/A

Indications and Limitations of Coverage and/or Medical Necessity

Testosterone is an endogenous androgen. Endogenous androgens are responsible for the normal growth and development of the male sex characteristics. Testosterone levels vary from hour to hour; periodic declines below the normal range can occur in some otherwise normal men. An overall diurnal rhythm is also present, the highest levels of circulating testosterone occurring during the early morning hours. In certain medical conditions such as hypogonadism, the endogenous level of testosterone falls below normal levels. The diagnosis of androgen deficiency is made in men with consistent signs and symptoms and unequivocally low serum testosterone levels. Testosterone levels should be determined in the morning, and studies should be repeated in patients with subnormal levels.

Testosterone pellets (Testopel®) have been approved by the Food and Drug Administration (FDA) for the treatment of primary hypogonadism (congenital or acquired) and hypogonadotrophic hypogonadism (congenital or acquired). Primary hypogonadism includes such conditions as testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchidectomy. Hypogonadotrophic hypogonadism (secondary hypogonadism) includes conditions such as idiopathic or gonadotropic luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma or radiation.

Indications:

Testosterone pellets (Testopel®) will be considered medically reasonable and necessary for the following indications:

- Second line testosterone replacement therapy in males with congenital or acquired endogenous androgen absence or deficiency associated with primary or secondary hypogonadism when other standard replacement [intramuscular (IM), buccal, transdermal is not clinically effective; OR,
- For treatment of delayed male puberty
Testosterone pellets

Testosterone pellets (Testopel®) method of administration is subcutaneously by a health care professional.

Limitations:

Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate.

For patients that clearly meet the indication for testosterone replacement, the reason(s) for a transition to pellets from other effective replacement (IM, buccal, transdermal) must be specifically addressed in the medical record.

Clinical diagnosis of androgen deficiency (non-specific symptoms, low normal testosterone levels, and normal free testosterone) is not a covered indication. Office practices with high utilization of testosterone pellet implantations can be subject to pre- or post-payment review.

Implantable testosterone pellets for the treatment of symptoms associated with menopause is considered not reasonable and necessary as there is insufficient clinical evidence to support this use and is therefore non-covered.

Type of Bill Code

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<td>Hospital Inpatient (including Medicare Part A)</td>
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<td>13x</td>
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<td>85x</td>
<td>Critical Access Hospital</td>
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Revenue Codes

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<td>Pharmacy – Drugs Requiring Detailed Coding</td>
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CPT/HCPCS Codes

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<th>Code</th>
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<tr>
<td>J3490*</td>
<td>Testosterone pellets (Testopel®)</td>
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<tr>
<td>11980*</td>
<td>Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)</td>
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* Providers must bill HCPCS code J3490 and CPT code 11980 on the same claim. If HCPCS code J3490 and CPT code 11980 are not billed on the same claim, the claim will be subject to prepayment review.

ICD-10 Codes that Support Medical Necessity

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<tr>
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<td>E30.0</td>
<td>Delayed puberty</td>
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Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A
Testosterone pellets

Associated Information

Documentation Requirements

The medical record must substantiate the medical need for testosterone pellets (Testopel®) with documentation of unsuccessful treatments of standard replacement (IM, buccal, transdermal) on more than one occasion, in men with clinically significant symptoms of androgen deficiency.

The reason(s) for a transition to pellets from other effective replacement (IM, buccal, transdermal) must be specifically addressed in the medical record.

The medical record should reflect two total testosterone levels and free testosterone levels when indicated to determine the medical necessity of testosterone replacement. It is suggested to measure morning testosterone level by a reliable assay on two different days. The results of both tests must fall below the normal laboratory reference range. The medical record should include the Clinical Laboratory Improvement Amendments (CLIA) approved reference normal range for the testosterone assay used.

Medical record documentation must be made available upon request. When the documentation does not meet the criteria for the services rendered, or the documentation does not establish the medical necessity for the service(s), such services will be denied as not reasonable and necessary under Section 1862(a)(1) (A) of the Social Security Act.

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Sources of Information and Basis for Decision

FCSO reference LCD number(s) – L33002


Start Date of Comment Period

N/A
Testosterone pellets

End Date of Comment Period

N/A

Start Date of Notice Period

04/01/2014

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments

Coding Guidelines

Document formatted: 05/19/2014 (DA/et)