Local Coverage Determination (LCD): Testosterone pellets (Testopel®) (L33412)

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
<td>09101 - MAC A</td>
<td>J - N</td>
<td>Florida</td>
</tr>
<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
<td>09102 - MAC B</td>
<td>J - N</td>
<td>Florida</td>
</tr>
<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
<td>09201 - MAC A</td>
<td>J - N</td>
<td>Puerto Rico</td>
</tr>
<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
<td>09202 - MAC B</td>
<td>J - N</td>
<td>Puerto Rico</td>
</tr>
<tr>
<td>First Coast Service Options, Inc.</td>
<td>A and B MAC</td>
<td>09302 - MAC B</td>
<td>J - N</td>
<td>Virgin Islands</td>
</tr>
</tbody>
</table>

LCD Information

Document Information

**LCD ID**
L33412

**Original ICD-9 LCD ID**
L33004

**LCD Title**
Testosterone pellets (Testopel®)

**Proposed LCD in Comment Period**
N/A

**Source Proposed LCD**
N/A

**Original Effective Date**
For services performed on or after 10/01/2015

**Revision Effective Date**
For services performed on or after 10/01/2015

**Revision Ending Date**
N/A

**Retirement Date**
N/A

**Notice Period Start Date**
N/A

**Notice Period End Date**
N/A

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**
CPT only copyright 2002-2018 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The Code on Dental Procedures and Nomenclature (Code) is published in Current Dental Terminology (CDT). Copyright © American Dental Association. All rights reserved. CDT and CDT-2016 are trademarks of the American Dental Association.
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)

Coverage Guidance

Coverage Indications, Limitations, 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 (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

UB-04 Manual. OFFICIAL UB-04 DATA SPECIFICATIONS
MANUAL, 2014, is copyrighted by American Hospital Association ("AHA"), Chicago, Illinois. No portion of OFFICIAL UB-04 MANUAL may be reproduced, sorted in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior express, written consent of AHA. 
Health Forum reserves the right to change the copyright notice from time to time upon written notice to Company.
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.

**Coding Information**

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
013x Hospital Outpatient
085x Critical Access Hospital

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0636 Pharmacy - Drugs Requiring Detailed Coding

**CPT/HCPCS Codes**

**Group 1 Paragraph:** * 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.

J3490* Testosterone pellets (Testopel®)

11980* Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>XX000</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**ICD-10 Codes that Support Medical Necessity**

**Group 1 Paragraph:**

N/A

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E29.1</td>
<td>Testicular hypofunction</td>
</tr>
<tr>
<td>E30.0</td>
<td>Delayed puberty</td>
</tr>
</tbody>
</table>

**ICD-10 Codes that DO NOT Support Medical Necessity**
Additional ICD-10 Information
N/A

General Information

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


Revision History Information

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>06/05/2014 – The language and/or ICD-10-CM diagnoses were updated to be consistent with current LCD language and ICD-9-CM coding.</td>
<td>• Revisions Due To ICD-10-CM Code Changes</td>
</tr>
</tbody>
</table>
Associated Documents
Attachments
Coding guidelines

Related Local Coverage Documents
N/A

Related National Coverage Documents
N/A

Keywords
N/A