

Testosterone Pellets (Testopel®)

Guideline Number: MPG301.07
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[↪ Terms and Conditions](#)

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Related Medicare Advantage Coverage Summaries
<ul style="list-style-type: none"> Impotence Treatment Medications/Drugs (Outpatient/Part B)

Policy Summary

[↪ See Purpose](#)

Overview

Testosterone pellets (Testopel®) have been approved by the Food and Drug Administration (FDA) in adult males for the treatment of primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

- Primary hypogonadism includes such conditions as testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchidectomy.
- Hypogonadotropic 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.

Testopel Pellets are not FDA-approved for administration to females.

The benefit and safety of Testopel® (testosterone pellets) have not been established for the treatment of men with low testosterone levels due to aging (also referred to as “age-related hypogonadism” or “late-onset hypogonadism”).

Guidelines

Injectable testosterone pellets (brand name Testopel®) may be covered, by Medicare, for the FDA-approved indication, if the service meets all Medicare coverage requirements in the CMS Internet-Only Manual (IOM) Medicare Benefit Policy Manual Chapter 15, Section 50.4.3.2 for Injection Method Not Indicated. Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.

Pellet implantation is much less flexible for dosage adjustment and more invasive than oral medication, nasal administration, transdermal administration or intramuscular injection. Medicare coverage determinations indicate that the use of this product (Testopel®) should be rare since the "accepted method of medical practice" is to administer testosterone transdermally, but there may be reasons that require this injectable medication.

The number of pellets to be implanted depends upon the minimal daily requirements of testosterone propionate titrated to a serum testosterone level in the low normal range for a healthy adult male. The usual dosage is 150 mg to 450 mg subcutaneously every 3 to 6 months, which translates to 2 to 6 pellets every 3 to 6 months. Insertion of more than 6 pellets every 3 months will not be considered reasonable and necessary. Medicare may only cover the number of pellets actually implanted in the patient (maximum of 6 pellets); wastage is not covered.

Refer to the Local Coverage Determination (LCD) [References](#) for Medicare expectations on the establishment of a diagnosis of primary hypogonadism.

Contraindications

Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate. There are recent FDA listed warnings about thromboembolic disease, increase in erythrocythemia, and hypertension.

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

Refer to the Local Coverage Determination (LCD) [References](#) for limitations of coverage, as these may vary by jurisdiction.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

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HCPCS Code	Description
J3490	Unclassified drugs (Testopel®)

Diagnosis Code	Description
D35.2	Benign neoplasm of pituitary gland
D44.3	Neoplasm of uncertain behavior of pituitary gland
E23.0	Hypopituitarism
E23.1	Drug-induced hypopituitarism
E23.3	Hypothalamic dysfunction, not elsewhere classified
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
N50.89	Other specified disorders of the male genital organs

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36538 Treatment of Males with Low Testosterone	A57615 Billing and Coding: Treatment of Males with Low Testosterone	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV

LCD	Article	Contractor	Medicare Part A	Medicare Part B
	A55056 Billing and Coding: Testopel Coverage			
L36569 Treatment of Males with Low Testosterone	A57616 Billing and Coding: Treatment of Males with Low Testosterone	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
	A55057 Billing and Coding: Testopel Coverage			
L39086 Treatment of Males with Low Testosterone	A58828 Billing and Coding: Treatment of Males with Low Testosterone	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV

CMS Benefit Policy Manual

[Chapter 15; § 50 Drugs and Biologicals](#)

CMS Claims Processing Manual

[Chapter 17; § 10 Payment Rules for Drugs and Biologicals, § 20 Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis, § 70 Claims Processing Requirements – General](#)

UnitedHealthcare Commercial Policy

[Testosterone Replacement or Supplementation Therapy](#)

Other(s)

[FDA Drug Safety Communication for testosterone products](#)

[Medicare Coverage Article: Testopel Coverage, Noridian Healthcare Solutions Website](#)

[TESTOPEL Information, Testopel Website](#)

[TESTOPEL Testosterone pellet, Endo Pharmaceuticals, Inc.: package insert prescribing information](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
06/08/2022	<p>Policy Summary</p> <p><i>Guidelines</i></p> <ul style="list-style-type: none"> Revised language to indicate: <ul style="list-style-type: none"> Injectable testosterone pellets (brand name Testopel®) may be covered, by Medicare, for the FDA-approved indication, if the service meets all Medicare coverage requirements in the Centers for Medicare & Medicaid (CMS) <i>Internet-Only Manual (IOM) Medicare Benefit Policy Manual Chapter 15, Section 50.4.3.2 for Injection Method Not Indicated</i>; medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration Pellet implantation is much less flexible for dosage adjustment and more invasive than oral medication, nasal administration, transdermal administration or intramuscular injection; Medicare coverage determinations indicate that the use of this product (Testopel®) should be

Date	Summary of Changes
	<p>rare since the "accepted method of medical practice" is to administer testosterone transdermally, but there may be reasons that require this injectable medication</p> <ul style="list-style-type: none"> ○ The number of pellets to be implanted depends upon the minimal daily requirements of testosterone propionate titrated to a serum testosterone level in the low normal range for a healthy adult male <ul style="list-style-type: none"> ▪ The usual dosage is 150 mg to 450 mg subcutaneously every 3 to 6 months, which translates to 2 to 6 pellets every 3 to 6 months; insertion of more than 6 pellets every 3 months will not be considered reasonable and necessary. ▪ Medicare may only cover the number of pellets actually implanted in the patient (maximum of 6 pellets); wastage is not covered ○ Refer to the list of available Local Coverage Determination (LCD) references for Medicare expectations on the establishment of a diagnosis of primary hypogonadism in the <i>Supporting Information</i> section of the policy <p>Contraindications</p> <ul style="list-style-type: none"> ● Removed language indicating the clinical records shall reflect that these issues were discussed with the patient before initiating therapy ● Added instruction to refer to the list of available LCD references for limitations of coverage, as these may vary by jurisdiction, in the <i>Supporting Information</i> section of the policy <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>References</i> section to reflect the most current information ● Archived previous policy version MPG301.06

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).