Testosterone Pellets (Testopel®)

Guideline Number: MPG301.05
Approval Date: June 10, 2020

➲ Terms and Conditions

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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 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.

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.

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. Medicare may only cover the number of pellets actually implanted in the patient (maximum of six pellets); wastage is not covered.

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. The

main disadvantage of the topical agents are their high cost, 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.

Medicare 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.

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. The clinical records shall reflect that these issues were discussed with the patient before initiating therapy.

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

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)

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
E30.0	Delayed puberty (Removed 08/23/2019)

Diagnosis Code	Description
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 A55056 Billing and Coding: Testopel Coverage	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36569 Treatment of Males with Low Testosterone	A57616 Billing and Coding: Treatment of Males with Low Testosterone A55057 Billing and Coding: Testopel Coverage	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A54880 Billing and Coding: Additional Claim Documentation Requirements for Not Otherwise Classified (NOC) Drugs and Biological Products with Specific FDA Label Indications	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L33412 Testosterone pellets (Testopel®) First Coast Retired 08/23/2019	N/A	First Coast	FL, PR, VI	FL, PR, VI

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
Palmetto GBA Unclassified or Not Otherwise Classified (NOC) Drug Codes: Rejected if Not Submitted Correctly, Palmetto GBA 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
04/01/2021	Template Update • Reformatted policy; transferred content to new template

06/10/2020	**Title Change** • Previously titled *Testosterone Replacement Therapy* **Policy Summary** *Overview* • Removed language defining testosterone/endogenous androgens • Added language to indicate the benefit and safety of Testopel® (testosterone pellets) has 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* • Revised language to indicate: ○ 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 ▪ 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 ▪ Medicare may only cover the number of pellets actually implanted in the patient (maximum of six pellets); wastage is not covered ○ 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 ▪ The main disadvantage of the topical agents are their high cost, 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 ○ Medicare 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 *Contraindications (previously titled Limitations)* • Added language to indicate: ○ 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

Date	Summary of Changes
	○ Long term testosterone therapy will shrink testicular tissue and can lead to infertility, and therefore would be contraindicated in those interested in reproduction • Removed language indicating: ○ Patients who meet the indication for testosterone replacement must have the specific reason(s) for transitioning from other effective replacement (IM, buccal, transdermal) 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 *Documentation Requirements* (removed) • Removed content/language addressing documentation requirements Applicable Codes • Added notation to indicate ICD-10 diagnosis code E30.0 was "removed Aug. 23, 2019" • Removed HCPCS code S0189 • Removed ICD-10 diagnosis codes C75.1, C75.2, D35.3, N44.00, N44.01, N44.02, N44.03, N44.04, N45.1, N45.2, N45.3, N50.0, N51, Q53.00, Q53.01, Q53.02, Q53.10, Q53.11, Q53.12, Q53.20, Q53.21, Q53.22, Q53.9, Z85.47, Z90.721, Z90.722, and Z90.79 Supporting Information • Updated *References* section to reflect the most current information • Archived previous policy version MPG301.04

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.

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*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.