Clinical Policy: Testosterone Pellet (Testopel)

Reference Number: CP.PHAR.354
Effective Date: 08.01.17
Last Review Date: 11.17
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Testosterone pellet (Testopel®) is an implantable androgen.

FDA approved indication
Testopel is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy
- Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic lutenizing hormone-releasing hormone (LHRH) deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation

Limitation of use: Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Testopel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Endogenous Testosterone Deficiency or Absence (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. Primary hypogonadism [congenital or acquired] (i.e., testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, or orchiectomy);
   b. Hypogonadotropic hypogonadism [congenital or acquired] (i.e., idiopathic or gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation);
   c. Delayed puberty that is not secondary to a pathological disorder (i.e., puberty is expected to occur spontaneously at a relatively late date);
2. Failure of topical (e.g., patch, gels) and injectable testosterone unless contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 450 mg (6 pellets) every 3 months.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to CP. PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Endogenous Testosterone Deficiency or Absence (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., improvement in hypogonadal symptoms);
3. If request is for a dose increase, new dose does not exceed 450 mg (6 pellets) every 3 months.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP. PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PHAR.57 or evidence of coverage documents

B. Age-related hypogonadism (also referred to as "late-onset hypogonadism")

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

LHRH: luteinizing hormone releasing hormone

Appendix B: General Information

- If primary hypogonadism or hypogonadotrophic hypogonadism occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.
- Androgens may be used cautiously to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support.

The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

- Testopel implantation has much less flexibility for dosage adjustment than oral administration of or intramuscular injections of oil solutions or aqueous suspensions, requires surgical removal if testosterone should be discontinued, and carries a risk of sloughing out of the skin.
- A 2010 clinical guideline from the Endocrine Society states a diagnosis of androgen deficiency in men is made only when there are consistent symptoms and signs and unequivocally low serum testosterone levels. They recommend testosterone therapy for men with symptomatic androgen deficiency to induce and maintain secondary sex characteristics and to improve their sexual function, sense of well-being, muscle mass and strength, and bone mineral density. They recommend against starting testosterone therapy in patients with breast or prostate cancer, a palpable prostate nodule or induration or prostate-specific antigen greater than 4 ng/ml or greater than 3 ng/ml in men at high risk for prostate cancer such as African Americans or men with first-degree relatives with prostate cancer without further urological evaluation, hematocrit >50%, untreated severe obstructive sleep apnea, severe lower urinary tract symptoms with International Prostate Symptom Score (IPSS) > 19, or uncontrolled or poorly controlled heart failure. They suggest initiating testosterone therapy with any of the following regimens, chosen on the basis of the patient's preference, consideration of pharmacokinetics, treatment burden, and cost:
  - 75–100 mg of testosterone enanthate or cypionate administered intramuscularly (IM) weekly, or 150–200 mg administered every 2 weeks.
  - One or two 5-mg nongenital, testosterone patches applied nightly over the skin of the back, thigh, or upper arm, away from pressure areas.
  - 5–10 g of a 1% testosterone gel applied daily over a covered area of nongenital skin (patients should wash hands after application).
  - 30 mg of a bioadhesive buccal testosterone tablet applied to buccal mucosa every 12 hours.
  - Testosterone pellets implanted subcutaneously at intervals of 3 to 6 months; the dose and regimen vary with the formulation used.
  - Oral testosterone undecanoate, injectable testosterone undecanoate, testosterone-in-adhesive matrix patch, and testosterone pellets where available
- Per the guidelines, it is recommended to evaluate the patient 3 to 6 months after testosterone treatment initiation to assess whether symptoms have responded to treatment and whether the patient is suffering any adverse effects, and to check compliance.

Appendix D: Codes Related To This Policy

- The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

- On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

ICD-9 Codes	
253.4	Pituitary hypogonadism
257.2	Testicular hypogonadism
259.0	Delay in sexual development and puberty, not elsewhere classified
627.0-627.9	Menopausal and Postmenopausal disorders
ICD-10 Codes	
E23.6	Other disorders of pituitary gland
E29-E29.9	Testicular dysfunction
E29.1	Testicular hypofunction
E30.0	Delayed puberty
N92.4	Excessive bleeding in the premenopausal period
N95 – N95.9	Menopausal and other perimenopausal disorders
CPT Codes	
11980	Subcutaneous hormone pellet implantation (implantation of Estradiol and/or testosterone pellets beneath the skin)
HCPCS Codes	
S0189	Testosterone pellet, 75mg

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypogonadism	150—450 mg (2—6 pellets) SC every 3—6 months For every 25 mg/week of testosterone propionate, 150 mg (2 pellets) should be implanted every 3—6 months. If testosterone therapy needs to be discontinued (e.g., for severe adverse reactions), the pellets may need to be removed by a health care professional.	450 mg (6 pellets) every 3 months

VI. Product Availability

Pellet for implantation: 75 mg

VII. References

1. Testopel [prescribing information]. Malvern, PA: Endo Pharmaceutical Inc.; October 2016. Available at: www.testopel.com. Accessed June 21, 2016.
2. The Endocrine Society Clinical Guideline. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes. J Clin Endocrinol Metab, June 2010, 95(6):2536–2559. Available at: https://www.endocrine.org/education-and-practice-management/clinical-practice-guidelines.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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