Effective Date: 6-25-14

Nevada Health Solutions LLC

NHS MEDICAL POLICY

Testopel – Testosterone pellets
Medicine 2014-002

Implantable testosterone pellets (e.g., Testopel pellets) may be medically necessary as replacement therapy in adult males with conditions associated with a deficiency or absence of endogenous testosterone when ALL the following are present:

1	Deficiency is documented by 2 testosterone levels drawn at least 2 weeks apart
2	There has been a failure or intolerance of patch, gels, and injectable testosterone.
3	There is documented congenital or acquired primary hypogonadism (i.e., testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome or orchidectomy); OR There is documented congenital or acquired hypogonadotrophic hypogonadism (i.e., idiopathic or gonadotropic LHRH deficiency, or pituitary — hypothalamic injury from tumors, trauma or radiation).
4	There is no evidence of carcinoma of the breast.
5	There is no evidence of carcinoma of the prostate.

Pediatric and Adolescent use:

If the above conditions 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.

EXCLUSION:

a) NHS considers implantable testosterone pellets (e.g., Testopel pellets) investigational for routine use in men with low testosterone levels due to inconclusive evidence in the peer review literature regarding its potential benefits versus unknown long-term risks.
b) Use of the subcutaneous testosterone pellet TestopelTM is considered **INVESTIGATIVE** for all other indications, including but not limited to, symptoms associated with female menopause, due to lack of FDA approval of any other indications.
c) The subcutaneous administration of formulations of testosterone other than TestopelTM is considered **INVESTIGATIVE** due to lack of FDA approval of any other products.

SOURCES

The testosterone pellet, TestopelTM, has received approval from the U.S. Food and Drug Administration (FDA) as replacement therapy for the following 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 orchidectomy;
- Hypogonadotrophic hypogonadism or secondary hypogonadism (congenital or acquired) - idiopathic or gonadotropic LHRH deficiency, or pituitary- hypothalamic injury from tumors, trauma or radiation.

The FDA approval also states:

> If the above conditions 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.

- American Association of Clinical Endocrinologists. AACE Medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients, 2002 update. Endocr Pract. 2002; 8: 439-456.

- Testopel. [Product Information]. Rye, NY, Bartor Pharmacal. January 2013. Available at: http://www.testopel.com/site/assets/files/1026/testopel-prescribing-information.pdf.

CODE REFERENCE (This may not be a comprehensive list of codes to apply to this policy.)

Coding: The *following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

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

HCPCS: J3490 Unclassified drugsS0189 Testosterone pellet, 75 mg

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
06/19/2015	Annual Medical Policy Review and approval
09/25/2015	Changed "testosterone levels drawn between 8 am and 10 am and at least two weeks apart"
09/14/2016	Annual review and approval by UM Committee
09/12/2017	Annual review and approval by UM Committee
09/12/2018	Annual review and approval by UM Committee
09/12/2019	Annual review and approval by UM Committee
09/10/2020	Annual review and approval by UM Committee
09/10/2021	Annual review and approval by UM Committee
09/19/2022	Annual review and approval by UM Committee
08/23/2023	Annual review and approval by UM/QM Committee
08/23/2024	Annual review and approval by UM/QM Committee