



Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Testosterone Pellets, Implantable (Testopel™)

Policy Number: HS-192

Original Effective Date: 3/20/2011

Revised Date(s): 7/7/2011; 5/3/2012;
2/7/2013; 2/6/2014; 2/5/2015; 8/6/2015;
9/27/2016; 7/6/2017; 7/12/2018

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Implantable testosterone pellets may be indicated as second-line testosterone replacement therapy for males. Testosterone implants (Testopel™) are commercially available in the United States. Androgens are primarily indicated in males as replacement therapy when congenital or acquired endogenous androgen absence or deficiency is associated with primary or secondary hypogonadism. Primary hypogonadism includes conditions such as: testicular failure due to cryptorchidism, bilateral torsion, orchitis, or vanishing testis syndrome; inborn errors in testosterone biosynthesis; or bilateral orchidectomy. Hypogonadotropic hypogonadism (secondary hypogonadism conditions include gonadotropin-releasing hormone (GnRH) deficiency or pituitary-hypothalamic injury as a result of surgery, tumors, trauma, or radiation, and are the most common forms of hypogonadism seen in older adults. If testosterone implants are to be used for treatment of androgen deficiency due to primary or secondary hypogonadism, the usual adult dosage is 150 to 450 mg subcutaneously every three to four months, or, in some

cases, as long as six months. Dosage adjustment is needed to accommodate individual clinical requirements for such life changes as induction of puberty, development of secondary sexual characteristics, impotence due to testicular failure, or infertility due to oligospermia.

For treatment of delayed male puberty, a 6-month-or-shorter course of androgen is indicated for induction of puberty in patients with familial delayed puberty, a condition characterized by spontaneous, nonpathologic, late-onset puberty, if the patient does not respond to psychological treatment. If subcutaneous testosterone implants are to be used, the usual dosage is to be determined by the physician. Low doses are used initially and increased gradually as puberty progresses.

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicare – All Markets

Implantable testosterone pellets (Testopel™) **are considered medically necessary** for EITHER of the following:

- As second line testosterone replacement therapy in males with congenital or acquired endogenous androgen absence or deficiency associated with primary or secondary hypogonadism when neither topical, intra-muscular or buccal testosterone replacement therapy is effective or appropriate; **OR**,
- For third or fourth line treatment of delayed male puberty following IM injections, Testosterone gel and or oral preparations.

NOTE: A bone age x-ray should be conducted for members under age 25 who are taking the medication to ensure that excess bone maturation does not occur while the member being treated.

In addition, the following criteria **for Medicare members** applies:

- A statement indicating diagnosis of male hypogonadism; **AND**
- Pretreatment testosterone level below normal physiological value of 300 ng/dl or below normal reference level (provided by the laboratory).

In addition, the following criteria **for Medicaid members** applies:

- A statement indicating diagnosis of male hypogonadism; **AND**
- Laboratory results indicating:
 - At least one low total testosterone level (below 300 ng/dl or the normal range for the laboratory); **AND**
 - ALT and AST – within normal limits (AST – 5-40IU/L and/or ALT 7-56 IU/L), tested within the last 3 to 6 months.
- Baseline PSA and hematocrit levels

Preferred alternatives for Testopel™ are:

- Testim Gel for external use
- Testosterone cypionate or Testosterone enanthate for injection

CODING

Covered CPT®* Code

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

Covered HCPCS Level II© Codes

J1071 Injection, testosterone cypionate, 1 mg

J3121 Injection, testosterone enanthate, 1 mg

J3490 Unclassified drugs

S0189* Testosterone pellet, 75 mg

* Note: S-Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes For Medicare, bill the appropriate CPT code listed above.

Covered ICD-10 CM Diagnosis Codes – *This list may not be all inclusive*

E29.1 Testicular hypofunction

E30.0 Delayed puberty; i.e. delayed sexual development

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Fennell, C., Sartorius, G., Ly, L.P., & et al. (2009). Randomized cross-over clinical trial of injectable vs. implantable depot testosterone for maintenance of testosterone replacement therapy in androgen deficient men. *Clinical Endocrinology*, 73(1), 102-109.
2. Local Coverage Determination Testosterone pellets (Testopel®) (L33412). Centers for Medicare and Medicaid Services Website. <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Published October, 2015. Accessed June 15, 2018.
3. Testopel (Auxilium Pharmaceuticals Inc.) Implantable Testosterone Pellet for Hypogonadism. Hayes Directory Web site. www.hayesinc.com Published November 13, 2014. Accessed June 15, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
7/5/2018, 7/6/2017, 9/27/2016 8/6/2015	<ul style="list-style-type: none"> • Approved by MPC. No changes. • Approved by MPC. Clarifying items to Position Statement re: when used as a second line therapy as well as criteria for baseline PSA and hematocrit levels.
2/5/2015, 2/6/2014 2/7/2013	<ul style="list-style-type: none"> • Approved by MPC. No changes. • Approved by MPC. Expanded medical necessity criteria and drug alternatives.
5/3/2012, 12/1/2011 7/7/2011	<ul style="list-style-type: none"> • Approved by MPC. No changes. • Approved by MPC. New.