

Title: Implantable Hormone Pellets

Origination: 05/25/11	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

- Implantable testosterone pellets may be indicated as second-line testosterone replacement therapy for males. 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 includes the following diagnoses:
 - **Primary hypogonadism** (congenital or acquired):
Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and above normal gonadotropin levels (Follicle Stimulating Hormone, Luteinizing Hormone).
 - **Hypogonadotropic hypogonadism** (congenital or acquired):
Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone levels, but have gonadotropins in the normal or low range.

Eligibility Criteria

- 1.) Must be Male over the age of 18 years old;
 - 2.) Medical records must document the diagnosis of primary or secondary hypogonadism / hypogonadotropic hypogonadism (congenital or acquired);
 - 3.) Laboratory documentation supporting at least:
 - a. One (1) total testosterone level < 300 ng/dl; OR
 - b. Free testosterone level < 50 pg/ml (baseline level);
 - 4.) For continuation from a previous insurance carrier, there must be clinical documentation of a baseline (prior to starting therapy):
 - a. Total testosterone level < 300 ng/dl; OR
 - b. Free testosterone level < 50 pg/ml.
- For the use in the treatment of sexual dysfunction, Testosterone can be considered for coverage of sexual dysfunction only for those Members with such coverage in their Member contract.

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Background Information, continued:

Exclusions

- Implantable testosterone pellets are considered experimental and investigational for the treatment of symptoms associated with female menopause and are considered experimental and investigational for all other indications.

Procedure:

- 1.0 This procedure provides implantable hormone pellets guidelines for the Medical Department staff to reference when making benefit determinations and defines AvMed's coverage position. The list of procedures is not considered to be all inclusive.

References:

1. United States Pharmacopeial Convention, Inc. USP Dispensing Information. Volume I -- Drug Information for the Health Care Professional. Greenwood Village, CO: Micromedex; 2007.
2. American Society of Health-System Pharmacists, Inc. AHFS Drug Information 2009. Bethesda, MD: American Society of Health-System Pharmacists; 2009.
3. Thomson Reuters. Physicians' Desk Reference. 63rd Ed. Montvale, NJ: Physicians' Desk Reference, Inc.; 2009.
4. Basaria S, Dobs AS. Hypogonadism and androgen replacement therapy in elderly men. *Am J Med.* 2001;110(7):563-572.
5. Nieschlag E, Behre HM, Bouchard P, et al. Testosterone replacement therapy: Current trends and future directions. *Hum Reprod Update.* 2004;10(5):409-419.
6. Nieschlag E. Testosterone treatment comes of age: New options for hypogonadal men. *Clin Endocrinol (Oxf).* 2006;65(3):275-281.
7. Edelstein D, Sivanandy M, Shahani S, Basaria S. The latest options and future agents for treating male hypogonadism. *Expert Opin Pharmacother.* 2007;8(17):2991-3008.
8. Fennell C, Sartorius G, Ly LP, et al. Randomized cross-over clinical trial of injectable vs. implantable depot testosterone for maintenance of testosterone replacement therapy in androgen deficient men. *Clin Endocrinol (Oxf).* 2009 Nov 5.

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.