



**Subject:** **Implantable Testosterone Replacement Therapy for Adult Male Hypogonadism (Testopel)\***

**Effective Date:** **March 24, 2015**

**Department(s):** **Utilization Management**

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**Policy:** Testosterone replacement therapy by implantable formulation for adult male hypogonadism is reimbursable under Plans administered by QualCare, Inc. when the criteria delineated in this policy are met.

**Objective:** To provide proper and consistent reimbursement and to define the indications for a specific type of therapy.

**Procedure:** Implantable testosterone pellets (Testopel pellets) (**CPT 11980; HCPCS S0189**) for adult male hypogonadism (**ICD-9 253.4, 257.1 through 257.8; ICD-10 E23.6, E29.1, E29.8, E89.5**) will be approved **as second line therapy** when **all** of the following criteria are met:

1. Three of the following signs or symptoms are present
  - Reduced sexual desire (libido) and activity
  - Decreased spontaneous erections
  - Breast discomfort, gynecomastia
  - Loss of body (axillary and pubic) hair
  - Very small (especially <5 ml) or shrinking testes
  - Decreased energy/strength
  - Depressed mood
  - Poor concentration and memory

**AND**

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2. Documentation of morning ( 8-10 am) serum total testosterone levels below the reporting laboratory lower limit reference range (typically <300ng/dl) on **two** different dates.

**AND**

3. Documentation of failure to achieve therapeutic serum testosterone levels and improvement of symptoms, or intolerance to the formulation for **both of the following**:
  - an injectable ( testosterone enanthate or testosterone cypionate intramuscularly every one to two weeks)
  - and one topical formulation of testosterone (transdermal gel, patch, solution or buccal system- Testogel, Testim, AndroGel, Androderm, Fortesta, Axiron, Striant).

When the above criteria are met the initial authorization period will be for one year. Subsequent authorization will require documentation of clinical benefit regarding symptoms or exam findings and that appropriate monitoring of therapy is being conducted to include, among other things, periodic clinical evaluation, serum testosterone levels, cholesterol, hematocrit and prostate specific antigen (as indicated by history).

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\*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.

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