Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization Number: 07.032

Title: Testosterone Products Page 1 of 4

Approval: Robert Bonnell, M.D., Med. Dir.  DATES - Origination: 02/02/99
Responsible Party: CPM Director  Revised: 11/11/11  Effective: 11/14/11
Distribution: Medical Department  P&T Review: 08/24/16  Annual Review: 08/23/17

Purpose:

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

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

   3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
Background Information, continued:

Medication Summary

- Testosterone is the primary androgen found in the body and is endogenously synthesized by cells in the testis, ovary, and adrenal cortex;
- Testosterone is used in the management of hypogonadism, either congenital or acquired;
- Topical products include Androgel, Testim 1% topical gel, Fortesta, Axiron, and Androderm transdermal system;
- Testosterone is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone and includes the following diagnoses:
  - **Primary hypogonadism** (congenital or acquired):
    Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes 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.

Coverage Guidelines

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- For the use in the treatment of sexual dysfunction due to the prescription benefit exclusion: **Exception:** Testosterone will be covered for sexual dysfunction only for those Members with such coverage;
  - Males less than 18 years of age;
  - Female;
  - A male with prostate carcinoma or breast carcinoma (contraindicated for use).

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
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Procedure:

1. Is the request for initial coverage, or for continuation of coverage?
   □ Initial, continue to 2.
   □ Continuation, continue to 5.

2. Is the member a male, and at least 18 years of age?
   □ Yes = continue to question 3
   □ No = deny. The plan only allows for use in members that are male, and age 18 or greater based on FDA-approved indications. Based on the information provided, this member does not meet coverage criteria.

3. Is there documentation from the Member’s medical records verifying the diagnosis of primary or secondary hypogonadism/hypogonadotropic hypogonadism (congenital or acquired)?
   □ Yes, continue to 4
   □ Other = Deny, the patients plan does not cover this medication for the diagnosis provided.

4. Is there clinical documentation (laboratory value) supporting at least one low total testosterone level < 300 ng/dl, OR low free testosterone level < 50 pg/ml (baseline level)?
   □ Yes = Approve indefinitely, within standard dosing guidelines.
   □ No = Deny, the plan requires baseline testosterone levels below the normal range. Based on the information provided, this member does not meet coverage criteria.

5. For continuation (i.e. new AvMed member who has been on medication with previous insurance provider), is there clinical documentation of a baseline (prior to starting therapy) low total testosterone level < 300 ng/dl, OR low free testosterone level < 50 pg/ml?
   □ Yes = Approve indefinitely, within standard dosing guidelines.
   □ No = Deny, the plan requires baseline testosterone levels below normal range. Based on the information provided, this member does not meet coverage criteria.
References:


10. Axiron (testosterone) Topical Solution Prescribing Information. Lilly USA, LLC Indianapolis, IN. Revised July 2011.