

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis or product:

1. For conditions associated with a deficiency or absence of endogenous testosterone.

- Must have one of the following diagnoses:
 - Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy
 - Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation.
- Must have repeated morning serum total testosterone level <300ng/dL

For brand injectable testosterone products

- Must have documentation of trial and failure or intolerance to testosterone cypionate

For brand topical testosterone products:

- Must have documentation of trial and failure or intolerance to TWO generic topical testosterone products

2. For methyltestosterone for treatment of breast cancer:

- Must be prescribed by or in consultation with an oncologist or hematologist
- Must be using for a FDA approved or compendia (i.e. NCCN guidelines) supported indication
 - Includes appropriate dosage, testing, and any applicable prior drug requirements

3. For requests related to transgender services, please refer to *RX.PA.434* Transgender Services policy for coverage criteria.

Reauthorization Criteria

Methyltestosterone for treatment of breast cancer:

All prior authorization renewals are reviewed on a 6-month basis to determine the Medical Necessity for continuation of therapy. Authorizations may be extended at 6-month intervals based upon documentation from the prescriber that the member's

condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	<ul style="list-style-type: none"> • Testosterone deficiency: Up to duration of membership with plan • Breast cancer: Up to 6 months
Reauthorization	Breast cancer: Up to 6 months

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Genitourinary Disorders; Male Reproductive Endocrinology: Male Hypogonadism. The Merck Manuals Online Medical Library: The Merck Manual for Healthcare Professionals, updated April 2007. Accessed 9/14/07 at
2. <http://www.merck.com/mmpe/sec17/ch227/ch227b.html#sec17-ch227-ch227b-214>
3. Androderm® [package insert]. Corona, CA: Watson Pharma, Inc.; June 2001.
4. Androgel [package insert]. Marietta, GA: Unimed Pharmaceuticals, Inc.; November 2002.
5. Delatestryl® [package insert]. Princeton, NJ: Bristol-Myers Squibb; October 1995.
6. Androxy [package insert]. Minneapolis, MN: Upsher-Smith Laboratories, Inc; May 2004.
7. Bremner WJ, Vitiello MV, Prinz PN. Loss of circadian rhythmicity in blood testosterone levels with ageing in normal men. *J Clin Endocrinol Metab.* 1983; 56:1278.
8. Axiron® [package insert]. Eli Lilly and Company. Indianapolis, IN. July 11, 2011.
9. Fortesta® [package insert]. Pharbil Walthrop GmbH, Im Wirrigen 25, 45731 Walthrop, Germany. April 2011.
10. Striant® [package insert]. Mipharm S.p.A, Milan, Italy. 2003.
11. Testim® [package insert]. DPT Laboratories, Ltd. San Antonio, TX. September 2009.
12. Methitest™ [package insert]. Global Pharmaceutical Corporation, Philadelphia, PA, 2005.
13. Android® [package insert]. ICN Pharmaceuticals, Inc, Costa Mesa, CA, 2001.
14. Aveed [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc., 2014.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>02/16, 02/17, 02/18</i>

Testosterone Products
POLICY NUMBER: RX.PA.009.E
REVISION DATE: 12/18
PAGE NUMBER: 4 of 4

<i>Criteria update</i>	06/16, 12/16, 12/18
------------------------	---------------------