

ANDROGENS

UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Androgens
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Generic (Brand) NAMES:

- Fluoxymesterone (Androxy[®])
- Methyltestosterone (Android[®], Methitest[®], Testred[®])
- Testosterone, topical
 - A. Androderm[®], Androgel[®] - *Preferred topical testosterone*
 - B. Testim[®], Fortesta[®], Axiron[®], Bio-T-Gel[™]
- Testosterone, buccal (Striant[®])
- Testosterone cypionate (e.g., Depo-Testosterone[®])
- Testosterone enanthate (e.g., Delatestryl[®])

FDA-APPROVED INDICATIONS:

Replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired): Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

Hypogonadotropic hypogonadism (congenital or acquired): Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.

Delayed puberty: To stimulate puberty in carefully selected males with clearly delayed puberty.

Metastatic mammary cancer in women: Used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal

COVERAGE AUTHORIZATION CRITERIA for the androgen products listed above:

1. Being used for **ONE** of the following:
 - a. **Males for the treatment of hypogonadism (low testosterone):**
 - i. patient has symptoms of androgen deficiency **AND**
 - ii. has a baseline (pre-treatment) morning serum total testosterone level of less than or equal to 300 ng/dL or a serum total testosterone level that is below the testing laboratory's lower limit of the normal range **OR**
 - iii. baseline morning serum free testosterone level, measured by the equilibrium dialysis method, of less than or equal to 50 pg/ml or a free serum testosterone level that is below the testing laboratory's lower limit of the normal range, **OR**
 - b. **For palliative treatment of metastatic inoperable breast cancer; OR**
 - c. **Males with delayed puberty**

AND
2. If requested agent is a topical testosterone product, a preferred topical testosterone

(Androgel or Androderm) must have been tried and failed before the non-preferred topical testosterone will be covered;

- a. The patient's medication history demonstrates use of a preferred topical androgen (Androgel or Androderm) **OR**
- b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a preferred topical androgen

BLACK BOX WARNING for transdermal testosterone:

Virilization has been reported in children who were secondarily exposed to transdermal testosterone. Children should avoid contact with unwashed or unclothed application sites in men using transdermal testosterone. Advise patients to strictly adhere to recommended instructions for use.

REFERENCES:

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Androderm (testosterone patch). Product Information. Watson Pharma, Inc. 2010. http://pi.watson.com/data_stream.asp?product_group=1200&p=pi&language=E

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Striant (testosterone buccal system). Product Information. Columbia Laboratories, Inc. 2004. http://striant.com/Professional/prescribing_info/58816-10_Striant_full_PI_4pager.pdf

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Delatestryl (testosterone enanthate injection). Product Information. Indevus Pharmaceuticals, Inc. 2007. http://www.endo.com/pdf/products/Delatestryl_PI.pdf

Fortesta (testosterone gel). Product Information. Endo Pharmaceuticals. 2010. http://www.endo.com/pdf/products/fortesta_pi.pdf

Axiron (testosterone). Product Information. Lilly USA. 2010. <http://pi.lilly.com/us/axiron-pi.pdf>