

## ANDROGENS UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Androgens

**Generic (Brand) NAMES:**

- Fluoxymesterone (Androxy<sup>®</sup>)
- Methyltestosterone (Android<sup>®</sup>, Methitest<sup>®</sup>, Testred<sup>®</sup>)
- Testosterone, topical (e.g., Androderm<sup>®</sup>, Androgel<sup>®</sup>, Testim<sup>®</sup>, Fortesta<sup>®</sup>, Axiron<sup>®</sup>)
- Testosterone, buccal (Striant<sup>®</sup>)
- Testosterone cypionate (e.g., Depo-Testosterone<sup>®</sup>)
- Testosterone enanthate (e.g., Delatestryl<sup>®</sup>)

**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:**

- **Males for the treatment of hypogonadism (low testosterone):**
  - patient has symptoms of androgen deficiency **AND**
  - has a baseline (pre-treatment) morning serum total testosterone level of less than or equal to 300 ng/dL (less than 10.4 nmol/L) **OR**
  - baseline morning serum free testosterone level, measured by the equilibrium dialysis method, of less than or equal to 50 pg/ml (0.17 nmol/liter), **OR**
- **For palliative treatment of metastatic inoperable breast cancer**
- **Males with delayed puberty**

**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:**

Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism*, doi:10.1210/jc.2005-2847. 2010. 91 (6); 1995-2010.

Drug Facts and Comparisons 4.0. Wolters Kluwer. 2009. (methyltestosterone, other androgens)

Testim (testosterone gel 1%). Product Information. Auxilium Pharmaceuticals, Inc. 2009. [http://www.testim.com/pdf/20090918\\_Testim\\_PI\\_DPT\\_FDA\\_approved.pdf](http://www.testim.com/pdf/20090918_Testim_PI_DPT_FDA_approved.pdf)

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

AndroGel (testosterone gel 1%). Product Information. Solvay Pharmaceuticals, Inc. 2009 [http://www.androgel.com/pdf/500122-500127\\_Rev\\_1E\\_Sep\\_2009\\_FPI\\_with\\_MedGuide.pdf](http://www.androgel.com/pdf/500122-500127_Rev_1E_Sep_2009_FPI_with_MedGuide.pdf)

Androxy (fluoxymesterone). Product Information. Upsher-Smith Laboratories, Inc. 2004. <http://www.drugs.com/pro/androxy.html>

Striant (testosterone buccal system). Product Information. Columbia Laboratories, Inc. 2004. [http://striant.com/Professional/prescribing\\_info/58816-10\\_Striant\\_full\\_PI\\_4pager.pdf](http://striant.com/Professional/prescribing_info/58816-10_Striant_full_PI_4pager.pdf)

Depo-Testosterone (testosterone cypionate injection). Product Information. Pharmacia. 2002. [http://www.pfizer.com/files/products/uspi\\_depo\\_testosterone.pdf](http://www.pfizer.com/files/products/uspi_depo_testosterone.pdf)

Delatestryl (testosterone enanthate injection). Product Information. Indevus Pharmaceuticals, Inc. 2007. [http://www.endo.com/pdf/products/Delatestryl\\_PI.pdf](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](http://www.endo.com/pdf/products/fortesta_pi.pdf)

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