Pharmacy Policy Bulletin

Category:	Prior Authorization
Number:	J-98
Subject:	Testosterone (Androgens)
Effective Date Begin:	December 3, 2008
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Policy Applies to: *Commercial* and *Medicare* plans

Background:

This policy pertains to the testosterone products categorized as androgens which include: testosterone propionate, testolactone (Teslac®), testosterone enanthate (Delatestryl®) testosterone cypionate (Depo-Testosterone®), testosterone pellets (Testopel®) testosterone buccal (Striant™), testosterone transdermal (Testoderm®, Testoderm® TTS, Androderm®), testosterone gel (AndroGel® and Testim®), methyltestosterone (Android®, etc.), and fluoxymesterone (Halotestin®, etc.).

Testosterone, the primary androgen produced in the testes, is responsible for a variety of physiologic functions that include: the normal growth and development of male sex organs, maintenance of secondary sex characteristics, stimulating and maintaining sexual function in men, the growth spurt of that seen in adolescence, increasing lean body mass and weight, increasing the formation of clotting factors in the liver, and stimulating the production of red blood cells. Anabolic steroids, products closely related to or derived from testosterone, also possess the same pharmacologic functions as that of the androgens; however, have a much higher ratio of nitrogen-containing properties to increase muscle mass. Depending upon the formulation, testosterone has been shown to have a variable effect on lipid changes.

Androgens are used to treat primary (hypergonadotropic) hypogonadism (i.e. Klinefelter's syndrome, certain androgen resistance syndromes responsive to high dose testosterone and myotonic dystrophy), secondary (hypogonadotropic) hypogonadism (i.e. Kallmann's & related syndromes, Prader-Willi syndrome, pituitary disorders, and AIDS wasting disorders), delayed puberty in males, metastatic, inoperable breast cancer in females and vulvar dystrophies in females (*testosterone ointment)*.

Androgens in some instances have been used to enhance athletic performance. Athletes are motivated to use these products to increase muscle mass and strength, decrease muscle recovery time to allow more frequent weight training, decrease healing time after muscle injury and increase aggressiveness.

In addition to athletic performance, there is emerging information about the use of androgens for the treatment of andropause in aging men. Recent clinical trials support the view that an age-related decline in testicular function is associated with symptoms of

men. Recent clinical trials support the view that an age-related decline in testicular function is associated with symptoms of decreased libido, impotence, decreased muscle mass, fatigue, increased risk of myocardial infarction, and decreased bone mass in conjunction with osteoporosis. Short-term studies have shown that replacement therapy may restore body weight and lean muscle mass, increase hematocrit, decrease biochemical indexes of bone turnover and decrease LDL. To date, there are no long-term studies evaluating the testosterone replacement therapy in aging men with hypogonadism. The exact benefit of testosterone replacement therapy in aging men remains to be defined.

Approval Criteria: When a benefit, androgens will be approved for the following treatment conditions:

1. Primary or secondary hypogonadism in males who have documented testosterone deficiency as defined by a total testosterone level of < 270 ng/dl OR a total testosterone level < 350 ng/dl AND a free testosterone level of < 50 pg/ml or < 9 nmol/L.
2. Delayed puberty in males ≥ 15 years of age with either physical or laboratory evidence of hypogonadism (total testosterone level of < 270 ng/dl OR a total testosterone level < 350 ng/dl AND a free testosterone level of < 50 pg/ml or < 9 nmol/L).
3. Vulvar dystrophies in women (topical ointment only)
4. Palliative treatment in female patients with metastatic breast cancer

Androgens are not indicated for male contraception and will not be approved for this diagnosis. For patients with acquired hypogonadotropic hypogonadism with reduced libido and impotence, prolactin levels should be evaluated. Testosterone-containing products will not be approved for untreated hyperprolactinemia.

Duration of Authorization:

If approved, up to a lifetime authorization may be granted.

References:

1. American Association of Clinical Endocrinologists Medical Guidelines For Clinical Practice For the Evaluation And Treatment of Hypogonadism in Adult Male Patients—2002 Update. *Endocrine Practice*. 2002 Nov/Dec; 8(6).
2. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in adult men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2006 Jun; 91(6):1995-2010.
3. Wood AJ. Androgens in Men – Uses and Abuses. *New England Journal of Medicine*. 2003; 334(11): 707-14.
4. Drug Facts and Comparisons®. St. Louis MI: Facts and Comparisons, 2002.
5. American Association of Clinical Endocrinologists Medical Guidelines For Clinical Practice For the Evaluation And Treatment of Male Sexual Dysfunction: A Couple's Problem—2003 Update. *Endocrine Practice*. 2003 Jan/Feb; 9(1).

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