



Therapeutic Class ReviewSM

Topical/Buccal Testosterone Replacement Products

March 2005

New Product for Review

testosterone gel 1% (AndroGel[®]) [Unimed/Solvay]
 testosterone gel 1% (Testim[™]) [Auxilium]
 testosterone transdermal system (Androderm[®]) [Watson]
 testosterone buccal system (Striant[®]) [Columbia]

Dossier Provided by Manufacturer:

Dossier: yes
Dossier: yes
Dossier: requested -- Not received
Dossier: requested -- Not received

Available Therapeutic Alternative(s)

Preferred/Formulary	Non-Preferred/Non-Formulary
None*	None

*Testosterone injectable products are generally covered under the medical benefit

Executive Summary

- The American Association of Clinical Endocrinologists hypogonadism guidelines recommend maintaining serum testosterone within the physiological limits during testosterone replacement therapy (TRT).
- All testosterone analogues, such as gels, transdermal patches or buccal adhesive tablets, can rapidly restore and maintain serum testosterone levels within the recommended physiological limits. However, TRT with intramuscular injections is associated with abnormal fluctuations in serum testosterone.
- TRT increases the lean muscle mass, muscle strength, bone mineral density, and improves certain sexual parameters in hypogonadal men. However, there are no long-term, placebo controlled clinical trials to determine the medical value and the potential risks of TRT.
- All testosterone products cause varying degrees of polycythemia, prostate enlargement and elevate the prostate specific antigen. However, there is no evidence that TRT using any delivery system increases the incidence adverse health outcomes in hypogonadal men.
- Testosterone transdermal patches cause more skin reactions than gel formulations. Testosterone gels carry minimal risk of virilization of a female partner through dermal transfer. However, some patients do not prefer the musky odor of Testim. The buccal adhesive testosterone tablets often dislodge and are

swallowed. These tablets also cause gum irritation, have bitter taste, and its long-term effects on oral mucosa is unknown.

- AndroGel, Testim, Androderm, and Striant have similar clinical efficacy. However, there is no evidence that these new products offer any superior clinical benefit over injectable testosterone products.

Conclusions

AndroGel, Testim, Androderm and Striant are non-formulary/non-preferred because:

- There is no evidence that TRT provides an overall medical value in health outcomes.
- These products do not offer superior clinical benefits over injectable testosterone products.

Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	AWP Cost*	Potential Off-Label Use(s)
testosterone (AndroGel®), 1% gel	02/28/2000	All products listed in this table are indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: 1) <u>Primary hypogonadism (congenital or acquired)</u> : testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone levels and gonadotropins (FSH, LH) above the normal range. 2) <u>Hypogonadotropic hypogonadism (congenital or acquired)</u> : idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range.	Transdermal	\$7.0 for 50 mg <i>\$210 per month</i>	To improve muscle strength, mobility and quality of life in elderly. ^[1, 2] To treat refractory depression. ^[3, 4] To improve cognitive function. ^[5] To increase bone mineral density in elderly. ^[6, 7] To improve angina threshold. ^[8]
testosterone (Testim™), 1% gel	10/31/2002		Transdermal	\$7.4 for 50 mg <i>\$222 per month</i>	
testosterone transdermal (Androderm®) 2.5 and 5mg patches	09/29/1995		Transdermal	\$6.6 for 1 patch (5 mg/24 hours) <i>\$198 per month</i>	
testosterone buccal (Striant®) 30 mg tablet	06/19/2003		Buccal	\$6.6 for 60 mg (2 x 30 mg) <i>\$198 per month</i>	

*AWP (average wholesale price) based on First Data Bank as of January 10, 2005. Indicated price is for one-month supply

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