



Adult Male Testosterone Therapy Medical Policy

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April 20, 2016

Presentation Objectives

- To provide **background information** relevant to testosterone therapies for adult males
- To present the proposed **medical policy** for **testosterone therapy**

Background Information

Available Testosterone Therapies

Name	Market Entry	Indications	Restrictions
Delatestryl (enanthate)	12/1953	Primary H; Hypogonadotropic H; Delayed Puberty; Metastatic Breast Cancer	LOH not studied
Depo-Testosterone (cypionate)	07/1979	Primary H; Hypogonadotropic H	LOH not studied; not <18
AndroDerm (patch)	09/1995	Primary H; Hypogonadotropic H	LOH not studied; not <18
AndroGel 1% (gel)	02/2000	Primary H; Hypogonadotropic H	LOH not studied; not <18
Testim (gel)	10/2002	Primary H; Hypogonadotropic H	LOH not studied; not <18
Striant (buccal system)	06/2003	Primary H; Hypogonadotropic H	LOH not studied; not <18
Axiron (topical solution)	11/2010	Primary H; Hypogonadotropic H	LOH not studied; not <18
Fortesta (gel)	12/2010	Primary H; Hypogonadotropic H	LOH not studied; not <18
AndroGel 1.62% (gel)	04/2011	Primary H; Hypogonadotropic H	LOH not studied; not <18
Vogelxo (gel)	06/2014	Primary H; Hypogonadotropic H	LOH not studied; not <18

H: hypogonadism. Hypogonadotropic hypogonadism is sometimes referred to as secondary hypogonadism.

Medical Policy

Medical Policy: TRT for Adult Males

Testosterone Replacement Therapy (TRT) may be considered medically necessary for the treatment of hypogonadism when the patient meets the following criteria:

INCLUSION CRITERIA

1. Patient is male, 18 years of age or older; **AND**

2. Patient has had **TWO** morning tests (between 8 a.m. to 10 a.m.), at least 1 week apart but no more than 3 months apart, demonstrating low testosterone levels. The second test should be done after excluding other causes of low testosterone such as reversible illnesses, drugs, and nutritional deficiencies. Low testosterone levels are defined as below the normal range for the reference lab / assay used or below the values proposed by the Endocrine Society Guidelines:
 - a. Total serum testosterone level < 300ng/dL (10.4nmol/L); **OR**
 - b. Total serum testosterone level < 350ng/dL (12.1nmol/L) **AND** free serum testosterone level < 50pg/mL (or 0.174nmol/L)

1.) Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM; Task Force, Endocrine Society. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010 Jun;95(6):2536-59.

2.) Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM. 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

Medical Policy: TRT for Adult Males

3. Patient has received **ONE** of the following diagnoses:

a. Primary Hypogonadism

Defined as low testosterone, elevated FSH and LH, and testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, or Klinefelter's syndrome

b. Hypogonadotropic Hypogonadism

Defined as low testosterone due to such conditions as idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors or radiation

c. HIV-associated weight loss

Defined as HIV-associated weight loss is defined as $< 90\%$ of ideal body weight or weight loss of $> 10\%$ in the last 6 months

d. Chronic high-dose glucocorticoid therapy

Defined as more than 5mg/day of prednisone or equivalent daily for greater than six (6) months as part of a treatment regimen for a separate documented medical condition

e. Men less than 50 years of age with osteoporosis (T-score < -2.5) or with low trauma fractures

Medical Policy: TRT for Adult Males

EXCLUSION CRITERIA

1. Patient has **ANY** of the following contraindications or other precautions:
 - a. Breast cancer or known or suspected prostate cancer
 - b. Elevated hematocrit (>50%)
 - c. Untreated severe obstructive sleep apnea
 - d. Severe lower urinary tract symptoms
 - e. Uncontrolled or poorly-controlled heart failure

2. Patient has experienced a major cardiovascular event (such as myocardial infarction, stroke, acute coronary syndrome) in the past six months

3. Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or is at higher risk of prostate cancer, such as elevation of PSA after initiating TRT

4. Testosterone is being prescribed for late-onset hypogonadism (also known as age-related hypogonadism) or for sexual dysfunction

1.) Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM; Task Force, Endocrine Society. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2010 Jun;95(6):2536-59.

3.) Testosterone enanthate injection [prescribing information]. Eatontown,NJ: West-Ward Pharmaceutical; July 2014.

Medical Policy: TRT for Adult Males

PRIOR AUTHORIZATION APPROVAL DURATION AND LIMITS

Patients meeting the criteria above may receive TRT. Approved medications are listed in Table 1 on the following slide (slide 10). Quantity level limits are listed along with each product.

Approval is for one (1) year except for patients who meet the diagnosis criteria for (3c) HIV-associated weight loss or for (3d) chronic high-dose glucocorticoid therapy.

- For men with HIV-associated weight loss, the approval is set for 6 months.
- For men receiving chronic high-dose glucocorticoid therapy, the approval is set for the expected duration of chronic high-dose glucocorticoid therapy with a maximum of one (1) year.

Patient must try and fail at least one injectable and at least one transdermal testosterone therapy before being eligible for methyltestosterone therapy.

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Table 1. Quantity Level Limits for Testosterone Replacement Therapy in Adult Males

Name	Dosage Form	Strength	Quantity Level Limit
Androderm	transdermal patch	2mg	60 patches per 30 days
		2.5mg	60 patches per 30 days
		4mg	30 patches per 30 days
		5mg	30 patches per 30 days
AndroGel	gel packet (2.5g)	1%	300g (4x75g) per 30 days
	gel packet (5g)	1%	150g (2x75g) per 30 days
	gel pump	1%	300g (4x75g) per 30 days
AndroGel	gel packet (1.25g)	1.62%	37.5 (30 packets) per 30 days
	gel packet (2.5g)	1.62%	150g (60 packets) per 30 days
	gel pump	1.62%	150g (2x75g) per 30 days
Axiron	topical solution	30mg	180mL (2x90mL) per 30 days
Fortesta	gel	2%	120g (2x60g) per 30 days
Striant	buccal system	30mg	60 systems per 30 days
Testim	gel	1%	300g (2x5g tubes/day) for 30 days
Vogelxo	gel packet	1%	300g (4x75g) per 30 days
	gel pump	1%	300g (60x5g tubes) per 30 days
Depo-Testosterone (cypionate)	injectable solution	100mg/mL	400mg per 28 days
		200mg/mL	400mg per 28 days
Delatestryl (enanthate)	injectable solution	200mg/mL	400mg per 28 days
Methitest (methyltestosterone)	oral	10mg	150 tablets per 30 days
Android (methyltestosterone)	oral	10mg	150 tablets per 30 days
Testred (methyltestosterone)	oral	10mg	150 tablets per 30 days

Note: Testopel (implanted pellets) is excluded from this policy and is covered under medical benefit

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Questions?

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Works Cited

1. Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM; Task Force, Endocrine Society. Testosterone therapy in men with androgen deficiency syndromes: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2010 Jun;95(6):2536-59.
2. Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS, Montori VM. 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. Testosterone enanthate injection [prescribing information]. Eatontown, NJ: West-Ward Pharmaceutical; July 2014.