Androgenic Agents –
Testosterone Replacement Therapy (TRT)

WA.PHAR.28 Androgenic Agents- Testosterone Replacement Therapy (TRT)

Effective: July 1, 2018

Background:

The Food and Drug Administration (FDA) approved testosterone products for testosterone replacement therapy in males with primary hypogonadism (congenital or acquired) or hypogonadrotropic hypogonadism (congenital or acquired). Primary hypogonadism originates from a deficiency or disorder in the testicles. Secondary hypogonadism indicates a problem in the hypothalamus or the pituitary gland.

Medical necessity

Drug	Medical Necessity
Testosterone • Androderm (Transdermal patch, ER) • AndroGel (Topical gel) • Axiron (Topical solution) • Fortesta (Topical gel) • Nastesto (Nasal gel) • Striant (Buccal patch, ER) • Testim (Topical gel) • Vogelxo (Topical gel) **Methyltestosterone** • Android (Oral capsule) • Methitest (Oral tablet) • Testred (Oral capsule) • generic (Oral capsule) **Testosterone Enanthate** • Delatestryl (IM Injection) • generic (IM injection) **Testosterone Cypionate** • Depo-Testosterone (IM Injection) • generic (IM injection)	Testosterone replacement therapy (TRT) may be considered medically necessary when used for the following conditions: • Primary Hypogonadism (congenital or acquired) • Hypogonadotropic Hypogonadism (congenital or acquired) • HIV-associated weight loss • Chronic, high-dose glucocorticoid-therapy • Men with osteoporosis or young men with low trauma fractures • Delayed Puberty • Metastatic Breast Cancer • Transgender Health

Clinical policy:

Clinical Criteria

Testosterone Replacement Therapy for Adult Males	*Testosterone Replacement Therapy (TRT) may be considered medically necessary for the treatment of hypogonadism when the patient meets criteria 1–3 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. Quantity and dispensing limits are listed in Table 1. (Documentation from the patient's chart is REQUIRED):* **INCLUSION CRITERIA** 1. Patient is male, 18 years of age or older; **AND** 2. Patient has had **TWO** morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) at baseline demonstrating low testosterone levels as defined by the following criteria: **a.** Total serum testosterone level less than 300ng/dL (10.4nmol/L); **OR** b. Total serum testosterone level less than 350ng/dL (12.1nmol/L) **AND** free serum testosterone level less than 50pg/mL (or 0.174nmol/L) c. Second morning test should follow excluding reversible illnesses, drugs, and nutritional deficiencies. Providers should also include LH and FSH draws to guide diagnosis as primary or secondary hypogonadism; AND 3. Patient has received **ONE** of the following diagnoses: a. Primary Hypogonadism (congenital or acquired): as defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; **OR** b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation; **OR** c. HIV-associated weight loss; **OR** i. 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; **OR** i. Defined as more than 5mg/day of prednisone or equivalent daily for greater than two (2) weeks e. Men with osteoporosis or young men with low trauma fractures **EXCLUSION CRITERIA** *1.* Patient has **ANY** of the following contraindications: 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 a myocardial infraction, stroke, acute coronary syndrome) in the past six months 3. Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating TRT **PRIOR AUTHORIZATION APPROVAL DURATION AND LIMITS** • Patients meeting the criteria above may receive TRT. Approved medications are listed in Table 1. Quantity level limits are listed along with each product. • Approval is for one (1) year except for patients who met the diagnosis criteria for (c) HIV-associated weight loss or (d) men receiving chronic, high-dose glucocorticoid-therapy. • For men who meet criterion (c) HIV-associated weight loss, the approval is set for 6 months. • For men who meet criterion (d) men receiving chronic, high-dose glucocorticoid-therapy, the approval is set upon the expected regimen of chronic, high-dose glucocorticoid-therapy with a maximum of one (1) year. **Criteria (Reauthorization)** Testosterone may be continued when **ALL** of the following are met: 1. Patient continues to meets criteria 1 and 3 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. 2. Patient has documentation of positive clinical response for one of the diagnosis listed above
Testosterone for use in Delayed Puberty	*Testosterone Therapy may be considered medically necessary for treatment of delayed puberty when the patient meets criteria 1–3 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. The treatment recommendations follow this policy. (Documentation from the patient's chart is REQUIRED):* **INCLUSION CRITERIA** *1.* Patient is male, 14 years of age or older; **AND** a. Under very severe and unusual circumstances, the patient may be under 14 years of age with documentation on why the patient cannot wait until 14 years of age for the treatment of delayed puberty ***2.*** Patient has received the diagnosis of delayed puberty that is **NOT** secondary to a pathological cause; **AND** a. Diagnosis should include family history to demonstrate familial delayed puberty b. Provider should obtain random measurements of serum LH, FSH, and testosterone to support diagnosis

	3. Patient must try and fail "watchful waiting" with reassurance and psychological support a. Failure of "watchful waiting" may be demonstrated by psychological concerns about delayed puberty and cannot be addressed by reassurance and psychological support alone **EXCLUSION CRITERIA** 1. Patient has **ANY** of the following contraindications: 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 a myocardial infarction, stroke, acute coronary syndrome) in the past six months 3. Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or are at higher risk of prostate cancer, such as elevation of PSA after initiating TRT **Criteria (Reauthorization)** Testosterone may be continued when **ALL** of the following are met: **1.** Patient continues to meet criteria 1–3 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. **2.** Patient has documentation of positive clinical response
Testosterone for use in Metastatic Breast Cancer	*Testosterone therapy may be considered medically necessary for treatment of metastatic breast cancer when the patient meets criteria 1–4 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. The treatment recommendations follow this policy. (Documentation from the patient's chart is REQUIRED):* **INCLUSION CRITERIA** *1.* Patient is female, 18 years of age or older; **AND** ***2.*** Patient has received a diagnosis of advancing, inoperable metastatic breast cancer; **AND** ***3.*** Patient is 1 to 5 years postmenopausal **OR** is premenopausal and has demonstrated benefit from oophorectomy and has a hormone-responsive tumor; **AND** *4.* Testosterone treatment is considered secondarily to failure of first-line therapies and is being prescribed by oncologist with expertise in the field **EXCLUSION CRITERIA** 1. Patient has **ANY** of the following contraindications: a. Elevated hematocrit (>50%)

	b. Untreated severe obstructive sleep apnea c. Severe lower urinary tract symptoms d. Uncontrolled or poorly-controlled heart failure 2. Patient has experienced a major cardiovascular event (such as a myocardial infarction, stroke, acute coronary syndrome) in the past six months **Criteria (Reauthorization)** Testosterone may be continued when **ALL** of the following are met: **1.** Patient meets criteria 1–4 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. **2.** Patient has documentation of positive clinical response
Testosterone Hormone Replacement Therapy [Transgender Health]	*The intent of this section is to describe an existing medical benefit where testosterone is used as hormone replacement therapy (HRT) as covered under Transgender Health. Pharmacists may process claims for testosterone therapy as an expedited authorization (EA) during the following circumstances when:* **INCLUSION CRITERIA** ***1.*** Patient identifies as a female-to-male (FTM); **AND** *2.* Patient has received the diagnosis of gender dysphoria as defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria by a licensed behavioral health practitioner, **OR** a licensed physician, advanced registered nurse practitioner (ARNP), physician's assistant (PA), or psychologist who is treating the patient for primary care or transgender services who is continuing to treat the patient with a comprehensive patient-centered treatment plan **AND** demonstrates that gender dysphoria is not due to another mental or physical health conditions Testosterone for HRT should be prescribed under the following guidelines for provider to follow as part of standard of practice: ***1.*** Provider has documentation that the patient has the capacity to make fully informed decisions and consents for the treatment of gender dysphoria; **AND** ***2.*** Provider prescribing hormone replacement therapy must meet the following criteria; **AND** a. Meet the requirements of professional licensure and practice according to the scope of practice for their license; **AND** b. Demonstrate specialized competencies in managing hormone therapies for gender dysphoria (including documentation of supervised training or mentoring by a more experienced physician); **AND**

	c. Follow the standards of care for the health of transgender, transsexual and gender-nonconforming people outlined by the World Professional Association for Transgender Health (WPATH) *3.* Patient does not have any of the following contraindications or other precautions: a. Breast cancer b. Elevated hematocrit (>50%) c. Untreated severe obstructive sleep apnea d. Severe lower urinary tract symptoms e. Uncontrolled or poorly-controlled heart failure f. Experienced a major cardiovascular event (such as an MI, stroke, acute coronary syndrome) in the past six months g. Is intending on using testosterone therapy for the indications of testosterone replacement therapy, delayed puberty, or for metastatic breast cancer.
	Criteria (Reauthorization)
	Documentation of positive clinical response **Approval for 12 months**

Table 1

Dosage and quantity limits

Name	Dosage Form	Strength	Quantity Level Limit
Androderm	transdermal patch	2mg	#60 patches per 30-days
		4mg	#30 patches per 30-days
AndroGel	gel packet (2.5g)	1%	300g (4x75g) per 30-days
	gel packet (5g)	1%	300g (2x150g) per 30-days
	gel pump	1%	300g (4x75g) per 30-days
AndroGel	gel packet (1.25g)	1.62%	37.5g (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 buccal systems per 30-days
Testim	gel	1%	300g (60x5g) per 30-days
Vogelxo	gel packet	1%	300g (4x75g) per 30-days
	gel pump	1%	300g (60x5g) 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

Coding:

HCPCS Code	Description
J3130	Injection, testosterone enanthate, up to 200 mg
J1071	Injection, testosterone cypionate, 1 mg

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