Testosterone

Included Products: Androgel 1% (testosterone 1% gel), Androgel (testosterone gel 1.62% pump), Aveed (testosterone undecanoate), Testim (testosterone 1% gel), Vogelxo (testosterone 1% gel)

Aveed nonformulary for outpatient benefit. PA required on medical benefit.

Created: 07/28/2008 *Revised:* 11/09/23 *Reviewed:* 11/09/23 *Updated:* 12/01/2023

AIDS Wasting Syndrome

Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of AIDS wasting syndrome, defined by an involuntary loss of more than 10 percent of body weight?	Continue to #2.	Do not approve.
2.	Is there chart note documentation of at least one of the following: 1) trial and failure of injectable testosterone, 2) an accepted reason to avoid injections, or 3) contraindication to injectable testosterone?	Continue to #3.	Do not approve.
3.	Approve for lifetime.		

Breast Cancer

Initial Criteria		If yes	If no
1.	Is testosterone being used for the palliation of inoperable metastatic (skeletal) mammary cancer in a member who is 1 to 5 years postmenopausal?	Continue to #2.	Do not approve.
2.	Is there chart note documentation of at least one of the following: 1) trial and failure of injectable testosterone, 2) an accepted reason to avoid injections, or 3) contraindication to injectable testosterone?	Continue to #3.	Do not approve.
3.	Approve for lifetime.		

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Gender Dysphoria

Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of gender dysphoria?	Continue to #2.	Do not approve.
2.	Approve for lifetime.		

Hypogonadism

Initial Criteria		If yes	If no
1.	Is the member male and 18 years of age or older?	Continue to #2.	Do not approve.
2.	Does the member have one of the following hypogonadism 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.	Continue to #3.	Do not approve.
3.	Does the member have 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	Do not approve.	Continue to #4.
4.	Has the member experienced a major cardiovascular event (such as a myocardial infraction, stroke, acute coronary syndrome) in the past six months?	Do not approve.	Continue to #5.

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5.	Does the member have uncontrolled or poorly controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating testosterone replacement therapy?	Do not approve.	Continue to #6.
6.	Is the member new to CareOregon and already receiving testosterone replacement for at least 6 months or an existing member with documented use of testosterone replacement for at least 6 months?	Continue to #8.	Continue to #7.
7.	Has the member 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).	Continue to #8.	Do not approve.
8.	Is there chart note documentation of at least one of the following: 1) trial and failure of injectable testosterone, 2) an accepted reason to avoid injections, or 3) contraindication to injectable testosterone?	Continue to #9.	Do not approve.
9.	Approve for lifetime.		