Androgens with Quantity

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Treatment of delayed puberty: 6 months; For continuation of therapy documentation of bone age and effects of treatment on epiphyseal growth centers must be provided at time of request. All other diagnoses: 1 year

Medication	Strengths	Quantity Limit
Androderm	2 mg patch	1 patch per day
	2.5 mg patch	2 patches per day
	4 mg patch	1 patch per day
	5 mg patch	1 patch per day
AndroGel	1% (2.5 g) packet	2 packets per day
	1% (5 g) packet	1 packet per day
	1.62% pump	1 pump bottle per 30 days
	1.62% (1.25 g) packet	1 packet per day
	1.62% (2.5 g) packet	1 packet per day
Fortesta	Gel pump (10 mg per actuation)	1 pump bottle per 30 days
Natesto	5.5 mg/actuation Nasal Gel	3 pump bottles per 30 days
Jatenzo	158 mg, 198 mg capsules 237 mg capsules	4 capsules per day 2 capsules per day
Kyzatrex	100mg, 150mg, 200mg capsules	2 capsules per day
Testim	1% gel	1 tube per day
Testosterone gel	25 mg/2.5 g packet (1%)	2 packets per day
	50 mg/5 g packet	1 packet per day
	50 mg/5 g tube	1 tube per day
Testosterone 1% gel	12.5 mg/1.25 g pump	2 pump bottles per 30 days
Testosterone gel pump (generic Fortesta)	Gel Pump (10 mg per actuation) 120 pumps per bottle	1 pump bottle per 30 days
Testosterone topical solution	Topical solution (30 mg per actuation)	1 bottle per 30 days
Tlando	112.5 mg capsules	4 capsules per day
Vogelxo gel	50 mg/5 g packet	1 packet per day
	50 mg/5 g tube	1 tube per day
	1 % (12.5 mg/1.25 g) pump (60 pumps per bottle)	2 pump bottles per 30 days

APPROVAL CRITERIA

Requests for non-preferred oral or topical testosterone agents may be approved based on the following criteria, in addition to the prior authorization criteria below:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to two preferred testosterone agents.

Preferred testosterone agents: testosterone gel (generic AndroGel, generic Fortesta, generic Testim, generic Vogelxo), generic testosterone cypionate IM.

Non-preferred oral/topical testosterone agents**:** Androderm, brand AndroGel, brand Fortesta, Jatenzo, Kyzatrex, Natesto, brand Testim, testosterone topical solution, Tlando, Vogelxo.

Prior Authorization

Requests for all oral/topical testosterone agents (preferred and non-preferred) must meet the following criteria:

I. Initial requests for androgen agents for replacement therapy in the treatment of hypogonadism may be approved if the following criteria are met**:**

A. Individual is male; **AND**
B. Individual is 18 years of age or older; **AND**
C. Individual has a diagnosis of one of the following:
   1. Primary hypogonadism (defined in males as low testosterone due to primary testicular failure [originating from a problem in the testicles]; congenital or acquired), (for example, bilateral torsion, cryptorchidism, chemotherapy, Klienfelter Syndrome, orchitis, orchiectiomy, toxic damage from alcohol or heavy metals, vanishing testis syndrome, idiopathic primary hypogonadism, age-related hypogonadism [also referred to as late-onset hypogonadism]); **OR**

OR

   2. Hypogonadotropic hypogonadism, also called secondary hypogonadism (defined in males as low testosterone originating from a problem in the hypothalamus or pituitary gland; congenital or acquired), (for example, idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency pituitary-hypothalamic injury;

AND

D. Prior to starting therapy, an initial and a repeat (at least 24 hours apart) morning total testosterone level is provided to confirm a low testosterone serum level indicating one of the following:
   1. Individual is 70 years of age or younger with a serum testosterone level of less than 300 ng/dL; **OR**
   2. Individual is over 70 years of age with a serum testosterone level of less than 200 ng/dL;

AND

E. Individual presents with symptoms associated with hypogonadism, such as but not limited to the following:
    1. Reduced sexual desire (libido) and activity; **OR**
    2. Decreased spontaneous erections; **OR**
    3. Breast discomfort/gynecomastia; **OR**
    4. Loss of body (axillary and pubic) hair, reduced shaving; **OR**
    5. Very small (especially <5 mL) or shrinking testes; **OR**
    6. Inability to father children or low/zero sperm count; **OR**
    7. Height loss, low trauma fracture, low bone mineral density; **OR**
    8. Hot flushes, sweats; **OR**
    9. Other less specific signs and symptoms including decreased energy, depressed mood/dysthymia, irritability, sleep disturbance, poor concentration/memory, diminished physical or work performance.

Requests for continuation of therapy with androgen agents for replacement therapy in the treatment of hypogonadism may be approved if the following criteria are met:

I. Individual met all diagnostic criteria for initial therapy; **AND**
II. Individual has had serum testosterone level measured in the previous 180 days; **AND**
III. Individual has obtained clinical benefits as noted by symptom improvement.

Androgen agents for the treatment of hypogonadism may not be approved for the following:
I. Untreated obstructive sleep apnea (OSA); **OR**
II. Polycythemia as defined by hematocrit greater than 48% and 50% for men living at higher altitudes (Bhasin et al, 2018); **OR**
III. Severe congestive heart failure (CHF); **OR**
IV. Known, suspected, or history of prostate cancer unless individual has undergone radical prostatectomy, or radiation therapy for prostate cancer was organ-confined, has been disease free for two (2) years and has an undetectable prostate-specific antigen (PSA) level (such as <0.1 ng/dL); **OR**
V. Individual is trying to conceive (Mulhall JP, et al, 2018); **OR**
VII. Individual is requesting Jatenzo, Kyzatrex, or Tlando (oral testosterone undecanoate) for hypogonadal conditions, such as “age-related hypogonadism”, that are not associated with structural or genetic etiologies.

FDA-approved products: testosterone gel (AndroGel/AndroGel Pump, Fortesta, Testim, Vogelxo, Testosterone Gel tube/packet, Testosterone Pump), transdermal testosterone (Androderm),) testosterone solution, testosterone nasal gel (Natesto), testosterone undecanoate (Jatenzo, Kyzatrex, or Tlando).

Requests for testosterone agents for gender dysphoria/incongruence individuals may be approved if the following criteria are met:

I. Individual has experienced puberty to at least Tanner Stage 2; **AND**
II. Individual has a diagnosis of gender dysphoria/incongruence.

Appropriate agents: Testosterone gel (AndroGel/AndroGel Pump, Fortesta, Testim, Vogelxo, Testosterone Gel tube/packet, Testosterone Pump), transdermal testosterone (Androderm), testosterone solution, testosterone nasal gel (Natesto) (Endocrine Society, 2009).

Notes:

1. Testosterone gel and transdermal testosterone have not been evaluated clinically in males younger than 18 years of age
2. Androgens may be used to stimulate puberty in carefully selected males. In males with clearly delayed puberty, brief treatment with conservative doses of testosterone may occasionally be justified.
3. Testosterone topical gel has a black box warning for secondary exposure to testosterone due to direct skin contact. Virilization has been reported in children who were secondarily exposed to testosterone gel. Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel.
4. Jatenzo, Kyzatrex, and Tlando have a black box warning regarding possible blood pressure increases that can lead to major adverse cardiovascular events (MACE). Prior to initiation, baseline cardiovascular risk should be assessed and blood pressure should be adequately controlled. New onset hypertension or exacerbation of existing hypertension should be cause for re-evaluation of risk versus benefit for continuation of therapy. Due to this risk, Jatenzo, Kyzatrex, or Tlando should only be used for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.

Requests for quantities greater that the allowed limits may be approvable under the following criteria for each medication:

I. **Natesto (testosterone nasal gel)**
A. 5.5 mg/0.122 g
1. Other diagnoses or greater quantities will be sent for physician review.

II. **Testosterone (testosterone gel)**
a. 1% 25 mg/2.5 g packet
1. #90 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 2 packets per day.
2. Renewal of #90 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

B. 50 mg/5 g packet
1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

C. 50 mg/5 g tube
1. #60 of the tubes per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 tube per day.
2. Renewal of #60 tubes per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

D. 1% Pump

1. Up to #8 pumps per day (4 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
2. Renewal of #8 pumps per day (4 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

E. 10 mg/actuation Pump
1. #120 g (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
2. Renewal of #120 g (2 bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

III. **Testosterone** (solution)

a. 30 mg/actuation solution
1. #180 mL (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #2 pumps per day.
2. Renewal of #180 mL (2 bottles) per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

IV. **Vogelxo (testosterone gel)**

A. 50 mg/5 g packet
1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

B. 50 mg/5 g tube
1. #60 of the tubes per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 tube per day.
2. Renewal of #60 tubes per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

C. 1% Pump
1. Up to #8 pumps per day (4 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
2. Renewal of #8 pumps per day (4 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

V. **Androderm (testosterone transdermal system)**

A. 2 mg and 4 mg

1. #30 of the 2mg **AND** #30 of the 4mg patches per 30 days may be approved for a total of 6 mg daily, if the serum testosterone is below normal range after at least 30 days of therapy on lower dose.
2. Renewal of #30 of the 2mg **AND** #30 of the 4mg patches per 30 days may be approved for a total of 6 mg daily may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

B. 2.5 mg
1. #90 transdermal patches per 30 days may be approved if the serum testosterone is below normal range while on 5mg daily.
2. Renewal of #90 transdermal patches per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

VI. **Androgel (testosterone gel)**

A. 1% 2.5 gm
1. #90 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 2 packets per day.
2. Renewal of #90 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

B. 1% 5 gm
1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

C. 1.62% 1.25 gm
1. #90 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #90 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

D. 1.62% 2.5 gm
1. #60 of the packets per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 packet per day.
2. Renewal of #60 packets per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

E. 1.62% Pump
1. Up to #4 pumps per day (2 pump bottles per 30 days) may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #2 pumps per day.

2. Renewal of #4 pumps per day (2 pump bottles per 30 days) may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

VII. Testim (testosterone gel)

A. 5 gm
1. #60 tubes per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with 1 tube per day.
2. Renewal of #60 tubes per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

VIII. Fortesta (testosterone gel)

A. 10 mg/actuation gel
1. #120 g (2 bottles) per 30 days may be approved if the serum testosterone is below normal range after at least 30 days of therapy with #4 pumps per day.
2. Renewal of #120 g (2 bottles) per 30 days may be approved if the provider has evaluated use of this dose and has determined that continuation of the current dose is appropriate for the individual.
3. Other diagnoses or greater quantities will be sent for physician review.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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