PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2015
LAST REVIEW DATE: 5/19/2022
LAST CRITERIA REVISION DATE: 5/19/2022
ARCHIVE DATE:

TESTOSTERONE REPLACEMENT THERAPY:
ANDRODERM® transdermal patch
ANDROGEL® pump transdermal gel and transdermal gel
FORTESTA® transdermal gel
JATENZO® (testosterone undecanoate) oral capsule
METHITEST™ (methyltestosterone) oral tablet
Methyltestosterone oral capsule
NATESTO™ nasal gel
TESTIM® transdermal gel
Testosterone pump transdermal gel and transdermal gel
TLANDO™ (testosterone undecanoate) oral capsule
VOGELXO® pump transdermal gel and transdermal gel
XYOSTED™ (testosterone enanthate) solution auto-injector

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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TESTOSTERONE REPLACEMENT THERAPY

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

ANDRODERM® transdermal patch
ANDROGEL® pump transdermal gel and transdermal gel
FORTESTA® transdermal gel
METHITEST™ (methyltestosterone) oral tablet
Methyltestosterone oral capsule
NATESTO™ nasal gel
TESTIM® transdermal gel
Testosterone pump transdermal gel and transdermal gel
VOGELXO® pump transdermal gel and transdermal gel
XYOSTED™ (testosterone enanthate) solution auto-injector

- **Criteria for initial therapy: For male individuals** Testosterone Replacement Therapy for **ALL** of the above drugs is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Urologist, HIV/AIDS Specialist, or Infectious Disease depending upon indication or use

  2. A confirmed diagnosis of **ONE** of the following:
     a. Male individual 18 years of age or older with an established diagnosis of **primary** hypogonadism who has at least **three** specific clinical signs and symptoms consistent with hypogonadism (See Definitions section) **and** has persistently low testosterone levels

b. Male individual 18 years of age or older with an established diagnosis of **hypogonadotropic** hypogonadism who has at least **three** specific clinical signs and symptoms consistent with hypogonadism (See Definitions section) **and** has persistently low testosterone levels

c. HIV-infected male individual 18 years of age or older with documented unexplained involuntary weight loss of greater than 10% baseline body weight **and** has persistently low testosterone levels

d. Male individual 18 years of age or older on chronic corticosteroid treatment (daily dose of at least 5-7.5 mg of prednisone or equivalent for at least 6 weeks) **and** has persistently low testosterone levels

e. Individual 14 years or older with delayed male puberty and pre-pubertal testis

3. Has persistently low baseline testosterone levels defined as **ONE** of the following:
   a. Total testosterone level less than the reference lab normal value on two separate occasions (copy of laboratory data must be submitted with the request), must be obtained from the same laboratory or from a laboratory using the same assay

   b. Serum free testosterone level **and** total testosterone less than reference lab normal on the same day (copy of laboratory data must be submitted with the request)

4. Androgen/testosterone deficiency diagnosis is not made during an acute or sub-acute illness

5. Documented failure, contraindication per FDA label, intolerance to **Testim (brand or generic)** (documentation from the prescriber must be submitted)

6. Documented failure, contraindication per FDA label, intolerance to **intramuscular testosterone injection** (documentation from the prescriber must be submitted)

7. **ALL** of the following **baseline** tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
   a. **For Methitest and methyltestosterone:** Liver function tests
   b. Male individual over age 50 years (or over age 40 years with a first-degree relative with prostate cancer or an unevaluated prostate nodule or induration or is African American) is screened for prostate cancer with **both** of the following:
      i. Digital prostate examination done within the last 12 months with continued monitoring as clinically appropriate for age, race, and risk factors for prostate cancer
      ii. Prostate specific antigen (PSA) measurement done within the last 12 months with continued monitoring as clinically appropriate for age, race, and risk factors for prostate cancer
   c. Hematocrit is within the normal range

8. Individual does not have **ANY** of the following:
   a. Palpable prostate nodule or prostate-specific antigen (PSA) greater than 4 ng/mL or PSA more than 3 ng/mL in a man at high risk of prostate cancer (such as such as African-Americans, or

those with first-degree relative with prostate cancer or an unevaluated prostate nodule or induration), unless cleared by Urological evaluation
   b. Male with other hypogonadal conditions, such as age-related hypogonadism, which are not associated with structural or genetic etiologies
   c. Hematocrit greater than laboratory normal limits
   d. Untreated severe obstructive sleep apnea
   e. Severe lower urinary tract symptoms ([AUA]/ IPSS greater than 19)
   f. Uncontrolled or poorly controlled heart failure

9. There are **NO** FDA-label contraindications, such as:
   a. Known carcinoma of the breast
   b. Known or suspected carcinoma of the prostate

Initial approval duration: 6 months

- **Criteria for initial therapy: For female individuals** Testosterone Replacement Therapy is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

2. Women with a diagnosis of metastatic / inoperable breast cancer

3. There are **NO** FDA-label contraindications, such as:
   a. Woman of childbearing potential who is pregnant or not currently using effective contraception
   b. Woman who is breast feeding an infant or child

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Testosterone product is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Urologist, HIV/AIDS Specialist, Infectious Disease, or Oncologist depending upon indication or use

2. The individual has met all of the initial criteria for Testosterone Replacement Therapy

3. The individual's condition responded while on therapy
   a. Response is defined as:
      i. For hypogonadism with clinical signs and symptoms consistent with hypogonadism
         1. Testosterone levels are within the normal range with therapy
         2. Clinical symptoms have improved
         3. Hematocrit is within laboratory normal limits

      ii. For HIV-infected male individual 18 years of age or older with documented weight loss

1. Increase in weight over baseline of 1.1-1.54 kg body weight **OR** increase 1.4 kg fat-free mass **OR** increase 1.22-1.3 kg lean body mass
2. Hematocrit is within laboratory normal limits

iii. For male individual 18 years of age or older on chronic corticosteroid treatment
1. Continues to require chronic corticosteroid therapy
2. Hematocrit is within laboratory normal limits

iv. For individual 14 years or older with delayed male puberty and pre-pubertal testis
1. Secondary male sex characteristics have developed but have not reached full development (*once fully developed, testosterone replacement therapy is no longer needed*)
2. Cryptorchidism is still present or there is evidence of small testes
3. Hematocrit is within laboratory normal limits
4. Determine bone age obtained every six months to assess the effect of treatment on the epiphyseal centers

v. For women with a diagnosis of metastatic / inoperable breast cancer
1. There is no disease progression

4. Individual has been adherent with the medication

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
   a. Contraindications as listed in the criteria for initial therapy section
   b. Significant adverse effect such as:
      i. Developed a deep vein thrombosis (DVT) or pulmonary embolism (PE)
      ii. Severe hepatotoxicity such as peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, jaundice
      iii. Hematocrit is persistently greater than laboratory normal limits

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

TESTOSTERONE REPLACEMENT THERAPY

JATENZO (testosterone undecanoate)
TLANDO (testosterone undecanoate)

- **Criteria for initial therapy: For male individuals** Jatenzo (testosterone undecanoate) or Tlando (testosterone undecanoate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist or Urologist

  2. Individual is 18 years of age or older male

  3. A confirmed diagnosis of **ONE** of the following:
     a. **Primary** hypogonadism who has at least **three** specific clinical signs and symptoms of hypogonadism (See Definitions section) **and** has persistently low testosterone levels

     b. **Hypogonadotropic** hypogonadism who has at least **three** specific clinical signs and symptoms of hypogonadism (See Definitions section) **and** has persistently low testosterone levels

  4. Has persistently low baseline testosterone levels defined as **ONE** of the following:
     a. Total testosterone level less than the reference lab normal value on two separate occasions (copy of laboratory data must be submitted with the request), must be obtained from the same laboratory or from a laboratory using the same assay

     b. Serum free testosterone level **and** total testosterone less than reference lab normal on the same day (copy of laboratory data must be submitted with the request)

  5. Androgen/testosterone deficiency diagnosis is not made during an acute or sub-acute illness

  6. Documented failure, contraindication per FDA label, intolerance to **Testim (brand or generic)** documentation from the prescriber must be submitted)

  7. Documented failure, contraindication per FDA label, intolerance to **intramuscular testosterone injection** (documentation from the prescriber must be submitted)

  8. **ALL** of the following **baseline** tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Male individual over age 50 years (or over age 40 years with a first-degree relative with prostate cancer or an unevaluated prostate nodule or induration or is African American) is screened for prostate cancer with **both** of the following:
        i. Digital prostate examination done within the last 12 months with continued monitoring as clinically appropriate for age, race, and risk factors for prostate cancer
        ii. Prostate specific antigen (PSA) measurement done within the last 12 months with continued monitoring as clinically appropriate for age, race, and risk factors for prostate cancer
     b. Hematocrit is within the normal range

c. Blood pressure is adequately controlled

9. Individual does not have **ANY** of the following:
    a. Palpable prostate nodule or prostate-specific antigen (PSA) greater than 4 ng/mL or PSA more than 3 ng/mL in a man at high risk of prostate cancer (such as such as African Americans, or those with first-degree relative with prostate cancer or an unevaluated prostate nodule or induration), unless cleared by Urological evaluation
    b. Hematocrit greater than laboratory normal limits
    c. Untreated severe obstructive sleep apnea
    d. Severe lower urinary tract symptoms ([AUA]/ IPSS greater than 19)
    e. Uncontrolled or poorly controlled heart failure

10. There are **NO** FDA-label contraindications, such as:
    a. Male with other hypogonadal conditions, such as age-related hypogonadism, which are not associated with structural or genetic etiologies
    b. Male with carcinoma of the breast
    c. Male with known or suspected carcinoma of the prostate
    d. Known hypersensitivity to drug product
    e. Woman who is pregnant

11. Individual does not use other anabolic androgenic steroids

12. Jatenzo and Tlando will not be used interchangeably or concurrently

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request): For male individuals** Jatenzo (testosterone undecanoate) or Tlando (testosterone undecanoate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist or Urologist

2. The individual has met all of the initial criteria for Jatenzo (testosterone undecanoate) or Tlando (testosterone undecanoate)

3. The individual's condition responded while on therapy
    a. Response is defined as **ALL** of the following:
        i. Testosterone levels are within the normal range with therapy
        ii. Clinical symptoms have improved
        iii. Hematocrit is within the normal range
        iv. Blood pressure is controlled

4. There is ongoing evaluation for the development of prostate cancer such as a digital rectal exam (DRE) or a prostate specific antigen (PSA) measurement done within the last 12 months with continued monitoring as clinically appropriate for age, race, and risk factors for prostate cancer

5. Individual has been adherent with the medication

6. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Myocardial infarction
        ii. Stroke
        iii. Developed deep vein thrombosis (DVT) or pulmonary embolism (PE)
        iv. Severe hepatotoxicity such as peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, or jaundice
        v. Hematocrit is persistently elevated above the normal range
        vi. New onset or worsening depression, suicidal ideation, anxiety, or other mood changes

7. Jatenzo and Tlando will not be used interchangeably or concurrently

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

Description:

Testosterone is an androgen hormone that is responsible for normal growth and maintenance of male secondary sex characteristics, stimulation and maintenance of sexual function in males, growth spurt seen in adolescents, lean body mass and weight, and other physiologic functions. Testosterone is produced in males by the testes in response to stimuli from the hypothalamic and pituitary glands. Low serum testosterone is caused by deficient production of the hormone and is also known as androgen deficiency. Other terms used to describe the clinical syndrome of low serum testosterone include testosterone deficiency syndrome, hypogonadism, late-onset hypogonadism, androgen insufficiency syndrome, andropause, Low-T, and male menopause.

Endogenous androgens, including testosterone and dihydrotestosterone (DHT), are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include the growth and maturation of prostate, seminal vesicles, penis and scrotum; the development of male hair distribution, such as facial, pubic, chest and axillary hair; laryngeal enlargement, vocal cord thickening, alterations in body musculature and fat distribution.

Male hypogonadism is a clinical syndrome resulting from insufficient secretion of testosterone, that has two main etiologies. Primary hypogonadism caused by defects of the gonads, such as Klinefelter syndrome or Leydig cell aplasia, whereas secondary hypogonadism (also known as hypogonadotropic hypogonadism) is the failure of the hypothalamus (or pituitary) to produce sufficient gonadotropins (FSH, LH).

TESTOSTERONE REPLACEMENT THERAPY

As men age there is a decrease in testosterone level and function. Cross-sectional and longitudinal studies confirm a decline of 1-2% per year. Symptoms of low testosterone may include one or more of the following: decrease in sexual activity, loss of libido or sexual interest, sexual thoughts or fantasies, erectile dysfunction, impotence, decrease in volume of ejaculate, decreased orgasmic intensity, irritability, depression and other mood disorders, nervousness, generalized weakness, loss of muscle mass and strength, osteoporosis with a potential for fractures, decrease in height, decrease in body hair, abdominal obesity, gynecomastia or breast tenderness, lack of energy, fatigue, sleep disturbances, poor ability to concentrate, and other symptoms. Expression of the clinical symptoms may vary depending upon the severity and cause of the disorder. It should be noted that androgen deficiency and erectile dysfunction are two independently distributed clinical disorders with distinct pathophysiology.

The clinical significance of age-related decline in testosterone levels remains controversial. The same sign and symptoms may also be seen with aging but without a decrease in testosterone level. Androgen supplementation is increasingly being used as a lifestyle therapy for men who are older, frail, or want to look better or feel younger and stronger. There is continued debate on whether older men, with or without androgen deficiency and symptoms of hypogonadism, will benefit from long-term testosterone replacement therapy. There are no published long-term trials using meaningful outcomes in hypogonadal men or older men with low testosterone levels. Long-term risks of replacement therapy are also unclear. Some reported risks include potential worsening of cardiovascular disease, polycythemia, increased risk for benign prostatic hypertrophy and prostate cancer, lipid disturbances such as increased LDL and reduced HDL levels, worsening of obstructive sleep apnea, and sodium and water retention. Recent published studies have suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy.

Symptoms along with measured low testosterone level may be indicative of testosterone deficiency syndrome in men. Normal total testosterone levels range from 280-300 to 1000 ng/dL and levels below 300 ng/dL typically result in symptoms. Serum free testosterone levels range is often given as 5-9 pg/mL. Testosterone levels vary from laboratory to laboratory dependent upon the type of assay used. Testing should be done in the morning, before 10 AM, due to diurnal cycle of testosterone. As men age there is a progressive decrease in both total testosterone and free testosterone levels.

Testosterone replacement therapy is primarily indicated for the treatment of male congenital or acquired hypogonadism when symptoms of hypogonadism are present along with low testosterone levels. Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone because of reasons such as genetic problems or chemotherapy. Other examples include problems with the hypothalamus and pituitary that control the production of testosterone by the testicles. None of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition. Some products have FDA approval for the treatment of delayed puberty and androgen-responsive recurrent breast cancer in women who are 1-5 years post-menopausal.

The latest 2010 clinical practice guideline from the Endocrine Society recommend that only men who have unequivocally low serum testosterone levels AND signs and symptoms consistent with low testosterone be diagnosed and treated with testosterone replacement therapy. They recommend against routine screening for testosterone deficiency in the general population and they recommend against testosterone replacement therapy in ALL older men with low testosterone levels. They also do not recommend starting testosterone replacement therapy in male patients with breast or prostate cancer or in individuals with a palpable prostate nodule or

induration or prostate-specific antigen greater than 4 ng/mL or greater than 3 ng/mL in men at high risk for prostate cancer without further urological evaluation.

Multiple formulations of exogenous testosterone are available. Testosterone replacement therapy may be delivered by mouth (including buccal and nasal formulations), intramuscular injection, topically (as a gel, patch, solution, or cream formulations), or subcutaneously (using pellets).

Definitions:

Hypogonadism:
The clinical syndrome associated with androgen deficiency. The clinical syndrome results from failure of the testis to produce physiological levels of testosterone and normal number of spermatozoa due to disruption of one or more levels of the hypothalamic-pituitary-testicular axis. Symptoms are dependent upon age, severity of androgen deficiency, duration of androgen deficiency, individual sensitivity to androgen, and comorbid illness.

Primary hypogonadism *defined as* testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals

Hypogonadotropic hypogonadism *defined as* gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumor, trauma, or radiation having low testosterone serum concentrations, but gonadotropins are in the normal to low range

The Endocrine Society 2010 Clinical Practice Guidelines on Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes classifies signs and symptoms of hypogonadism as follows:

More specific signs and symptoms of hypogonadism:
- Breast discomfort, gynecomastia
- Decreased spontaneous erections
- Height loss, low trauma fracture, low bone mineral density
- Hot flashes, sweats
- Inability to father children, low or zero sperm count
- Incomplete or delayed sexual development, eunuchoidism
- Loss of body (axillary and pubic) hair, reduced shaving
- Reduced sexual desire (libido) and activity
- Very small (especially <5 ml) or shrinking testes

Less specific signs and symptoms of hypogonadism:
- Decreased energy, motivation, initiative, and self-confidence
- Diminished physical or work performance
- Feeling sad or blue, depressed mood, dysthymia
- Increased body fat, body mass index
- Mild anemia (normochromic, normocytic, in the female range)
- Poor concentration and memory
- Reduced muscle bulk and strength
- Sleep disturbance, increased sleepiness

TESTOSTERONE REPLACEMENT THERAPY

Chronic Corticosteroid Treatment:

- Corticosteroid used in men for the treatment of manifestations of a chronic condition, as opposed to episodic treatment for an acute condition or acute flare of a chronic condition. The length of acute episodic corticosteroid treatment may vary from several days to several months, but in most cases will be less than 4-6 weeks.

Testosterone Products:

- Androderm® Transdermal Patch*
- Androgel® Pump Transdermal Gel*
- Androgel® Transdermal Gel*
- Fortesta® Transdermal Gel*
- Jatenzo (testosterone undecanoate) oral capsule*
- Tlando (testosterone undecanoate) oral capsule*
- Methitest™ (methyltestosterone) oral tablet*
- Methyltestosterone oral capsule*
- Natesto™ Nasal Gel*
- Striant® Buccal Mucoadhesive System*
- Testopel® (testosterone) implant pellet (refer to BCBSAZ Evidence-Based Criteria *Hormone Pellet Therapy* found in InterQual® anon)
- **Testim® Transdermal Gel (brand or generic, preferred agent)***
- Testosterone Cypionate Intramuscular Solution
- Testosterone Enanthate Intramuscular Solution
- Testosterone Pump Transdermal Gel*
- Testosterone Transdermal Gel*
- Vogelxo® Pump Transdermal Gel*
- Vogelxo® Transdermal Gel*
- Xyosted™ (testosterone enanthate) injection*

* requires precertification

Resources:

Androderm (testosterone transdermal system) 2mg & 4mg patch product information, revised by manufacturer Allergan, Inc. 05-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

AndroGel (testosterone gel) 1% (25 mg & 50 mg) packets product information, revised by manufacturer AbbVie 05-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Testosterone gel 1% pump & 25 mg & 50 mg packets product information, revised by manufacturer Actavis Pharma, Inc. 05-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

AndroGel (testosterone gel) 1.62% pump (20.25 mg, & 40.5 mg) packets product information, revised by manufacturer AbbVie 11-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

TESTOSTERONE REPLACEMENT THERAPY

Testosterone gel 1.62% pump (20.25 mg, & 40.5 mg) packets product information, revised by manufacturer Actavis Pharma, Inc 08-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Androxy (fluoxymesterone) 10 mg tablets product information, revised by manufacturer Upsher-Smith Laboratories, LLC. 09-2017, at DailyMed http://dailymed.nlm.nih.gov. Accessed November 30, 2020. Discontinued in the United States.

Halotestin (fluoxymesterone) 2 mg, 5 mg, & 10 mg tablets product information, revised by manufacturer Pharmacia and Upjohn Company, LLC. 02-2006, at DailyMed http://dailymed.nlm.nih.gov. Accessed November 30, 2020. Discontinued in the United States.

Aveed (testosterone undecanoate) injection 250 mg/mL product information, revised by manufacturer Endo Pharmaceuticals, Inc. 08-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Axiron (testosterone) topical solution 30 mg pump solution product information, revised by manufacturer Eli Lilly and Company 05-2015. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 30, 2020.

Testosterone topical solution 30 mg pump solution product information, revised by manufacturer Lupin Pharmaceuticals, Inc. 04-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 14, 2022.

Depo-Testosterone (testosterone cypionate) 100 mg/mL & 200 mg/mL injection product information, revised by manufacturer Pharmacia and Upjohn Company, LLC. 08-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 15, 2022.

Testosterone cypionate 100 mg/mL & 200 mg/mL injection product information, revised by manufacturer Sun Pharmaceutical Industries, Inc. 11-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Fortesta (testosterone) 2% gel pump (10 mg per actuation) product information, revised by manufacturer Endo Pharmaceutical, Inc. 01-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Testosterone 2% gel pump (10 mg per actuation) product information, revised by manufacturer Actavis Pharma, Inc. 06-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Jatenzo (testosterone undecanoate) 158 mg, 198 mg, & 237 mg capsules product information, revised by manufacturer Clarus Therapeutics, Inc., 03-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Tlando (testosterone undecanoate) 112.5 mg capsules product information, revised by manufacturer Antares Pharma, Inc., 03-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed April 20, 2022.

Methitest (methyltestosterone) 10 mg tablet product information, revised by manufacturer Amneal Pharmaceuticals of New York, LLC. 10-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Methyltestosterone 10 mg capsule product information, revised by manufacturer Amneal Pharmaceuticals of New York, LLC. 05-2019, at DailyMed http://dailymed.nlm.nih.gov. Accessed November 30, 2020.

TESTOSTERONE REPLACEMENT THERAPY

Natesto (testosterone) 5.5 mg per actuation nasal gel product information, revised by manufacturer Acerus Pharmaceuticals Corporation 12-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Striant testosterone) 30 mg buccal system product information, revised by manufacturer Columbia Laboratories, Inc. 11-2009. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 30, 2020. Discontinued on 05-31-2020.

Testim (testosterone) 1% gel (50 mg tube) product information, revised by manufacturer Endo Pharmaceuticals, Inc. 08-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Testopel (testosterone) 75 mg pellet product information, revised by manufacturer Endo Pharmaceuticals, Inc. 08-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Xyosted (testosterone enanthate) 50 mg/0.5 mL, 75 mg/0.5 mL, & 100 mg/0.5 mL injection product information, revised by manufacturer Antares Pharma, Inc. 11-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Testosterone enanthate injection product information, revised by manufacturer West-Ward Pharmaceuticals Corp. 12-2018, at DailyMed http://dailymed.nlm.nih.gov. Accessed November 30, 2020. Discontinued 2020.

Vogelxo (testosterone) gel 50 mg tube, 50 mg packet, & 12.5 mg pump product information, revised by manufacturer Upsher-Smith Laboratories, LLC. 04-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 14, 2022.

Snyder PJ. Clinical features and diagnosis of male hypogonadism. In: UpToDate, Matsumoto AM, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated February 09, 2022. Accessed March 16, 2022.

Snyder PJ. Approach to older men with low testosterone. In: UpToDate, Matsumoto AM, Schmader KE, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated May 04, 2020. Accessed March 16, 2022.

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