Testosterone
Policy Number: C2270-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/12/2018	10/2018	10/2019
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J3121, J1071	RxPA	Q4 2018

PRODUCTS AFFECTED:
ANDROID (methyltestosterone), ANDRODERM (testosterone topical), ANDROGEL (testosterone topical), AVEED (testosterone undecanoate), AXIRON (testosterone topical), DELATESTRYL (testosterone enanthate), DEPO-TESTOSTERONE (testosterone cypionate) FORTEST(testosterone topical), METHITEST (methyltestosterone), NATESTO (testosterone nasal gel), STRIANT (testosterone buccal), TESTIM* (testosterone topical), TESTOPEL (testosterone implant), TESTRED* (methyltestosterone), VOGELXO* (testosterone topical)

DRUG CLASS: Androgens

ROUTE OF ADMINISTRATION:
injectable, topical

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS: Androderm transdermal patch 2mg, 4mg
AndroGel gel packet (2.5g) 1%, gel packet (5g) 1% , gel pump 1%
AndroGel gel packet (1.25g) 1.62%, gel packet (2.5g) 1.62%, gel pump 1.62%
Axiron topical solution 30mg
Fortestagel 2%
Striant buccal system 30mg
Testim gel 1%
Vogelxo gel packet 1%, gel pump 1%
Depo-Testosterone (cypionate) injectable solution 100mg/ml, 200mg/mL
Delatestryl (enanthate) injectable solution 200mg/mL
Methitest (methyltestosterone) oral 10mg
Android (methyltestosterone) oral 10mg
Testred (methyltestosterone) oral 10mg

FDA-APPROVED USES:
Primary or Hypogonadotropic Hypogonadism (congenital or acquired), Delayed Puberty, Metastatic Breast Cancer, Transgender Health

COMPENDIAL APPROVED OFF-LABELED USES: None. See other special considerations.

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: Hypogonadism, Delayed Puberty

REQUIRED MEDICAL INFORMATION:

A. HYPOGONADISM:

1. (a) Documentation of diagnosis for a male patient with congenital or acquired hypogonadotropic hypogonadism (i.e., gonadotropin or luteinizing hormone-releasing hormone [LHRH] deficiency, orpituitary-hypothalamic injury from tumors, trauma, or radiation)
   OR
   (b) Documentation of a diagnosis for a male patient with congenital or acquired primary hypogonadism (i.e.,testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, ororchidectomy)
   AND
2. Documentation of at least two morning (before 10am) total testosterone baseline levels done on separate days that are considered low per laboratory testing reference values.
   AND
3. Documentation of a trial and failure of at least 1 generic injectable product AND least 1 generic topical product

B. DELAYED PUBERTY- TESTOSTERONE CYPIONATE/ENANTHATE ONLY:

1. Documentation of random measurements of serum LH, FSH and testosterone that support diagnosis.
   *Other testosterone products are not labeled for this indication and would fall under off-label policy **

2. METASTATIC BREAST CANCER:

Refer to Molina Standard Oncology Criteria

3. TRANSGENDER HEALTH:

See Molina Gender Dysphoria Treatment Policy

DURATION OF APPROVAL: Initial authorization: 12 months, Continuation of Therapy: for up to 12 months

QUANTITY: No requirements

PRESCRIBER REQUIREMENTS:

HYPOGONADISM: None

DELAYED PUBERTY: Prescribed by or in consultation with a pediatric endocrinologist

AGE RESTRICTIONS:

HYPOGONADISM: 18 years of age or older

DELAYED PUBERTY: 14 years of age or older

GENDER:

Male and Female

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation of clinical benefit specific to indication being treated

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: Hematocrit greater than or equal to 50%

OTHER SPECIAL CONSIDERATIONS:

1. Injectable testosterone (e.g., testosterone cypionate, testosterone enanthate, Aveed, Testopel) has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.) Use in Females for Indications Other than Female-to-Male (FTM) Gender Reassignment and Palliative Treatment of Metastatic Breast Cancer (see above). All of the injectable testosterone products are contraindicated for use in pregnant women. In the 2006 guidelines on androgen therapy in women from the Endocrine Society, despite some short-term efficacy evidence, it recommends against the generalized use of testosterone by women because the indications are inadequate and the evidence of safety in long-term (> 24 weeks) studies is lacking. The American College of Obstetricians and Gynecologists (ACOG) clinical management guidelines for management of female sexual dysfunction (reaffirmed in 2013) mentions testosterone as an option for the short-term treatment (e.g., 6 months) of hypoactive sexual desire disorder. However, the FDA-approved testosterone formulations provide doses larger than the dosages studied in and typically required by women. More data are needed regarding long-term safety of testosterone use in women and patient selection before it can be recommended in this patient population. Testosterone supplementation has also been evaluated in a small number of women for the effect on follicle stimulation with no significant effect noted.
2. To Enhance Athletic Performance. Injectable testosterone products are not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.
3. Use in Males with Carcinoma of the Breast. All of these testosterone replacement products are contraindicated for use in men with carcinoma of the breast.
4. Use in Males with Known or Suspected Carcinoma of the Prostate (excluding males with treated and cured prostate cancer). All of these testosterone replacement products are contraindicated for use in men with known or suspected carcinoma of the prostate.

BACKGROUND: None

APPENDIX: None

REFERENCES:

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15. Testim® (testosterone) 1% gel. Prescribing information. Malvern, PA: Endo Pharmaceuticals, Inc., October 2016.
16. Striant® (testosterone) buccal system. Prescribing information. Endo Pharmaceuticals. Malvern, PA. October 2016.
17. Natesto® (testosterone) nasal gel. Prescribing information. Endo Pharmaceuticals. Malvern, PA. May 2015.
18. Vogelxo® (testosterone) gel. Prescribing information. Maple Grove, MN: Upsher-Smith Laboratories, September 2016.
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