PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**TESTOSTERONE PRODUCTS – ORAL**
BRAND NAME (generic)	**ANDROID (methyltestosterone oral capsule)** **METHITEST (methyltestosterone oral tablet)** **TESTRED (methyltestosterone oral capsule)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Males

Androgens are indicated for replacement therapy in conditions associated with deficiency or absence of endogenous testosterone:

Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance.)

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of oral testosterone in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every 6 months to assess the effect of treatment on the epiphyseal centers.

Females

Androgens may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has experienced an inadequate treatment response to one non-oral form of testosterone supplementation
  OR
- The patient has experienced an intolerance to one non-oral form of testosterone supplementation
  OR
- The patient has a contraindication that would prohibit a trial of non-oral forms of testosterone supplementation

AND

- The requested drug is being prescribed for primary or hypogonadotropic hypogonadism [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
  AND
  - Before the start of testosterone therapy, the patient has at least two confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values **OR**
  - For continuation of testosterone therapy: before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values

OR

- The requested drug is being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal AND the patient had an incomplete response to other therapy for metastatic breast cancer

OR

- The requested drug is being prescribed for a premenopausal patient with breast cancer who has benefited from oophorectomy and is considered to have a hormone-responsive tumor

OR

- The requested drug is being prescribed for delayed puberty

REFERENCES

1. Android [package insert]. Aliso Viejo, CA: Valeant Pharmaceuticals North America; September 2016.
2. Methitest [package insert]. Philadelphia, PA: Global Pharmaceutical Corporation; May 2019.
3. Testred [package insert]. Aliso Viejo, CA: Valeant Pharmaceuticals North America; September 2016.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed October 2019.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed October 2019.
6. Petak S, Nankin H, Spark R, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update. *Endocrine Practice* 2002;8(6):439-456.
7. Bhasin S, Cunningham G, Hayes F, et al. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism* 2018 103(5):1715-1744.