PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**TESTOSTERONE PRODUCTS – ORAL**
BRAND NAME*	
(generic)	
	METHITEST
	(methyltestosterone oral tablet)
	(methyltestosterone oral capsule)
Status: CVS Caremark® Criteria	
Type: Initial Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

1. Males

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

- Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.
- Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or luteinizing hormone-releasing hormone (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 methyltestosterone 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.

2. 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 antiestrogen 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 an alternative testosterone product (e.g., topical testosterone, transdermal testosterone, injectable testosterone)
  OR
- The patient has experienced an intolerance to an alternative testosterone product (e.g., topical testosterone, transdermal testosterone, injectable testosterone)
  OR
- The patient has a contraindication that would prohibit a trial of alternative testosterone products (e.g., topical testosterone, transdermal testosterone, injectable testosterone)
  AND
- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)
  AND
    - The requested drug is being prescribed for primary or hypogonadotropic hypogonadism
      AND
        - The request is NOT for continuation of therapy
          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
        - The request is for continuation of therapy
          AND
            - 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 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

Duration of Approval:

- 878-A: DOA: 36 months

REFERENCES

1. Methitest [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2018.
2. Methyltestosterone capsule [package insert]. East Windsor, NJ: Novitium Pharma LLC; June 2021.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed January 11, 2024.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/11/2024).
5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2018;103(5):1715-1744.