Testosterone Pellets (Testopel®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

FDA-APPROVED INDICATIONS

Males

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

a. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy.
b. Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex 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 Testopel (testosterone pellets) in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

c. 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 taken every 6 months to assess the effect of treatment on epiphyseal centers.

Compendial Uses

Gender Dysphoria (also known as transgender or gender diverse (TGD) persons)

COVERAGE CRITERIA

Delayed Puberty

Authorization may be granted when the requested drug is being prescribed for delayed puberty when the following criteria is met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)

Gender Dysphoria

*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)
- The patient's comorbid conditions are reasonably controlled
- The patient has been educated on ANY contraindications AND side effects to therapy
- Before the start of therapy, the patient has been informed of fertility preservation options
- If the patient is less than 18 years of age, the patient meets ALL of the following criteria:
  - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider
  - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater

Primary or Hypogonadotropic Hypogonadism
Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:
•The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)
•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

CONTINUATION OF THERAPY

Delayed Puberty
All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Gender Dysphoria
*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law
All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Primary or Hypogonadotropic Hypogonadism
Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)
- 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

DURATION OF APPROVAL (DOA)

- 12 months

OTHER

- Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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4. 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.
5. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*. 2022;23(S1):S1-S258.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.
7. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2021;137:e75-88.

EFFECTIVE DATE 12/31/2024

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