Pharmacy Drug Policy & Procedure

Policy Name:	Testosterone, Implantable, Topical, Oral, and Nasal	Policy #:	1817P

Purpose of the Policy

The purpose of this policy is to provide coverage information for testosterone replacement products.

Statement of the Policy

Health Alliance considers the use of testosterone products medically necessary when the following criteria are met.

Definitions

1. Causes of primary hypogonadism	Testicular failure due to cryptorchidism, bilateral torsion, orchitis, or vanishing testis syndrome, inborn errors in testosterone biosynthesis, or bilateral orchiectomy
2. Causes of secondary hypogonadism	Gonadotropin-releasing hormone (GnRH) deficiency or pituitary-hypothalamic injury as a result of surgery, tumors, trauma, or radiation
3. Clinically important signs and symptoms of androgen deficiency	Incomplete or delayed sexual development, decreased libido, decreased spontaneous erections, breast discomfort/gynecomastia, loss of axillar/body hair, very small (<5 mL) or shrinking testes, infertility due to low sperm count, height loss due to vertebral fractures, low trauma fractures, low bone density, hot flushes/sweats

Criteria

1. Topical, Oral, and Nasal Administration

1.1 Individual is male

1.2 Initial therapy ordered by an endocrinologist (hormone doctor) or urologist (urinary tract doctor)

1.3 Documentation of at least two clinically important sign and symptom of androgen deficiency (see Definition 3) as defined by the Endocrine Society Guidelines (2018)

1.4 Two consecutive fasting lab results taken in the morning, on two different occasions within the previous 180 days indicating low testosterone (based on lab's reference range)

- Levels drawn during acute or subacute illness are not accepted
- First lab result should measure total testosterone level, second lab result should measure total testosterone and free testosterone

1.5 The following laboratory results from the previous 180 days:

- Complete blood count (CBC)
- Prostate-specific antigen test (PSA)
- Luteinizing hormone (LH)
- Follicle-Stimulating Hormone (FSH)
  - High LH and FSH levels are indicative or primary hypogonadism
  - Low or normal LH and FSH levels are indicative of secondary hypogonadism

1.6 Documented diagnosis of primary hypogonadism, secondary hypogonadism, or newly acquired secondary hypogonadism

- For diagnosis of newly acquired secondary hypogonadism, testosterone replacement therapy also requires the following:
  - Lab results: Thyroid-Stimulating hormone (TSH), free thyroxine (t4), and Prolactin levels
  - Documentation that secondary causes have been sought and treated (i.e. sleep apnea,

hypothalamic/pituitary tumor, iron overload syndromes, infiltrative/destructive disease of hypothalamus/pituitary, idiopathic hypogonadotropic hypogonadism).

1.7 Initial authorization: 12 months

1.8 Reauthorization: 12 months if member's treated fasting serum testosterone is less than or equal to 700 ng/dL or 3 months if fasting serum testosterone is greater than 700 ng/dl and provider agrees to dose adjustment to reach a level less than or equal to 700 ng/d

2. Implantable Testosterone (e.g., Testopel Pellets)

2.1 Individual is male

2.2 Initial therapy ordered by an endocrinologist (hormone doctor) or urologist (urinary tract doctor)

2.3 Documentation of at least two clinically important signs and symptoms of androgen deficiency (see Definition 3) as defined by the Endocrine Society Guidelines (2018)

2.4 Two consecutive fasting lab results taken in the morning, on two different occasions within the previous 180 days indicating low testosterone (based on lab's reference range)

- Levels drawn during acute or subacute illness are not accepted
- First lab result should measure total testosterone level, second lab result should measure total testosterone and free testosterone

2.5 The following laboratory results from the previous 180 days:

- Complete blood count (CBC)
- Prostate-specific antigen test (PSA)
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- Follicle-Stimulating Hormone (FSH)
  - High LH and FSH levels are indicative or primary hypogonadism
  - Low or normal LH and FSH levels are indicative of secondary hypogonadism

2.6 Documented diagnosis of primary hypogonadism, or newly acquired secondary hypogonadism

- For diagnosis of newly acquired secondary hypogonadism, testosterone replacement therapy also requires the following:
  - Lab results: Thyroid-Stimulating hormone (TSH), free thyroxine (t4), and Prolactin levels
  - Documentation that secondary causes have been sought and treated (i.e. sleep apnea, hypothalamic/pituitary tumor, iron overload syndromes, infiltrative/destructive disease of hypothalamus/pituitary, idiopathic hypogonadotropic hypogonadism

2.7 Testosterone pellets (Testopel) require documentation indicating transdermal and intramuscular replacement therapy is not effective or appropriate

2.8 Initial authorization: 12 months

2.9 Reauthorization: 12 months if member's treated fasting serum testosterone is 700 ng/dL or provider indicates dose adjustment to reach a fasting serum testosterone 700 ng/dL

- Covered under the medical benefit only

3. Coverage for Gender Incongruence (Illinois fully-insured and select Illinois self-funded plans)

3.1 Prior authorization is prohibited per section 356z.60 of the Illinois Insurance code

3.2 The health plan has measures in place to allow for claims to process at $0 cost share without prior authorization being required

3.3 For further questions, please contact the plan

4. Coverage for Gender Incongruence (all other members)

4.1 Documented diagnosis of gender incongruence (defined as a person with a discrepancy between their gender identity and gender assigned at birth)

4.2 Individual intending to have more “male” characteristics

4.3 Individual is past puberty

4.4 Testosterone pellets (Testopel) are covered under the medical benefit only

4.5 Authorization: 12 months

5. Exclusion Criteria

5.1 Members who are new starts to therapy with uncontrolled hypothyroidism must provide documentation that they are adequately treated prior to coverage of drugs for the treatment of hypogonadism

5.2 Testosterone therapy is not recommended in men planning fertility in the near term or in men with breast or prostate cancer, a palpable prostate nodule or induration, elevated hematocrit, untreated severe

obstructive sleep apnea, severe lower urinary tract symptoms, uncontrolled heart failure, myocardial infarction or stroke within the last 6 months, or thrombophilia

5.3 Testosterone replacement therapy is considered experimental, investigational/or unproven in all other situations in which the above criteria are not met, including but not limited to men with low testosterone levels in the absence of clinical signs and symptoms of hypogonadism; hormone replacement therapy for female menopause; delayed puberty in females

5.4 Based on the Endocrine Society Guidelines (2010) the recommended goal treatment range is between 400 and 700 ng/dl. Requests for quantities of medication which previously resulted in a fasting serum testosterone level > 700 ng/dl are not covered

5.5 Patients with newly diagnosed secondary hypogonadism without an identified underlying medical condition

5.6 Patients with secondary hypogonadism with low total testosterone levels and normal free testosterone levels

CPT Codes

11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin) – estradiol not covered

HCPCS Codes

S0189	Testosterone pellet, 75 mg

References

1. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in adult men with Hypogonadism: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab March 2018.
2. Coleman E, Radix AE, Bouman WP, et al. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health. 2022 23:sup1, S1-S259.
3. Mulhall JP, Trost LW, Brt al, Evaluation and Management of Testosterone Deficiency, American Urological Association, 2018.
4. 215 ILCS 5/356z.60. Coverage for abortifacients, hormonal therapy, and human immunodeficiency virus pre-exposure prophylaxis and post-exposure prophylaxis. 2023.

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