Pharmacy Drug Policy Checklist

POLICY NAME	Testosterone, Implantable, Topical, Oral, and	POLICY #	1817P

Criteria

Exclusion Criteria – Any of the following prevents coverage

- ☐ **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 References 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

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

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, Statement of the Policy 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

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

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)
  - 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
- ☐ **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

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

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

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