Effective date: 12/2017
Revised: 7/2018, 12/2019 Reviewed: 12/2017, 7/2018, 12/2019, 7/2020, 5/2021, 4/2022, 4/2023, 5/2024, 4/2025 Scope: Medicaid

Testosterone Transdermal Gel 1%

POLICY

I. CRITERIA FOR APPROVAL

A. Primary or hypogonadotropic hypogonadism

Authorization of 12 months may be granted when all the following criteria are met:

1. The requested formulary 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.]
2. Patient meets either of the following criteria:
   a. Before the start of testosterone therapy, the patient has at least two confirmed low testosterone levels according to current practice guidelines or your standard lab reference values
   b. For continuation of testosterone therapy: before the patient started testosterone therapy, the patient had a confirmed low testosterone level according to current practice guidelines or your standard lab reference values
3. Patient has experienced an inadequate treatment response, intolerance or contraindication to formulary injectable testosterone (testosterone cypionate or testosterone enanthate)

B. Gender dysphoria

Authorization of 12 months may be granted when all of the following criteria are met:

1. The requested formulary drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy
2. Patient has experienced an inadequate treatment response, intolerance or contraindication to formulary injectable testosterone (testosterone cypionate or testosterone enanthate)

II. QUANTITY LIMIT

1. Testosterone transdermal gel 50mg/5gm (1%) [GPI 23100030004030] – 300 gm / 30 days
2. Testosterone transdermal gel pump 12.5mg/act (1%) [GPI 23100030004040] – 150 gm / 30 days

III. REFERENCES

1. Androgel 1% [package insert]. North Chicago, IL: Abbvie Inc; November 2020.
2. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed February 2019.
3. 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.
4. 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.

5. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al; Endocrine Society. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism* 2017;102(11):3869-3903.
6. Knezevich EL, Viereck LK, Drincic AT. Medical Management of Adult Transsexual Persons. Pharmacotherapy. 2012;32(1):54-66.
7. Coleman E, Bockting W, Botzer M, et al. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People. World Professional Association for Transgender Health. Last Updated 2012. Available at: https://www.wpath.org/media/cms/Documents/Web%20Transfer/SOC/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf. Accessed February 2019.
8. American Psychiatric Association. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V). 2013. Available at http://dsm.psychiatryonline.org/book.aspx?bookid=556.