Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE

Testosterone 1% gel (Testim)

Notes:

- Quantity Limits: No
- # Note: Testim is covered under the prescription drug benefit for HSDD only for members with coverage for medications used to treat sexual dysfunction. Others pay member cash price.
- ^ Adequate trial is defined as 3 months treatment duration
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **testosterone 1% gel (Testim)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has a diagnosis of Diagnosis of primary or secondary hypogonadism (the gonads [testes in males] produce little or no sex hormones); with documented luteinizing hormone (LH), follicle-stimulating hormone (FSH), and prolactin levels.
- Two low morning testosterone levels (below the normal range of the lab test used). The testosterone levels should be checked before testosterone treatment is started or 3 months after testosterone treatment has been stopped.
- If body mass index (BMI) is greater or equal to 30, both total and free testosterone must be below the normal range. If the "free" testosterone is normal and the total testosterone is low, the diagnosis of hypogonadism cannot be made.
- If patient is over 50 years of age: digital rectal exam (DRE) and prostate-specific antigen (PSA) test done in the last 12 months
- Hematocrit less than 50% (test that measures the percent of red blood cells in the blood) in the last 12 months.
- Adequate trial or intolerance/hypersensitivity with testosterone topical gel 1.62%.

-OR-

- Patient has a diagnosis of female to male gender dysphoria (when a person's gender identity does not match their biological sex)
  -AND-
- Intolerance/hypersensitivity with testosterone topical gel 1.62%.

-OR-

- Prescribed by a pediatric endocrinologist to cause puberty, or prior to genital surgery, or long-term puberty hormonal therapy
  -AND-
- Intolerance/hypersensitivity with testosterone topical gel 1.62%.

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-OR-

- Diagnosis of post-menopausal hyposexual drive disorder/dysfunction (HSDD).[#]
  -AND-
- Prescribed by Obstetrics/Gynecology, Urology, or Gender Pathways Clinic

Criteria for *new members* entering Kaiser Permanente and *current Kaiser Permanente members* already taking the medication who have not been reviewed previously: Non-formulary **testosterone 1% gel (Testim)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has a diagnosis of Diagnosis of primary or secondary hypogonadism (the gonads [testes in males] produce little or no sex hormones); with documented luteinizing hormone (LH), follicle-stimulating hormone (FSH), and prolactin levels.
- Two low morning testosterone levels (below the normal range of the lab test used). The testosterone levels should be checked before testosterone treatment is started or 3 months after testosterone treatment has been stopped.
- Both total and free testosterone must be below the normal range if body mass index (BMI) is greater or equal to 30. (If the free testosterone level is normal and the total testosterone is low, the diagnosis of hypogonadism cannot be made.)
- If patient is over 50 years of age: digital rectal exam (DRE) and prostate-specific antigen (PSA) test done in the last 12 months
- Hematocrit less than 50% (test that measures the percent of red blood cells in the blood) in the last 12 months.
- Adequate trial (at least 3 months) or intolerance/hypersensitivity with testosterone topical gel 1.62%.

-OR-

- Patient has a diagnosis of female to male gender dysphoria (when a person's gender identity does not match their biological sex)
  -AND-
- Intolerance/hypersensitivity with testosterone topical gel 1.62%.

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  -AND-
- Intolerance/hypersensitivity with testosterone topical gel 1.62%.

-OR-

- Diagnosis of post-menopausal hyposexual drive disorder/dysfunction (HSDD).[#]
  -AND-
- Prescribed by Obstetrics/Gynecology, Urology, or Gender Pathways Clinic