Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Testosterone 2% gel (Fortesta)

Initiation (new start) criteria: Non-formulary **testosterone 2% gel (Fortesta)** will be covered on the prescription drug benefit when the following criteria are met:

- All 5 of the following are met:

  1. 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.
  2. 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.
  3. If patient is over years of age 50: digital rectal exam (DRE) and prostate-specific antigen (PSA) test done in the last 12 months
  4. Hematocrit less than 50% (test that *measures the percent of red blood cells in the blood*) in the last 12 months.
  5. 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%.

-OR-

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

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Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Non-formulary **testosterone 2% gel (Fortesta)** will be covered on the prescription drug benefit when the following criteria are met:

- All 5 of the following are met:

  1. 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.
  2. 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.
  3. If patient is over years of age 50: digital rectal exam (DRE) and prostate-specific antigen (PSA) test done in the last 12 months.
  4. Hematocrit less than 50% (test that *measures the percent of red blood cells in the blood*) in the last 12 months.
  5. 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%.

-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%.