BlueCross BlueShield
Federal Employee Program

TESTOSTERONE POWDER

Testosterone (cypionate, enanthate, and propionate) powder, Fluoxymesterone powder, Methyltestosterone powder

Pre - PA Allowance

This drug is a covered benefit for female members greater than 50 years of age

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Prior-Approval Requirements

Age 12 years of age or older
Gender Male only

Diagnosis

Patient must have the following:

Delay in sexual development and/or puberty

a. **NO** dual therapy with another testosterone product

AND ALL of the following:

1. The requested dosage form is commercially available
2. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength of the requested dosage form

AND ONE of the following:

1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
2. The patient has an intolerance to the commercially available products' inactive ingredient(s) of preferred dosage form

AND confirmation that the following will be monitored every 6 months:

1. Assess bone age of the hand and wrist (as determined by radiographic evidence)
2. Liver function tests
3. Hematocrit levels

Age 18 years of age or older
Gender Male only

Diagnosis

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Patient must have the following:

Deficiency of testosterone (hypogonadism)

AND ALL of the following:

1. The requested dosage form is commercially available
2. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength for the requested dosage form
3. Two morning total testosterone levels less than 300 ng/dL on different days
4. Patients over 40 years of age must have baseline PSA less than 4 ng/ml
    a. Prostatectomy patients excluded from the requirement
5. Absence of prostate cancer / palpable prostate nodules
6. Hematocrit level less than 54%
7. If concurrent diagnosis of benign prostatic hypertrophy (BPH), then patient will be monitored for worsening symptoms
8. Evaluation of cardiovascular risk for MI, angina, stroke
9. Absence of un-treated sleep apnea
10. **NO** dual therapy with another testosterone product

AND ONE of the following:

1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
2. The patient has an intolerance to the commercially available equivalent products' inactive ingredient(s) of preferred dosage form

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Age 18 years of age or older
Gender Female only

Diagnosis

Patient must have **ALL** of the following:

1. Inoperable metastatic breast cancer
2. The patient has received at least one prior therapy
3. **NO** dual therapy with another testosterone product

AND ALL of the following:

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1. The requested dosage form is commercially available
2. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength for the requested dosage form

AND ONE of the following:

1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
2. The patient has an intolerance to the commercially available equivalent products' inactive ingredient(s) of preferred dosage form

AND confirmation that the following will be monitored every 6 months:

a. Hypercalcemia and agreement to discontinue the drug if present
b. Liver function tests
c. Hematocrit level

Diagnosis

Patient must have the following:

Gender Dysphoria (GD)

AND ALL of the following:

1. Female to male transition
2. **NO** dual therapy with another testosterone product
3. The requested dosage form is commercially available
4. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength of the requested dosage form

AND ONE of the following:

1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
2. The patient has an intolerance to the commercially available products' inactive ingredient(s) of preferred dosage form

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Prior - Approval Limits

Duration 6 months for all diagnoses except GD
2 years for GD (**age ≥ 19 years**)
Until end of plan year for GD (**age < 19 years**)

Prior – Approval *Renewal* Requirements

Age 12 years of age or older
Gender Male only

Diagnosis

Patient must have the following:

Delay in sexual development and/or puberty

a. **NO** dual therapy with another testosterone product

AND ALL of the following:

1. The requested dosage form is commercially available
2. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength of the requested dosage form

AND ONE of the following:

3. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
4. The patient has an intolerance to the commercially available products' inactive ingredient(s) of preferred dosage form

AND confirmation that the following will be monitored every 6 months:

1. Assess bone age of the hand and wrist (as determined by radiographic evidence)
2. Liver function tests
3. Hematocrit levels

Age 18 years of age or older
Gender Male

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Diagnosis

Patient must have the following:

Deficiency of testosterone (hypogonadism)

AND ALL of the following:

1. Total testosterone levels of 800 ng/dL or less
2. Absence of worsening effects of benign prostatic hypertrophy (BPH), if present
3. The requested dosage form is commercially available
4. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength for the requested dosage form
5. Re-evaluation of cardiovascular risk for MI, angina, stroke
6. **NO** dual therapy with another testosterone product

AND ONE of the following:

1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
2. The patient has an intolerance to the commercially available products' inactive ingredient(s) of preferred dosage form

AND confirmation that the following will be monitored every 12 months:

1. Serum testosterone concentrations
2. Prostate specific antigen (PSA) for patients over 40 years of age
    a. Prostatectomy patients excluded from the requirement
3. Hematocrit levels

Age 18 years of age or older
Gender Female only

Diagnosis

Patient must have **ALL** of the following:

1. Inoperable metastatic breast cancer
2. The patient has received at least one prior therapy

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3. **NO** dual therapy with another testosterone product

AND ALL of the following:
1. The requested dosage form is commercially available
2. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength for the requested dosage form

AND ONE of the following:
1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form
2. The patient has an intolerance to the commercially available products' inactive ingredient(s) of preferred dosage form

AND confirmation that the following will be monitored every 6 months:
a. Hypercalcemia and agreement to discontinue the drug if present
b. Liver function tests
c. Hematocrit level

Diagnosis

Patient must have the following:

Gender Dysphoria (GD)

AND ALL of the following:
1. Female to male transition
2. **NO** dual therapy with another testosterone product
3. The requested dosage form is commercially available
4. The requested dose/ strength is **NOT** equal to or exceeding the FDA-approved dose/strength of the requested dosage form

AND ONE of the following:
1. The patient has tried and failed at least one other commercially available product other than the requested dosage form and the requested dosage form

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2. The patient has an intolerance to the commercially available products' inactive ingredient(s) of preferred dosage form

Prior - Approval *Renewal* Limits

Duration 12 months for all diagnoses except GD
2 years for GD (**age ≥ 19 years**)
Until end of plan year for GD (**age < 19 years**)