

## 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

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**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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<b>Age</b>	18 years of age or older
<b>Gender</b>	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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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

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## **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  $\geq$  19 years**)  
Until end of plan year for GD (**age < 19 years**)

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### 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

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**Age** 18 years of age or older  
**Gender** Male

## TESTOSTERONE POWDER

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

### 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

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<b>Age</b>	18 years of age or older
<b>Gender</b>	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:

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**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

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## **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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Methyltestosterone powder

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  $\geq$  19 years**)  
                         Until end of plan year for GD (**age  $<$  19 years**)