

**TESTOSTERONE
Injectable and Implant Agents**

Aveed (testosterone undecanoate injection), Delatestryl (testosterone enanthate injection), Depo-Testosterone (testosterone cypionate injection), Testopel (testosterone propionate implant), Xyosted (testosterone enanthate injection)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 12 years of age or older

Gender Male

Diagnosis

Delatestryl, Depo-Testosterone, and Testopel only

Patient must have the following:

Delay in sexual development and/or puberty

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

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

Diagnosis

Patient must have the following:

Deficiency of testosterone (hypogonadism)

AND ALL of the following:

1. Two morning total testosterone levels less than 300 ng/dL on different days
2. Patients over 40 years of age must have baseline PSA less than 4 ng/ml
 - a. Prostatectomy patients excluded from the requirement
3. Absence of current prostate cancer / palpable prostate nodules
4. Hematocrit less than 54%
5. If concurrent diagnosis of *benign prostatic hypertrophy* (BPH), then patient will be monitored for worsening symptoms

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6. Evaluation of cardiovascular risk for MI, angina, stroke
7. Absence of un-treated sleep apnea
8. **NO** dual therapy with another testosterone product
9. **Aveed only:** Physician has been certified by the Aveed REMS program
10. **Xyosted only:** Patient has been counseled that Xyosted can increase blood pressure and the risk of major adverse cardiovascular events

Age 18 years of age or older
Gender Female only

Diagnosis
Delatestryl only

Patient must have the following:

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

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
Aveed, Delatestryl/Xyosted, Depo-Testosterone, Testopel only

The patient must have the following:

Gender Dysphoria (GD)

1. Female to male transition
2. **NO** dual therapy with another testosterone product

Prior - Approval Limits

Quantity

Injectable Testosterone	Gender	Quantity	Days Supply
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Aveed (18 years of age or older)		Male	6ml	90
Delatestryl (testosterone enanthate)		Male	15ml	90
		Female	15ml	90
Depo-Testosterone (testosterone cypionate)	100mg/ml	Male	30ml	90
	200mg/ml	Male	30ml	90
Xyosted autoinjector (testosterone enanthate)		Male	12 autoinjector s	84
Implant Testosterone		Gender	Quantity	Days Supply
Testopel Pellet		Male	6 pellets	90

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

Same as above

Age 18 years of age or older
Gender Male

Diagnosis

Patient must have the following:
 Deficiency of testosterone (hypogonadism)

AND 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. Re-evaluation of cardiovascular risk for MI, angina, stroke
4. **NO** dual therapy with another testosterone product

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

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

Age 18 years of age or older

Gender Female only

Same as above

Diagnosis

Aveed, Delatestryl/Xyosted, Depo-Testosterone, Testopel only

The patient must have the following:

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1. Female to male transition
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Prior - Approval *Renewal* Limits

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	200mg/ml	Male	30ml	90
Xyosted autoinjector (testosterone enanthate)		Male	12 autoinjector s	84
Implant Testosterone		Gender	Quantity	Days Supply
Testopel Pellet		Male (18 years of age or older)	6 pellets	90
		Male (12- 17 years	6 pellets	90 *One renewal

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