Generic Name: N/A.

Therapeutic Class or Brand Name: Androgens (all dosage forms)

Applicable Drugs (if Therapeutic Class): Methyltestosterone Capsule (generic), Testosterone Cypionate Injection (generic), Testosterone Enanthate Injection (generic), Testosterone Transdermal Gel (generic), Testosterone Transdermal Solution (generic), , AndroGel® (testosterone gel), Aveed™ (testosterone undecanoate injection), Depo®-Testosterone (testosterone cypionate injection), , Jatenzo® (testosterone undecanoate oral capsules), Methitest™ (methyltestosterone tablet), Natesto™ (testosterone nasal gel), Testim® (testosterone gel), Testone CIK™ (testosterone cypionate), Testopel® (testosterone pellet), Testosterone Transdermal Gel (brand), Vogelxo™ (testosterone gel), Xyosted™ (testosterone enanthate).

Preferred: Testosterone Cypionate Injection (generic), Testosterone Enanthate Injection (generic), Testosterone Transdermal Gel (generic), Testosterone Transdermal Solution (generic).

Non-preferred: AndroGel® (testosterone gel), Aveed™ (testosterone undecanoate injection), Depo®-Testosterone (testosterone cypionate injection), Jatenzo® (testosterone undecanoate oral capsules), Methitest™ (methyltestosterone tablet), Methyltestosterone Capsule (generic), Natesto™ (testosterone nasal gel), Testim® (testosterone gel), Testone CIK™ (testosterone cypionate), Testopel® (testosterone pellet), Testosterone Transdermal Gel (brand), and Vogelxo™ (testosterone gel), Xyosted™ (testosterone enanthate).

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and II are met)

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

A. Hypogonadism (for all products) and criteria 1 through 4 are met:

1. Males only.
2. Patient must have symptoms of testosterone deficiency.
3. Documentation of two morning testosterone levels below the individual lab's normal range.
4. Minimum age requirement: 18 years old.

B. Delayed Puberty (for Methitest™, Methyltestosterone, Testopel® only) and criteria 1 and 2 are met:

1. Males only.
2. Prescribing physician must indicate that patient's bone development has been checked and will be checked at least every 6 months.

C. Advancing inoperable metastatic (skeletal) mammary cancer (for Methitest™, Methyltestosterone only) and criteria 1 through 4 are met:
   1. Females only.
   2. Patient is 1 to 5 years postmenopausal.
   3. Patient has had an incomplete response to other therapies for metastatic mammary cancer.
   4. Prescribing physician is an oncologist.

II. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Men with carcinomas of the breast or with known or suspected carcinomas of the prostate.
- Women who are or may become pregnant.

OTHER CRITERIA

- N/A.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Hypogonadism:
  - Testosterone Transdermal Gel 1%: 60 packets or 4 pump bottles per 30 days.
  - AndroGel®: 1.62%: 60 packets or 2 pump bottles per 30 days.
  - Aveed™: 750mg (3mL) per 30 days for first two months, then 750mg (3mL) every 10 weeks thereafter.
  - Fortesta®/Testosterone Transdermal Gel 2%: 2 pump canisters per 30 days.
  - Jatenzo®: 60 capsules per 30 days; up to 396mg twice a day (158mg + 237mg capsules twice a day for total of 120 capsules per 30 days).
  - Methitest™: 150 tablets per 30 days.
  - Natesto™: 3 pump bottles per 30 days.
  - Testim®/Testosterone Transdermal Gel 1%: 60 tubes per 30 days.
  - Testone CIK™: up to 2 kits per 30 days.
  - Testopel®: 6 pellets per 90 days.

- Vogelxo™/Testosterone Transdermal Gel 1%: 60 tubes or packets or 4 pump bottles per 30 days.
- Xyosted™: 4 autoinjectors per 28 days.

- Delayed Puberty:
  - Methitest™: 150 tablets per 30 days.
  - Testone CIK™: 1 kit per 30 days.
  - Testopel®: 6 pellets per 90 days.
- Advancing Inoperable Metastatic Mammary Cancer:
  - Methitest™: 600 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:**
  - Hypogonadism: 12 months.
  - Delayed Puberty: 6 months
  - Advancing inoperable metastatic (skeletal) mammary cancer: 12 months.
- **Re-Authorization:**
  - Hypogonadism: 12 months. An updated letter of medical necessity or progress notes showing the medication is effective. Letter or notes must also be accompanied by one documented testosterone level in order to verify drug absorption. If the testosterone level exceeds the individual lab's normal range, then there must also be documentation included that the dose is being decreased.
  - Delayed Puberty: 6 months. An updated letter of medical necessity or progress notes showing the medication is effective. Letter or notes must also be accompanied by evidence that patient's bone development is being checked at least every 6 months.
  - Advancing inoperable metastatic (skeletal) mammary cancer: 12 months. An updated letter of medical necessity or progress notes showing the medication is effective.

APPENDIX

N/A.

REFERENCES

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