Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	**Testosterone**: methyltestosterone (Methitest), testosterone (Androderm, Androgel, Fortesta, Natesto, Striant, Testim, Vogelxo), testosterone cypionate (Depo-Testosterone), testosterone enanthate (Xyosted), testosterone undecanoate (Jatenzo)

1. Criteria

Product Name: Brand Methitest, generic methyltestosterone	
Diagnosis	Gender Dysphoria, Metastatic Breast Cancer
Approval Length	Approve indefinitely (12/31/2039)
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - One of the following:
- Patient is transgender or diagnosed with gender dysphoria
- Diagnosis of metastatic breast cancer

AND

2 - For new starts to therapy only: Patient has had a trial and failure of, or contraindication to, TWO different formulations of testosterone replacement therapies, i.e. an injectable and a topical testosterone medication (as demonstrated by paid claims in RxClaim history OR submitted medical records)

Product Name: Androderm, Brand Androgel gel (1.62%), Brand Androgel gel (1%), generic testosterone gel 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Brand Fortesta, Natesto, Striant, Brand Testim, generic testosterone gel 25 mg/2.5 g (1%), generic testosterone gel 50 mg/5 g (1%), generic testosterone topical solution 30 mg/act, generic testosterone gel 10 mg/act (2%), generic testosterone gel 20.25 mg/act (1.62%), generic testosterone pump (1%), Brand Vogelxo gel and pump, Brand Depo-Testosterone, generic testosterone cypionate, generic testosterone enanthate, Xyosted, Jatenzo	
Diagnosis	Gender Dysphoria, Metastatic Breast Cancer
Approval Length	Approve indefinitely (12/31/2039)
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - One of the following:
- Patient is transgender or diagnosed with gender dysphoria
- Diagnosis of metastatic breast cancer

AND

2 - For new starts to therapy and the request is for a non-formulary medication: Patient has had a trial and failure of, or contraindication to, TWO formulary alternative testosterone replacement therapies, one of which must be the generic equivalent of the requested medication, if available (as demonstrated by paid claims in RxClaim history OR submitted medical records)

Product Name: Brand Methitest, generic methyltestosterone	
Diagnosis	Hypogonadism, Human Immunodeficiency Virus (HIV), Treatment with High-Dose Glucocorticoids
Approval Length	12 Month(s)
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - One of the following diagnoses:
- Hypogonadism (low testosterone)
- Human Immunodeficiency Virus (HIV)
- Treatment with High-Dose Glucocorticoids

AND

2 - One of the following:

2.1 - Patient is currently on testosterone therapy (according to request form, claims history, or PA history) and ONE of the following lab values, obtained within the last 12 months, confirming low to normal testosterone levels:
- Total testosterone level of less than 1,200 ng/dL or a low to normal total testosterone level as indicated by the lab's reference range; OR
- Low to normal free or bioavailable testosterone level as indicated by the lab's reference range

OR

2.2 - Submission of documentation of ONE of the following lab values, obtained within the last 120 days, confirming low testosterone levels:
- Total testosterone level of less than 200 ng/dL, or less than the lab's reference range; OR
- Free or bioavailable testosterone level less than the lab's reference range AND one of the following: a total testosterone level on the low end of normal (e.g., less than 400 ng/dL) OR an altered sex-hormone binding globulin (SHBG) or a condition associated with an altered SHBG (e.g., HIV, thyroid disorder, liver disorder, diabetes, obesity)

AND

3 - For new starts to therapy only: Patient has had a trial and failure of, or contraindication to, TWO different formulations of testosterone replacement therapies, i.e. an injectable and a topical testosterone medication (as demonstrated by paid claims in RxClaim history OR submitted medical records)

Product Name: Androderm, Brand Androgel gel (1.62%), Brand Androgel gel (1%), generic testosterone gel 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Brand Fortesta, Natesto, Striant, Brand Testim, generic testosterone gel 25 mg/2.5 g (1%), generic testosterone gel 50 mg/5 g (1%), generic testosterone topical solution 30 mg/act, generic testosterone gel 10 mg/act (2%), generic testosterone gel 20.25 mg/act (1.62%), generic testosterone pump (1%), Brand Vogelxo gel and pump, Brand Depo-Testosterone, generic testosterone cypionate, generic testosterone enanthate, Xyosted, Jatenzo	
Diagnosis	Hypogonadism, Human Immunodeficiency Virus (HIV), Treatment with High-Dose Glucocorticoids
Approval Length	12 Month(s)
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - One of the following diagnoses:

- Hypogonadism (low testosterone)
- Human Immunodeficiency Virus (HIV)
- Treatment with High-Dose Glucocorticoids

AND

2 - One of the following:

2.1 - Patient is currently on testosterone therapy (according to request form, claims history, or PA history) and ONE of the following lab values, obtained within the last 12 months, confirming low to normal testosterone levels:

- Total testosterone level of less than 1,200 ng/dL or a low to normal total testosterone level as indicated by the lab's reference range; OR
- Low to normal free or bioavailable testosterone level as indicated by the lab's reference range

OR

2.2 - Submission of documentation of ONE of the following lab values, obtained within the last 120 days, confirming low testosterone levels:

- Total testosterone level of less than 200 ng/dL, or less than the lab's reference range; OR
- Free or bioavailable testosterone level less than the lab's reference range AND one of the following: a total testosterone level on the low end of normal (e.g., less than 400 ng/dL) OR an altered sex-hormone binding globulin (SHBG) or a condition associated with an altered SHBG (e.g., HIV, thyroid disorder, liver disorder, diabetes, obesity)

AND

3 - For new starts to therapy and the request is for a non-formulary medication: Patient has had a trial and failure of, or contraindication to, TWO formulary alternative testosterone replacement therapies, one of which must be the generic equivalent of the requested medication, if available (as demonstrated by paid claims in RxClaim history OR submitted medical records)

2. Background

Benefit/Coverage/Program Information
RATIONALE Ensure testosterone therapy is being used appropriately in males with a diagnosis of hypogonadism, HIV or during treatment with high-dose glucocorticoids, as confirmed by laboratory analysis, and in females with metastatic breast cancer. **FDA APPROVED INDICATIONS** ANDRODERM (testosterone transdermal system) is indicated for testosterone replacement therapy in men for conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy of Androderm in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established. ANDROGEL (testosterone transdermal gel), an androgen, is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy of Androgel in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established. DEPO-TESTOSTERONE INJECTION is indicated for replacement therapy in men for conditions associated with symptoms of deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established. FORTESTA (testosterone transdermal gel) is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). Important limitation of use: safety and efficacy of Fortesta in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established. JATENZO (testosterone undecanoate) is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Limitations of use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established. NATESTO (testosterone nasal gel) is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy of Natesto in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established. STRIANT (testosterone buccal system) is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy of Striant in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established. TESTIM (testosterone transdermal gel) is indicated for testosterone replacement therapy in

adult males for conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy of Testim in males <18 years old have not been established. Safety and efficacy in men with “age-related” hypogonadism have not been established.

TESTOSTERONE ENANTHATE INJECTION, USP is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy in males <18 years old have not been established. Safety and efficacy in men with “age-related” hypogonadism have not been established.

VOGELXO (testosterone transdermal gel) is indicated for testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. Important limitation of use: safety and efficacy of Vogelxo in males <18 years old have not been established. Safety and efficacy in men with “age-related” hypogonadism have not been established.

XYOSTED (testosterone enanthate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Limitations of Use: Safety and efficacy of Xyosted in males less than 18 years old have not been established.

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Created: 04/14
Revised: • Annual review (effective: 1/1/20) • 1/24/20 - Clarified criterion 2.2 under "Hypogonadism, Human Immunodeficiency Virus (HIV)" and "Treatment with High-Dose Glucocorticoids" (effective: 2/1/20) • 7/14/20 - Annual review: background updated; removed Android, Testred, and Axiron due to discontinuation; added Xyosted and Jatenzo; updated approval duration for a diagnosis of Hypogonadism, Human Immunodeficiency Virus (HIV), Treatment with High-Dose Glucocorticoids from 24 to 12 months; added requirement to verify labs and trials in claims/medical records for initial requests
P&T Approval: 12/7/20
Effective: 9/1/20