HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

TESTOSTERONE

Generic	Brand	HICL	GCN	Exception/Other
METHYLTESTOSTERONE	ANDROID METHITEST METHYLTESTOSTERONE TESTRED	01404		ROUTE ≠ MISCELL.
TESTOSTERONE	ANDRODERM ANDROGEL AXIRON FORTESTA NATESTO STRIANT TESTIM TESTOSTERONE VOGELXO	01403		ROUTE ≠ MISCELL.
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE TESTOSTERONE CYPIONATE	01400		ROUTE ≠ MISCELL.
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE	01401		ROUTE ≠ MISCELL.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, send the doctor a provider response letter and use reason code #142.

2. Is the patient transgender or diagnosed with gender dysphoria or with metastatic breast cancer?

   If yes, continue to #9.
   If no, continue to #3.

3. Does the patient have one of the following conditions?
   - Dx of hypogonadism (primary or secondary) [hypotestosteronism or low testosterone]
   - Dx of HIV
   - Treatment with high-dose glucocorticoids

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Testosterone guideline, the requested medication is only covered for patients with a diagnosis of hypogonadism (low testosterone), HIV, transgender, gender dysphoria, metastatic breast cancer, or who are being treated with high-dose glucocorticoids (i.e. prednisone, dexamethasone). Your provider did not indicate that you have one of these conditions and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient currently on testosterone therapy as indicated on the MRF, the claims history, or prior authorization history?

   If yes, continue to #7.
   If no, continue to #5.

5. Does the patient meet **at least one** of the following laboratory value conditions, obtained within the last 90 days, confirming low testosterone levels?
   - Total serum testosterone level of less than 200ng/dL, or less than the testing lab's reference range
   - free or bioavailable testosterone level less than the testing lab's reference range and one of the following:
     - A total serum testosterone level on the low end of normal (e.g. less than 400 ng/dL)
     - Documentation of altered sex-hormone binding globulin (SHBG) or a condition that may result in altered SHBG (e.g., HIV, thyroid disorder, liver disorder, diabetes, obesity)

   If yes, continue to #6.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Testosterone guideline, the requested medication is only covered when low testosterone is confirmed with laboratory values obtained within the last 90 days by one of the following: low total serum testosterone level or a low free or bioavailable testosterone level with either an altered sex-hormone binding globulin level or a total serum testosterone level on the low end of normal (e.g. less than 400 ng/dL). Your provider did not submit documentation of a low testosterone level as described above and therefore your request was not approved.

6. If the request is for a patient with hypogonadism, is the patient experiencing symptoms associated with low testosterone?

   If yes, continue to #9.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Testosterone guideline, the requested medication is only covered to treat hypogonadism (low testosterone) for patients who are experiencing symptoms of low testosterone (e.g. decreased muscle mass and strength, depressed mood). Your provider did not indicate that you are experiencing any symptoms of low testosterone and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

7. Does the patient meet **at least one** of the following laboratory value conditions, obtained within the last 12 months, confirming low testosterone levels?
   - Total serum testosterone level of less than 1,200ng/dL,
   - A low to normal total serum testosterone level as indicated by the testing labs reference range
   - Low to normal free or bioavailable testosterone level as indicated by the testing labs reference range.

   If yes, continue to #8.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Testosterone guideline, authorization for renewal requires documentation of testosterone level that does not exceed a normal threshold confirmed with laboratory values obtained within the last 12 months. Accepted lab values include total serum testosterone, free testosterone, or bioavailable testosterone levels as indicated by a lab result with a reference range. Your provider did not submit documentation of a testosterone level as described above and therefore your request was not approved.

8. Have the patient's symptoms associated with low testosterone improved while on testosterone therapy?

   If yes, continue to #9.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Testosterone guideline, authorization for renewal requires documentation of improvement of symptoms of low testosterone (e.g. decreased muscle mass and strength, depressed mood). Your provider did not indicate that your symptoms have improved and therefore your request was not approved.

9. Is the request for an oral methyltestosterone medication?

   If yes, continue to #10.
   If no, continue to #11.

10. Has the patient tried and failed therapy with, or does the patient have a contraindication or intolerance to, at least two different formulations of testosterone replacement therapies, i.e. an injectable and a topical testosterone medication?

    If yes, continue to #13.
    If no, do not approve. Please use status code #238 and the denial text provided.
    DENIAL TEXT: Per your health plan's Testosterone guideline, the requested medication is only covered if you first failed therapy with at least two different formulations of testosterone replacement medications, such as an injectable and a topical formulation. Your provider did not indicate that you tried the alternative formulations or that you cannot use them and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

11. Is the request for a non-formulary medication?

    If yes, continue to #12.
    If no, continue to #13.

12. Has the patient tried and failed therapy with at least two formulary alternative testosterone replacement therapies, one of which must be the generic equivalent of the requested medication (if available)?

    If yes, continue to #13.
    If no, do not approve. Please use status code #238 and the denial text provided.
    DENIAL TEXT: Per your health plan's Testosterone guideline, the requested medication is only covered if you first failed therapy with at least two formulary alternative testosterone replacement medications, one of which must be the generic equivalent of the requested medication (if available). Formulary alternatives include: generic testosterone 1% gel, testosterone cypionate injection, Androderm patch, Androgel 1.62%. Your provider did not indicate that you tried formulary alternatives or that you cannot use them and therefore your request was not approved.

13. Is the request for a patient with metastatic breast cancer or a transgender condition?

    If yes, **approve open-ended by HICL with the appropriate quantity limit.** (**PAC NOTE:** Please refer to notes for list of products with their appropriate quantity limits). Please use status code #056 and the approval text provided.

    Requests for products on formulary with a restriction:
    APPROVAL TEXT: Your request for _____ has been approved with a quantity limit of _____ per 30 days.

    Requests for products not on formulary:
    APPROVAL TEXT: Your request for _____ has been approved with a quantity limit of _____ per 30 days at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

    If no, continue to #14.

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GUIDELINES FOR USE (CONTINUED)

14. **Approve for 24 months by HICL.** (**PAC NOTE:** Please refer to notes for list of products with their appropriate quantity limits). Please use status code #056 and the approval text provided.

Requests for products on formulary with a restriction:
APPROVAL TEXT: Your request for _____ has been approved for 24 months with a quantity limit of _____ per 30 days. Please note, an approval for continued coverage after 24 months requires your provider submit documentation of a low to normal testosterone confirmed with laboratory values obtained within 12 months of the request.

Requests for products not on formulary:
APPROVAL TEXT: Your request for _____ has been approved for 24 months with a quantity limit of _____ per 30 days at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier. Please note, an approval for continued coverage after 24 months requires your provider submit documentation of a low to normal testosterone confirmed with laboratory values obtained within 12 months of the request.

NOTES ON QUANTITY LIMITS (applies to brand and generic formulations when available):

Product	Pkg Size	Strength per Dispensing Unit	Max Daily Dose	QL per 30 days
TOPICAL GELS				
TESTOSTERONE 1% 12.5 MG/1.25 GM PUMP (Androgel 1%; Vogelxo 1%)	75 gm bottle (60 actuations)	12.5 mg per actuation	100 mg (8 pumps)	4 bottles
TESTOSTERONE 1% 25 MG/2.5 GM PKT (Androgel 1%; Testim 1%)	30 packets (2.5 gm each)	25 mg per packet	100 mg (4 packets)	30 packets
TESTOSTERONE 1% 50 MG/5 GM PKT (Androgel 1%; Testim 1%)	30 packets (5 gm each)	50 mg per packet	100 mg (2 packets)	60 packets
TESTOSTERONE 1% 50 MG/5 GM TUBE (Androgel 1%; Testim 1%)	30 tubes (5 gm each)	50 mg per tube	100 mg (2 tubes)	60 tubes
ANDROGEL 1.62% GEL PUMP	75 gm bottle (60 actuations)	20.25 mg per actuation	81 mg (4 pumps)	2 bottles
ANDROGEL 1.62% (1.25G) GEL PCKT	30 packets (1.25 gm each)	20.25 mg per packet	81 mg (4 packets)	30 packets
ANDROGEL 1.62% (2.5G) GEL PCKT	30 packets (2.5 gm each)	40.5 mg per packet	81 mg (2 packets)	60 packets
TESTOSTERONE 2% 10 MG GEL PUMP (Fortesta 2%)	60 gm bottle (120 actuations)	10 mg per actuation	80 mg (8 pumps)	2 bottles
TOPICAL SOLUTION				
TESTOSTERONE 2% 30 MG/1.5 ML PUMP (Axiron)	90 ml bottle (60 actuations)	30 mg per actuation	120 mg (4 pumps)	2 bottles

TRANSDERMAL PATCH				
ANDRODERM 4 MG/24HR	30 patches (4 mg each)	4 mg per patch	4 mg (1 patch)	30 patches
ANDRODERM 2 MG/24HR	60 patches (2 mg each)	2 mg per patch	4 mg (2 patches)	60 patches
INTRAMUSCULAR INJECTION				
TESTOSTERONE CYP 1,000 MG/10 ML (Depo-Testosterone)	10 ml vial	100 mg/ml	400 - 800 mg per month	10 ml vial
TESTOSTERONE CYP 200 MG/ML (Depo-Testosterone)	1 ml vial	200 mg/ml		4 ml (4 SDVs)
TESTOSTERONE CYP 2,000 MG/10 ML (Depo-Testosterone)	10 ml vial	200 mg/ml		10 ml vial
TESTOSTERON ENAN 1,000 MG/5 ML (Delatestryl)	5 ml vial	200 mg/ml		5 ml vial
BUCCAL PATCH				
STRIANT BUCCAL SYSTEM 30 MG	60 patches (30 mg each)	30 mg per patch	60 mg (2 patches)	60 patches
INTRANASAL GEL				
NATESTO 5.5 MG/0.122 GM GEL PUMP	7.32 gm bottle (60 actuations)	5.5 mg per actuation	33 mg (6 pumps)	3 bottles (21.96 gm)

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TESTOSTERONE

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, 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 Androderm in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established.

AXIRON, an androgen is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterones: Primary hypogonadism (congenital or acquired); Hypogonadotropic hypogonadism (congenital or acquired). Not indicated in males <18 years of age. Safety and efficacy in men with "age-related" hypogonadism have not been established.

DEPO-TESTOSTERONE INJECTION is indicated for replacement therapy in the male in 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 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.

NATESTO 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 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.

TESTIM 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 Natesto in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established.

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FDA APPROVED INDICATIONS (CONTINUED)

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 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 Natesto in males <18 years old have not been established. Safety and efficacy in men with "age-related" hypogonadism have not been established.

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