STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLTESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST, METHYLTESTOS-TERONE		10380 10411	GPI-10 (2310002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
   - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history
   - The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
     - At least two total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
     - Free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient's prostate specific antigen (PSA) been evaluated for prostate cancer screening?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Has the patient had a trial of or contraindication to **TWO** lower cost testosterone agents (e.g., testosterone cypionate, testosterone enanthate)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder **AND** meets the following criterion?
   - The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #6.

6. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) **AND** the patient meets the following criterion?
   - The patient is 16 years of age or older

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, continue to #7.

7. Is the request for a female patient with a diagnosis of metastatic breast cancer **AND** meets the following criterion?
   - The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Delayed puberty not due to a pathological disorder (not due to disease) in a male
      3. Gender dysphoria (you identify yourself as a member of the opposite sex)
      4. Metastatic breast cancer (cancer spreading to other areas of body) in a female

   (Initial denial text continues on next page)

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

B. **If you are a male with primary or secondary hypogonadism, approval also requires:**
   1. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening
   2. You meet ONE of the following:
      a. You have a previously approved prior authorization for testosterone, or you have been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history
      b. You have ONE of the following lab values showing you have low testosterone levels:
         i. At least two total serum (blood) testosterone levels of less than 300 ng/Dl (10.4 nmol/L) taken on separate occasions
         ii. Free serum testosterone level of less than 5 ng/Dl (0.17 nmol/L)
   3. You had a trial of or contraindication (harmful for) to TWO lower cost testosterone agents (such as intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate)

C. **If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:**
   1. You had a trial of or contraindication (harmful for) to intramuscular (injected into the muscle) testosterone enanthate.

D. **If you have gender dysphoria, approval also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or Iib) for treatment of gender dysphoria may be approved
   2. You are 16 years of age or older

E. **If you are a female with metastatic breast cancer, approval also requires:**
   1. You had a trial of or contraindication (harmful for) intramuscular (injected into the muscle) testosterone enanthate.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHYLTESTOSTERONE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - There is documentation (e.g., chart notes, lab results) of normalized serum testosterone levels and hematocrit concentrations compared to baseline
   - If the patient is 40 years of age or older, the patient's prostate specific antigen (PSA) has been evaluated for prostate cancer screening

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #2.

2. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder?

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #3.

3. Is the request for a female patient with a diagnosis of metastatic breast cancer?

   If yes, **approve the requested agent for lifetime by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, continue to #4.

4. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 and override quantity limits.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (not due to disease) in a male
   3. Metastatic breast cancer (cancer spreading to other areas of body) in a female
   4. Gender dysphoria (you identify yourself as a member of the opposite sex)

B. **If you have gender dysphoria, renewal also requires:**
   1. Only agents supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or Iib) for treatment of gender dysphoria may be approved

C. **If you are a male with primary or secondary hypogonadism, renewal also requires:**
   1. You have shown improvement in your symptoms compared to baseline and tolerance to treatment
   2. There is documentation (such as chart notes, lab results) of normalized serum testosterone levels and hematocrit concentrations (type of blood test) compared to baseline
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated for prostate cancer screening

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Testred, Android, and Methitest.

REFERENCES

- Android [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals.; April 2015.
- Methitest [Prescribing Information]. Hayward, CA: Impax Generics.; May 2019.
- Testred [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals.; April 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 02/23
Client Approval: 02/23
P&T Approval: 01/23