1. Is the member diagnosis one of the following?
    - Metastatic breast cancer in female
    - Delayed puberty in male

    a. Yes – Go to question 2
    b. No – Go to question 3

2. Is the request for testosterone enanthate IM injection?
    a. Yes - Go to question 11
    b. No – Deny Cat 3 – *Only testosterone enanthate is FDA approved for use in these conditions.*

3. Is the diagnosis Primary or Hypogonadotropic Hypogonadism due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol, opioid use or heavy metals, idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury in a male over the age of 18?
    a. Yes- Go to question 4
    b. No- Go to question 6

4. Does submitted documentation include a minimum of 2 morning (drawn between 8 am and 10 am) testosterone levels, drawn at least a week apart, demonstrating the following levels:
    - Total serum testosterone level less than 300ng/dL (10.4nmol/L) **OR**
    - Total serum testosterone level less than 350ng/dL (12.1nmol/L) **AND** free serum testosterone level less than 50pg/mL (or 0.174nmol/L) **AND**
    - Baseline PSA in men over the age of 40

    a. Yes – Go to question 5
    b. No – Deny Cat 5- *Does not meet Guideline note 182 for treatment of testicular hypofunction: Testosterone replacement therapy is included on line 467 for testicular hypofunction or dysfunction only when all inclusion criteria are met and none of the exclusion criteria apply.*

5. Does the member have documentation of any of the following conditions:
    - Recent major cardiovascular event (MI, stroke or acute coronary syndrome) within past 6 months.
    - Uncontrolled heart failure (NYHA Class III or IV, presence of edema)
    - Benign prostatic hyperplasia with uncontrolled or severe symptoms
    - Breast cancer
    - Prostate cancer OR elevated PSA with prior use of testosterone
    - Untreated or undertreated Obstructive sleep apnea (non-compliant with CPAP)
    - Elevated hematocrit (50% or greater)

    a. Yes – Forward for review of clinical appropriateness/Cat 5 denial*. Above conditions were listed as "treatment is not recommended" by Endocrine Society as condition may worsen and are exclusions for coverage under GL note 182.*
    b. No – Go to question 8

6. Is the medication requested for cross sex hormone treatment for gender dysphoria?
   a. Yes – Go to question 7
   b. No – Deny Cat 3 – *Medication is being prescribed outside of FDA approved indications*

7. Does the member meet parameters of Guideline Note 127 for gender dysphoria?

To qualify for cross sex hormone treatment the member must have documentation of the following:

- Persistent, well documented gender dysphoria
- Capacity to make fully informed decision and give consent for treatment
- Significant medical or mental health concerns well controlled
- A comprehensive mental health evaluation in accordance with version 7 of the World Professional Association for Transgender Health (WPATH) standards of care

   a. Yes- Go to question 8
   b. No – Forward to pharmacist or medical director- Possible Cat 5 denial. - *Member does not meet GL note 127 and/or WPATH standards for cross sex hormone treatment.*

8. Is the request for preferred formulary agent of testosterone cypionate or enanthate injection?
   a. Yes – Go to question 11
   b. No – Go to question 9

9. Is the request for a formulary testosterone topical gel?
   a. Yes – Go to question 10
   b. No - Deny Cat 15 – *Member has access to testosterone injection and topical gel on formulary.*

10. Has the member had a 12 week trial of testosterone injection therapy with confirmed inability to achieve testosterone levels within normal limits OR a contradiction to therapy
    a. Yes – Go to question 11
    b. No – Forward to pharmacist or medical director for review- *Member has not demonstrated an inadequate response or contraindication to preferred agent of testosterone injection.*

11. Is the dosing and indication for requested testosterone agent within FDA approved indications and dosing guidelines for use? (check Up to Date for most current list of products/dosing)
    Note OHP does not cover testosterone therapy for sexual dysfunction

    Breast cancer-females - IM (testosterone enanthate): 200 to 400 mg every 2 to 4 weeks

    Delayed puberty in males- IM (testosterone enanthate): 50 to 200 mg every 2 to 4 weeks for a limited duration (usually 4 to 6 months)

    Hypogonadism in males
    IM
    (Testosterone enanthate or testosterone cypionate): Initial: 75 to 100 mg/week or 150 to 200 mg every 2 weeks; dosage range: 50 to 100 mg/week or 100 to 200 mg every 2 weeks

    Topical
    AndroGel 1%: Initial: 50 mg applied once daily in the morning to the shoulder and upper arms, or abdomen. Dosage range: 50 to 100 mg/day.

    AndroGel 1.62%: Initial: 40.5 mg applied once daily in the morning to the shoulder and upper arms. Dosage range: 20.25 mg to 81 mg/day; maximum: 81 mg/day.

    Fortesta: Initial: 40 mg once daily in the morning. Apply to the thighs. Dosing range: 10 to 70 mg/day; maximum dose: 70 mg/day

    Testim: Initial: 50 mg applied once daily (preferably in the morning) to the shoulder and upper arms, maximum dose: 100 mg/day.

    Vogelxo: Initial: 50 mg applied once daily in the morning to the shoulder and/or upper arms, maximum dose, 100 mg/day

    Solution (Axiron): Initial: 60 mg once daily (dosage range: 30 to 120 mg/day). Apply to the axilla at the same time each morning

    Cross Sex Hormone treatment for female to male transgender * Not an FDA approved use-dosing is from Endocrine Society guidelines

    IM - testosterone enanthate or testosterone cypionate 50 -100 mg weekly or 200 mg q 2 weeks

    Topical gel - 2.5 to 10 g/day

a. Yes – May approve up to 6 months for initial treatment –Endocrine Society recommends evaluation for response to therapy and adverse events in addition to monitoring of serum testosterone levels, blood pressure, liver function, lipid panel, hemoglobin and hematocrit at 3 to 6 months, at 12 months, then annually.
b. No – Deny – Cat 3 – Medication is being prescribed outside of FDA approved use and/or dosing guidelines.

Renewal Criteria

1. Has member had:

At least one serum testosterone level showing a value within normal limits

AND

At least one hematocrit showing a value within normal limits?

AND

A PSA within normal limits for any man aged 40 or older

- If hematocrit increases above the upper limit of normal, a cause should be sought and testosterone dose lowered or stopped. The Endocrine Society guidelines suggest stopping therapy if the hematocrit increases to ≥54 percent

a. Yes – May approve for up to 12 months

b. No- Forward to pharmacist or medical director for evaluation- *The Endocrine Society and the FDA have issued statements alerting clinicians to the potential concerns about testosterone therapy and cardiovascular safety. Routine monitoring is recommended. Testosterone therapy may elevated risk of prostate cancer*