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Prior Authorization Criteria Update: Androgens, Topical and Parenteral

Purpose of Update:

The purpose of this prior authorization (PA) update is to align current fee-for-service PA criteria with the Health Evidence Review Commission (HERC) guidance for use of testosterone replacement for testicular hypofunction. Testosterone products are used in a variety of conditions such as transgender health, primary hypogonadism, metastatic breast cancer, and weight loss with HIV-associated wasting. Currently for adults, topical formations and non-preferred products require PA. In patients less than 18 years of age, a PA is required for all patients. In October 2018, HERC recommended the following guidance on use of testosterone in patients with testicular hypofunction for implementation in January 2019.[1] Previous HERC guidance on androgens has only addressed use specifically for transgender health. This new guideline note does not apply to testosterone replacement therapy for HIV-associated weight loss, delayed puberty, treatment of metastatic breast cancer, or transgender health.

Line 467 Gonadal Dysfunction, Menopausal Management: Testosterone replacement therapy is included on this line for testicular hypofunction or dysfunction only when all of the following inclusion criteria are met and none of the exclusion criteria apply.

Inclusion criteria:

1) The patient is a male 18 years of age or older; AND
2) The patient has had TWO morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) at baseline demonstrating low testosterone levels as defined by the following criteria:
    a. Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR
    b. 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
3) Patient has received ONE of the following diagnoses:
    a. Primary Hypogonadism (congenital or acquired): defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; OR
    b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation

Exclusion criteria:

1) Patient has ANY of the following contraindications:
    a. Breast cancer or known or suspected prostate cancer

b. Elevated hematocrit (>50%)
c. Untreated severe obstructive sleep apnea
d. Severe lower urinary tract symptoms
e. Uncontrolled or poorly-controlled heart failure

2) Patient has experienced a major cardiovascular event (such as a myocardial infraction, stroke, acute coronary syndrome) in the past six months
3) Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating testosterone replacement therapy

Recommendation:

- Update the prior authorization criteria to align with HERC coverage guidance.

References:

1. Health Evidence Review Commission. HERC Draft Meeting Minutes. October 4, 2018. https://www.oregon.gov/oha/HPA/DSI-HERC/MeetingDocuments/HERC-Materials-10-4-18.pdf. Accessed October 22, 2018.

Appendix 1. Prior Authorization Criteria

Testosterone

Goal(s):

- Restrict use to medically appropriate conditions funded under the Oregon Health Plan (use for sexual dysfunction or body-building is not covered)

Length of Authorization:

- Up to 12 months

Requires PA:

All testosterone products

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the medication requested for AIDS-related cachexia?	**Yes:** Go to #8	**No:** Go to #3
3. Is the medication requested for one of the following diagnoses? a. Primary Hypogonadism (congenital or acquired): defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; OR b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation •	**Yes:** Go to #4	**No:** Go to #6
4. Is there documentation of 2 morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) demonstrating low testosterone levels at baseline as defined by the following criteria: a. Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR b. Total serum testosterone level less than 350ng/dL (12.1nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174nmol/L);	**Yes:** Go to #5	**No:** Deny; medical appropriateness

Approval Criteria		
5. Is there documentation based on submitted chart notes of any of the following diagnoses: a. A recent major cardiovascular event (i.e., myocardial infarction, stroke or acute coronary syndrome) within the past 6 months b. Heart failure with uncontrolled symptoms (i.e., NYHA Class III-IV, presence of edema, or evidence of fluid retention) c. Benign prostate hyperplasia with uncontrolled symptoms or presence of severe lower urinary tract symptoms (i.e., frequent symptoms of incomplete emptying, increased frequency, intermittency, urgency, weak stream, straining, or nocturia) d. Breast cancer e. Prostate cancer (known or suspected) or elevated PSA with prior use of testosterone f. Untreated obstructive sleep apnea with symptoms g. Elevated hematocrit (>50%)	**Yes:** Deny; medical appropriateness	**No:** Go to #8
6. Is the medication requested for gender dysphoria (ICD10 F642, F641)?	**Yes:** Go to #7	**No:** Go to #9
7. Have **all** of the following criteria been met? • Patient has the capacity to make fully informed decisions and to give consent for treatment; and • If patient <18 years of age, the prescriber is a pediatric endocrinologist; and • The prescriber agrees criteria in the Guideline Notes on the OHP List of Prioritized Services have been met.	**Yes:** Go to #8	**No**: Pass to RPh. Deny; medical appropriateness

Approval Criteria		
8. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require a co-pay. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class and approve for up to 12 months.	**No:** Approve for up to 12 months.
9. RPh only: all other indications need to be evaluated to see if funded under the OHP. Note: Testosterone should not be prescribed to patients who have any contraindicated diagnoses listed in question #5.	If funded and prescriber provides supporting literature: Approve for up to 12 months.	If not funded: Deny; not funded by the OHP

P&T Review: *11/18 (SS); 11/15; 2/12; 9/10; 2/06; 2/01; 9/00*
Implementation: *1/1/19; 5/1/16; 1/1/16; 7/31/14; 5/14/12, 1/24/12, 1/1/11, 9/1/06*