

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? <ul style="list-style-type: none"> • 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 • 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

Approval Criteria

<p>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:</p> <ul style="list-style-type: none">• 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)	<p>Yes: Go to #5</p>	<p>No: Deny; medical appropriateness</p>
<p>5. Is there documentation based on submitted chart notes of any of the following diagnoses:</p> <ul style="list-style-type: none">• A recent major cardiovascular event (i.e., myocardial infarction, stroke or acute coronary syndrome) within the past 6 months• Heart failure with uncontrolled symptoms (i.e., NYHA Class III-IV, presence of edema, or evidence of fluid retention)• 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)• Breast cancer• Prostate cancer (known or suspected) or elevated PSA with prior use of testosterone• Untreated obstructive sleep apnea with symptoms• Elevated hematocrit (>50%)	<p>Yes: Deny; medical appropriateness</p>	<p>No: Go to #8</p>
<p>6. Is the medication requested for gender dysphoria (ICD10 F642, F641)?</p>	<p>Yes: Go to #7</p>	<p>No: Go to #9</p>

Approval Criteria

<p>7. Have all of the following criteria been met?</p> <ul style="list-style-type: none"> • 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. <p>See: https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-127.docx</p>	<p>Yes: Go to #8</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Will the prescriber consider a change to a preferred product?</p> <p>Message:</p> <ul style="list-style-type: none"> • 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. 	<p>Yes: Inform prescriber of covered alternatives in class and approve for up to 12 months.</p>	<p>No: Approve for up to 12 months.</p>
<p>9. RPh only: all other indications need to be evaluated to see if funded under the OHP.</p> <p>Note: Testosterone should not be prescribed to patients who have any contraindicated diagnoses listed in question #5.</p>	<p>If funded and prescriber provides supporting literature: Approve for up to 12 months.</p>	<p>If not funded: Deny; not funded by the OHP</p>

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