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)
- Allow case-by-case review for members covered under the EPSDT program.

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 #7	**No:** Go to #3
3. Is the medication requested for one of the following diagnoses? • 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		
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: • Total serum testosterone level less than 300 ng/dL (10.4 nmol/L); OR • Total serum testosterone level less than 350 ng/dL (12.1 nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174 nmol/L)	**Yes:** Go to #5	**No:** Deny; medical appropriateness
5.Is there documentation based on submitted chart notes of any of the following diagnoses: • 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 prostate specific antigen (PSA) with prior use of testosterone • Untreated obstructive sleep apnea with symptoms • Elevated hematocrit (>50%)	**Yes:** Deny; medical appropriateness	**No:** Go to #8
6. Is the medication requested for gender-affirming care?	**Yes:** Go to #7	**No:** Go to #8

Approval Criteria		
7. 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 the preferred product for up to 12 months.	**No:** Approve the requested agent for up to 12 months.
8. RPh only: all other indications need to be evaluated for medical appropriateness under the OHP. Note: Testosterone should not be prescribed to patients who have any contraindicated diagnoses listed in question #5. Testosterone is FDA-approved only for primary hypogonadism and hypogonadotropic hypogonadism as defined in question #3. Safety and efficacy of testosterone therapy have not been established in people with late-onset (age-related) hypogonadism.	If not eligible for EPSDT review and prescriber provides evidence to supported off-label use: Approve for up to 12 months. If eligible for EPSDT review: prescriber provides documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc) AND evidence supported off-label use: Approve for up to 12 months.	If there is not adequate documentation to support therapy: Deny; medical appropriateness.

P&T Review: *10/24 (DE); 8/23 (SS); 11/18; 11/15; 2/12; 9/10; 2/06; 2/01; 9/00*
Implementation: *9/1/23; 1/1/19; 5/1/16; 1/1/16; 7/31/14; 5/14/12, 1/24/12, 1/1/11, 9/1/06*