Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
Salem, Oregon 97301-1079
Phone 503-947-5220 | **Fax** 503-947-1119

Prior Authorization Criteria Update: Estrogen Replacement (oral, topical, vaginal); Androgens (oral, topical, parenteral)

Plain Language Summary:

- The Oregon legislature recently passed a bill to ensure individuals receiving gender-affirming care have access to health care services.

Purpose of Update:

- The purpose of this update is to evaluate pharmacy utilization of drugs that can be used for gender-affirming care and review requirements in recently passed state legislation.

Conclusions:

- New legislation specifies that the Oregon Health Authority may not deny or limit coverage under the plan for gender-affirming treatment that is medically necessary and prescribed in accordance with accepted standards of care. Before denying gender-affirming treatment a provider with experience prescribing or delivering gender-affirming treatment must first review and approve the denial of or the limitation on access to the treatment.
- In an analysis of members with paid or denied FFS claims from 10/1/22 to 12/31/22, members were prescribed estrogen (n=318 members), testosterone (n=195), progesterone products (n=243), and gonadotropin-releasing hormone (GnRH) agonists (n= 11; e.g., leuprolide). Members with claims for more than one product within the same drug class or in different drug classes may be counted more than once.
- Most members with claims for estrogen or progesterone had initial paid claims which is consistent with the current policy where preferred products are available without prior authorization for many members. Denied claims were more common for vaginal estrogen products which are generally prescribed for diagnoses other than gender-affirming treatment.
- Claims for testosterone were initially paid for only 29% of members and paid within 90 days of an initial denial for 18% members. Fifty-three percent of members prescribed testosterone had an initial denied claim without any subsequent paid claims for a comparable product (n=105). Most of these members with denied claims for testosterone were enrolled in a CCO or had other insurance in the 90 days following an initial denial, which may be why claims were not paid by FFS. Only 8% of members had a denied prior authorization (PA) for testosterone and 17% of members had no PA submitted.
- The majority of requests for GnRH agonists were approved. Only 11 members had claims for GNRH agonists, and all but 1 member ultimately had a claim paid by FFS within 90 days following the first claim.

Recommendation:

- Update PA criteria for estrogen and testosterone products to align with recently passed state legislation **(Appendix 1**).

Author: Sarah Servid, PharmD and Deanna Moretz, PharmD, BCPS

Date: August 2023

Background

2023 Oregon Legislative Update

In June 2023, House Bill 2002-C was enacted to modify provisions relating to protections for providers and individuals receiving gender-affirming health services. Section 24 states: "Gender-affirming treatment means a procedure, service, drug, device or product that a physical or behavioral health care provider prescribes to treat an individual for incongruence between the individual's gender identity and the individual's sex assignment at birth.

The Oregon Health Authority or a coordinated care organization may not:

a) Deny or limit coverage under the plan for gender-affirming treatment that is:

1) medically necessary as determined by the physical or behavioral health care provider who prescribes the treatment; and

2) prescribed in accordance with accepted standards of care;

b) Deny or limit gender-affirming treatment unless a physical or behavioral health care provider with experience prescribing or delivering gender-affirming treatment has first reviewed and approved the denial of or the limitation on access to the treatment."[1]

A review of the estrogen and androgen replacement PA criteria resulted in additional language for requests of either agent to support gender-affirming therapy.

Brief Drug Use Evaluation

This brief drug use evaluation assessed members with paid or denied claims for drugs that can be used for gender-affirming care. Drug classes included androgens, estrogens, progestational agents, and GNRH agonists. Currently all androgens and GnRH agonists require prior authorization to ensure use for a funded and medically appropriate indication. Because estrogens are commonly used for other indications such as symptoms of menopause, PA is only required for members under 18 years of age. Preferred progesterone products are available without PA.

Members were included if they had paid or denied fee-for-service (FFS) claims for these drugs from 10/1/22 to 12/31/22. Members were categorized based on whether the IE was paid or denied and based on subsequent claims and enrollment status changes in the 90 days following the IE.

Table 1 shows initial claim status for members with paid or denied claims based on drug class. If members had claims in multiple drug classes or denied claims for more than one product, they may be counted more than once. The most commonly prescribed classes included androgens and oral estrogens. Paid claims were more common for estrogens and progestational agents which are available without PA for preferred products for many members. Denied claims were more common for androgens and GnRH agonists which require PA for all products. A paid claim in the subsequent 90 days generally indicates that a PA was submitted and approved based on clinical criteria. While the majority of these members had a paid claim within 30 days of the initial denial, this demonstrates a delay in care for these members. Eighteen percent (n=35) of members with claims for testosterone had an initial denial but subsequent claim paid by FFS. The number of members with claims for GnRH agonist was smaller, but a large proportion (36%, n=4) had a subsequent paid claim. More than half of members with claims for androgens (53%) had an initial denial and no subsequent paid claim within 90 days. Diagnoses available in medical claims in the 6 months prior to or during the evaluation window are listed in **Table 2**. About 75% of members with no subsequent paid FFS claims were enrolled in a CCO, lost eligibility, or had other primary insurance coverage within 90 days of the initial denial which may account for the lack of paid FFS claims (**Table 3**). A PA for testosterone was denied for 8 members (8%) and not requested for 17 members (16%).

Table 1. Members with paid or denied claims for drugs used in gender affirming treatment

	Initially Paid		Initially Denied & Paid Within 90 days		No Drugs Paid Within 90 Days		Total
	#	%	#	%	#	%	
Androgens, Topical & Parenteral	57	29%	35	18%	105	53%	195
Estrogen Replacement, Oral	169	93%	2	1%	10	6%	181
Estrogen Replacement, Topical	67	93%	1	1%	4	5%	72
Estrogen Replacement, Vaginal	52	80%	9	14%	4	6%	65
GnRH Agonists	5	45%	4	36%	1	18%	11
Progestational Agents	237	98%	5	2%	1	0%	243

Table 2. Diagnoses for members in the 6 months prior to or during the evaluation window

	Initially paid		Initially Denied & Paid Within 90 days		No Drugs Paid Within 90 days	
N=	522	%	54	%	125	%
Gender identity disorders (F64x)	74	14%	22	41%	39	31%
Testicular dysfunction (E29x)	11	2%	4	7%	28	22%
Menopausal and other perimenopausal disorders (N95x)	81	16%	3	6%	1	1%
Excessive, frequent and irregular menstruation (N92x)	46	8%	2	4%	4	3%
Other abnormal uterine and vaginal bleeding (N93x)	41	7%	4	7%	0	0%

Table 3. Enrollment and PA status for members with no paid claims after an initial denial

	Enrolled in CCO		Lost Eligibility		Has Other Insurance		PA Approved		PA Denied		PA Not Requested		Total #
	#	%	#	%	#	%	#	%	#	%	#	%	
Androgens, Topical & Parenteral	37	35%	3	3%	39	37%	1	1%	8	8%	17	16%	105
Estrogen Replacement, Oral	3	30%	1	10%	4	40%	0	0%	0	0%	2	20%	10
Estrogen Replacement, Topical	0	0%	0	0%	4	100%	0	0%	0	0%	0	0%	4
Estrogen Replacement, Vaginal	1	25%	0	0%	1	25%	0	0%	0	0%	2	50%	4
GnRH Agonists	0	0%	0	0%	1	100%	0	0%	0	0%	0	0%	1
Progestational Agents	0	0%	0	0%	0	0%	0	0%	0	0%	1	100%	1

Author: Servid

Date: August 2023

References:

1. Oregon Legislature 2023 Updates. https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB2002/Enrolled. Accessed June 28, 2023.

Appendix 1. Proposed Prior Authorization Criteria

Estrogen Derivatives

Goal(s):

- Restrict use to medically appropriate conditions funded under the OHP

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred estrogen derivatives

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. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require prior authorization • 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	**No:** Go to #3

Approval Criteria		
3. Is the request for a funded diagnosis?	**Yes**: Approve for up to 6 months	**No:** If non-funded and current age ≥21 years: Deny; not funded by the OHP If non-funded and current age < 21 years: Go to #4
4. Is there 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)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical necessity.
5. Is the request for: a) an FDA approved indication AND b) for a preferred product or has the patient failed to have benefit with, or have contraindications or intolerance to the preferred products?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness

P&T / DUR Review: *8/23 (SS); 8/22 (KS); 1/17; 11/15*
Implementation: *9/1/23; 4/1/17; 1/1/16*

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
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 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)	**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 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%)	**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
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 for up to 12 months.	**No:** Approve for up to 12 months.

Approval Criteria		
8. 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: Current age ≥ 21 years: Deny; not funded by the OHP Current age < 21 years: 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 supporting literature then approve for up to 12 months.

P&T Review: *8/23 (SS); 11/18 (SS); 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*