

Policy Proposal: Substance Use Disorder

Purpose:

The purpose of this policy proposal is to update current prior authorization (PA) criteria to comply with new legislation.

Background:

During the 2019 legislative session, the Oregon legislature passed House Bill 2257 which declared the legislative intent to consider substance use disorder as a chronic illness.¹ The new legislation requires the Oregon Health Authority to prohibit use of prior authorization (PA) during the first 30 days of medication-assisted treatment for both opioid- and alcohol-related substance use disorders.¹ This update recommends changes to PA and preferred drug list (PDL) status to comply with this new legislation and proposes a retrospective drug use review (DUR) program with the goals of avoiding interruptions in therapy and ensuring appropriate use of long-term second-line treatment options for opioid use disorder (OUD).

Currently in fee-for-service Medicaid, treatments for OUD or alcohol use disorder available without PA include acamprosate tablets, naltrexone tablets, naltrexone extended release injection, and preferred buprenorphine/naloxone sublingual tablets and film (unless the daily dose of buprenorphine exceeds 24 mg to prevent off-label use for treatment of pain). Drug therapy for OUD or alcohol use disorder which are currently non-preferred and require PA include Bunavail® (buprenorphine/naloxone film), buprenorphine sublingual tablets, buprenorphine extended-release injection, buprenorphine implants, disulfiram and lofexidine. Methadone for the treatment of OUD is required to be dispensed by a practitioner rather than dispensed through a pharmacy and is not subject to PA. The intent of the current PA criteria is to limit off-label use for pain, encourage use of monotherapy products for appropriate patients, and prevent concomitant opioid prescribing. In a previous policy evaluation of therapies for OUD, about 14% of patients prescribed OUD treatment had no diagnosis of opioid use, dependence or abuse based on claims history.

Recent high quality guidelines from the Veterans Affairs/Department of Defense (VA/DOD) recommend use of buprenorphine-naloxone or methadone as first-line treatment options for OUD (strong recommendation based on high quality evidence).² Similar recommendations were made in a high quality guideline from the Canadian Research Initiative in Substance Misuse published in 2018 recommending buprenorphine/naloxone as first-line therapy and methadone as a second-line option.³ Buprenorphine monotherapy is recommended only in patients who are pregnant.² Current evidence indicates that, while oral buprenorphine monotherapy has similar efficacy to combination buprenorphine/naloxone, it is associated with a significantly higher rate of abuse, misuse, and diversion compared to combination buprenorphine-naloxone products.⁴ Extended-release injectable naloxone may be considered as a treatment option for patients for whom buprenorphine/naloxone or methadone is contraindicated, unacceptable, or unavailable, and who have established opioid abstinence for at least 7 to 10 days based on moderate quality evidence.²

For treatment of alcohol use disorder, 2015 guidelines from the VA/DOD recommend choice of treatment with either acamprosate, disulfiram, naltrexone (oral or extended-release injection) or topiramate be based on individual risks/benefit assessment, specific needs, and patient preferences (strong recommendation).² There is insufficient evidence to recommend one agent over another, and in all cases, psychosocial interventions are recommended to successfully improve outcomes, decrease alcohol use, and improve abstinence in patients with alcohol use disorder (strong recommendation based on moderate quality evidence).²

Examples of psychosocial interventions may include behavioral couples counseling, cognitive behavioral therapy, 12-step programs, or motivational enhancement therapy.

In an evaluation of paid and denied claims for substance use disorder from 1/1/2019 to 3/31/2019, there were 632 patients prescribed therapies for OUD or alcohol use disorder. Patients may be counted more than once if they were prescribed multiple types of therapy. About 77% of prescribed therapy was for preferred products and 23% was for non-preferred products. All but one request for preferred therapy was initially paid or paid within 30 days of the request, indicating very little utilization of high dose buprenorphine (>24 mg/day) for preferred products. Doses exceeded 24mg per day in about 4% of members with denied claims for non-preferred buprenorphine monotherapy (n=7). The most commonly requested non-preferred product was oral buprenorphine monotherapy. Forty-four percent of patients requesting buprenorphine monotherapy (n=56) had a subsequent PA approved and 11% of patients (n=14) switched to a preferred agent. In 45% of patients with an initial denied claim, there were no paid claims for subsequent therapy. Of the patients with no subsequent paid fee-for-service claims for OUD, 92% were subsequently enrolled in a coordinated care organization, lost Medicaid eligibility, or had other insurance which may have paid for their therapy. Three patients had a PA approved but no subsequent paid claims for the therapy.

Recommendations:

- Recommend removal of PA requirement for all OUD products except if dose limit of 24 mg buprenorphine per day is exceeded for transmucosal products (**Appendix 1**).
- After evaluation of costs in executive session, buprenorphine sublingual tablets, disulfiram tablets, and buprenorphine/naloxone film (Bunavail®) were designated as voluntary non-preferred and buprenorphine injection (Sublocade®) was designated as preferred. The recommendation was made to designate new products in the class as voluntary non-preferred.
- Continue to monitor use of substance use disorder products to assess potential changes in medically appropriate use.

References:

1. House Bill 2257 (enrolled). 80th Oregon Legislative Assembly - 2019 Regular session. Available at <https://olis.leg.state.or.us/liz/2019R1/Downloads/MeasureDocument/HB2257>. Accessed 9/17/19.
2. Clinical Practice Guideline for Substance Use Disorders (2015). U.S. Department of Veterans Affairs/Department of Defense. <http://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf>. Accessed September 19, 2019.
3. Bruneau J, Ahamad K, Goyer ME, et al. Management of opioid use disorders: a national clinical practice guideline. *Canadian Medical Association journal*. 2018;190(9):E247-e257.
4. Canadian Agency for Drugs and Technologies in Health. Buprenorphine formulations for the treatment of opioid use disorders: a review of comparative clinical effectiveness, cost-effectiveness and guidelines. Ottawa: 2017 Jul. (CADTH rapid response report: summary with critical appraisal). <https://www.cadth.ca/sites/default/files/pdf/htis/2017/RC0908%20Buprenorphine%20Formulations%20Final.pdf>.

Appendix 1. Prior Authorization Criteria

Buprenorphine and Buprenorphine/Naloxone

Goals:

- Prevent use of high-dose transmucosal buprenorphine products for off-label indications.

Length of Authorization:

- Up to 6 months

Requires PA:

- Transmucosal buprenorphine products that exceed an average daily dose of 24 mg per day

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. Is the diagnosis funded by the OHP?	Yes: Go to #2	No: Pass to RPh. Deny; not funded by OHP
2. Is the prescription for opioid use disorder (opioid dependence or addiction)?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the prescription for a transmucosal formulation of buprenorphine (film, tablet) with an average daily dose of more than 24 mg (e.g., >24 mg/day or >48 mg every other day)?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #4

Approval Criteria		
<p>4. Is the requested medication a preferred agent?</p>	<p>Yes: Approve for anticipated length of treatment or 6 months, whichever is less.</p> <p>Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.</p>	<p>No: Go to #5</p>
<p>5. Will the prescriber switch to a preferred product?</p> <p>Note: Preferred products are reviewed for comparative safety and efficacy by the Oregon Pharmacy and Therapeutics Committee.</p>	<p>Yes: Inform prescriber of covered alternatives in class.</p>	<p>No: Approve for anticipated length of treatment or 6 months, whichever is less.</p> <p>Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.</p>

P&T/DUR Review: 11/19 (DM); 1/19; 1/17; 9/16; 1/15; 9/09; 5/09
Implementation: 1/1/2020; 3/1/2019; 4/1/2017; 9/1/13; 1/1/10

Lofexidine

Goal(s):

- Encourage use of substance use disorder medications on the Preferred Drug List.
- Restrict use of lofexidine under this PA to ensure medically appropriate use of lofexidine based on FDA-approved indications.

Length of Authorization:

- Up to 14 days

Requires PA:

- Lofexidine 0.18mg tablets

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		
<ul style="list-style-type: none"> • What diagnosis is being treated? 	Record ICD10 code.	
<ul style="list-style-type: none"> • Is this an FDA approved indication? (Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults) 	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
<ul style="list-style-type: none"> • Will the prescriber consider a change to a preferred product? <p>Message:</p> <ul style="list-style-type: none"> • Preferred products do not require a PA. Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee. 	Yes: Inform prescriber of covered alternatives in class.	No: Approve for up to 14 days of total therapy. Note: FDA approved indication is for up to 14 days of therapy AND Notify prescriber concomitant naloxone is recommended if not present in claims history.

P&T/DUR Review: 11/19 (DM); 1/19
 Implementation: 3/1/19