Buprenorphine and Buprenorphine/Naloxone

Goals:

- Encourage use of buprenorphine products on the Preferred Drug List.
- Restrict use of buprenorphine products under this PA to management of opioid use disorder.
- Restrict use of oral transmucosal buprenorphine monotherapy products (without naloxone) to pregnant patients or females actively trying to conceive.

Length of Authorization:

- Up to 6 months

Requires PA:

- Buprenorphine sublingual tablets
- Suboxone® and generics (buprenorphine/naloxone) film and sublingual tablets that exceed an average daily dose of 24 mg per day of buprenorphine
- Bunavail® (buprenorphine/naloxone buccal film)
- Zubsolv® (buprenorphine/naloxone sublingual tablets)
- Probuphine® (buprenorphine subdermal implants)
- Sublocade™ (buprenorphine extended-release subcutaneous injection)

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 request for renewal of therapy previously approved by the FFS system?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Is the prescription for opioid use disorder (opioid dependence or addiction)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is the patient part of a comprehensive treatment program for substance abuse that includes psychosocial support system (e.g. individual and group counseling, intensive outpatient treatment, recovery support services, or 12-step fellowship)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness. Buprenorphine therapy must be part of a comprehensive treatment program that includes psychosocial support.

Approval Criteria		
5. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com), evaluated the PDMP at least once in the past 6 months, and verified that the patient is not currently t prescribed any opioid analgesics from other prescribers?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the requested medication a preferred agent?	**Yes:** Go to #8	**No:** Go to #7
7. Will the prescriber switch to a preferred product? Note: Preferred products are reviewed for comparative safety and efficacy by the Oregon Pharmacy and Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Go to #8
8. Is the request for the buprenorphine implant system (Probuphine)?	**Yes:** Go to #9	**No:** Go to #10
9. Has the patient been *clinically stable* on 8 mg daily or less of Suboxone or Subutex (or equivalent, see Table 1) for at least 6 months? Note: see Table 1 for definition of clinical stability and for equivalent dosing of other buprenorphine products.	**Yes:** If <u>all</u> criteria in Table 1 met, approve 4 implants for 6 months. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	**No:** Pass to RPh. Deny; medical appropriateness
10. Is the request for extended-release subcutaneous buprenorphine injection (Sublocade™)?	**Yes:** Go to #11	**No:** Go to # 13

Approval Criteria		
11. Is the provider registered through the Sublocade™ REMS program? Note: Sublocade carries a boxed warning that stipulates healthcare settings and pharmacies that order and dispense Sublocade™ must be certified in the Sublocade™ REMS program and comply with the REMS requirements due to serious harm or death if this product is administered intravenously. Prescriber offices that only order Sublocade from a certified pharmacy for a specific patient are exempt from certification. Further information is available at www.SublocadeREMS.com or call 1-866-258-3905.	**Yes:** Go to #12	**No:** Pass to RPh. Deny; medical appropriateness.
12. Has the patient been clinically stable on a transmucosal buprenorphine-containing product at a dose of 8 to 24 buprenorphine per day (or equivalent-see note below) for a minimum of 7 days? Note: One Suboxone® (buprenorphine and naloxone) 8 mg/2 mg sublingual tablet provides equivalent buprenorphine exposure to one Subutex® (buprenorphine HCl) 8 mg sublingual tablet or one Bunavail® (buprenorphine and naloxone) 4.2mg/0.7 mg buccal film or one Zubsolv® (buprenorphine and naloxone) 5.7 mg/1.4 mg sublingual tablet Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	**Yes:** Approve 300mg once a month for 2 months followed by 100mg once a month for 6 months total Increasing the maintenance dose to 300mg once a month may be considered for patients who tolerate the 100mg dose but do not demonstrate a satisfactory clinical response as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use.	**No:** Pass to RPh. Deny; medical appropriateness.
13. 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 #14

Approval Criteria		
14. Is the prescribed product a buprenorphine monotherapy product (i.e., without naloxone)	**Yes:** Go to #15	**No:** Go to #17
15. Is the patient pregnant or a female actively trying to conceive?	**Yes:** Go to #17	**No:** Go to #16
16. Does the patient have a contraindication or intolerance to buprenorphine/naloxone combination products that prevents successful management of opioid use disorder?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness
17. What is the expected length of treatment?	Document length of therapy: _____ Approve for anticipated length of treatment or 6 months, whichever is shorter. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	

Table 1. Criteria for Approved Use of Probuphine (buprenorphine implant).[1]

PROBUPHINE implants are only for use in patients who meet ALL of the following criteria:

- Patients should not be tapered to a lower dose for the sole purpose of transitioning to PROBUPHINE
- Stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual Subutex or Suboxone sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments:
    - Examples of acceptable daily doses of transmucosal buprenorphine include:
        - Subutex (buprenorphine) sublingual tablet (generic equivalent) 8 mg or less
        - Suboxone (buprenorphine and naloxone) sublingual tablet (generic equivalent) 8 mg/2 mg or less
        - Bunavail (buprenorphine and naloxone) buccal film 4.2 mg/0.7 mg or less
        - Zubsolv (buprenorphine and naloxone) sublingual tablets 5.7 mg/1.4 mg or less

Consider the following factors in determining clinical stability and suitability for PROBUPHINE treatment:

- no reported illicit opioid use
- low to no desire/need to use illicit opioids
- no reports of significant withdrawal symptoms
- stable living environment
- participation in a structured activity/job that contributes to the community
- consistent participation in recommended cognitive behavioral therapy/peer support program
- stability of living environment
- participation in a structured activity/job

Reference: PROBUPHINE (buprenorphine implant for subdermal administration) [Prescribing Information]. Princeton, MJ: Braeburn Pharmaceuticals, Inc., May 2016.

Renewal Criteria		
1. Has the patient been assessed for the effectiveness of the treatment plan and overall progress that warrants continued treatment with buprenorphine?	**Yes:** Go to # 2.	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
2. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com), and has the prescriber verified evaluated the PDMP at least once in the past 6 months, and verified that the patient is not currently has not been prescribed any opioid analgesics from other prescribers?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Does the patient have a contraindication or intolerance to buprenorphine/naloxone combination products that prevents successful management of opioid use disorder?	**Yes:** Go to # 4	**No:** Pass to RPh. Deny; medical appropriateness
4. What is the expected length of treatment?	Document length of therapy: _____ Approve for anticipated length of treatment or 6 months, whichever is shorter. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	

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