

## MaineCare Extended-Release Buprenorphine Clinical Criteria

Preferred cost-effective options include buprenorphine/naloxone films and oral tablets of buprenorphine/naloxone. However, some members may qualify for extended-release buprenorphine (XRB) based on criteria listed below.

1. The prescriber attests (and is reflected in medical record documentation) that:
    - a. the member has a documented history of opioid use disorder (OUD),
    - b. XRB is being used for the treatment of OUD (rather than pain or any other non-FDA approved indication) and
    - c. the member's total daily dose of sublingual buprenorphine is less than or equal to 24 mg daily.
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AND at least one of the following is true:

1. The member's previous use of sublingual buprenorphine has included misuse, overuse, or diversion.
2. The member is at high risk of overdose (e.g., individuals leaving incarceration; those leaving abstinence-based treatment programs; individuals who are unhoused; or those facing potential gaps in care due to geographically limited treatment access or unavoidable delays in care).
3. The member has difficulty keeping OUD treatment medications safe (e.g., because they are unhoused or living in unstable settings)
4. The member has experienced significant medical complications of OUD and/or of injection drug use. Occurrence should be in the last 5 years, or it should be clearly documented that the risk indicated by this infection or complication is ongoing
  - Examples of medical complications of OUD include: threatened the function of organs or life, limb threatening and required medical and/or surgical therapy. Examples of medical complications of injection drug use include: osteomyelitis, endocarditis, renal failure, joint infection or other serious medical complications directly related to OUD.
5. The member has treatment-resistant OUD, including those with ongoing illicit substance use in the context of sublingual buprenorphine treatment as documented by positive urine drug screens or other clear objective evidence, and/or further functional decline with explicit documentation of the functional decline.
6. The member has a significant intolerance of, or documented allergy to, sublingual buprenorphine (either buprenorphine monotherapy or buprenorphine/naloxone combination therapy) that has resulted in the patient's inability to comply with continued treatment using the sublingual product.
  - A true allergy is usually accompanied by rash, respiratory symptoms, or anaphylaxis.
  - Other complaints such as bad taste, mouth tingling, etc. do not constitute evidence of allergy or significant intolerance.
  - Formulation preference or convenience are not, in and of themselves, indications for using XRB.
7. The member is in ongoing treatment with XRB and would like to continue the medication.

If to be used as an attestation form, will need explicit documentation in chart outlining the specific criteria met and rational for meeting the criteria.