Clinical Policy: buprenorphine and buprenorphine/naloxone (Bunavail™, Suboxone®, Zubsolv®)

Reference Number: ERX.NSMN.03
Effective Date: 06/15
Last Review Date: 09/16

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Description
The intent of the criteria is to ensure that patients follow selection elements established by Envolve Pharmacy Solutions for the use of buprenorphine and buprenorphine/naloxone (Bunavail™, Suboxone®, Zubsolv®).

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that buprenorphine and buprenorphine/naloxone (Bunavail™, Suboxone®, Zubsolv®) are medically necessary for members meeting the following criteria:

Initial Approval Criteria (must meet all):
A. Diagnosis of opioid dependence;
B. Age ≥ 16 years;
C. Prescriber has an “X” DEA number;
D. Member will undergo random urine drug screens at least monthly for the duration of treatment;
E. If request is for a non-PDL agent, failure of all PDL agents, unless contraindicated;
F. If request is for buprenorphine, member meets one of the following:
   i. Member is currently pregnant;
   ii. Member is allergic to naloxone;
   iii. Member is contraindicated or intolerant to buprenorphine/naloxone;
   iv. Request is for induction therapy;
G. Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: buprenorphine for induction therapy: 7 days
All other requests: 6 months
**Continued Approval (must meet all):**

A. Previously received medication via health plan benefit or member has previously met all initial approval criteria;

B. Member has not received an opioid analgesic within the last 30 days;

C. Negative monthly random urine drug screens since last approval;

D. If request is for buprenorphine, member continues to meet one of the following:
   i. Member is currently pregnant;
   ii. Member is allergic to naloxone;
   iii. Member has documented contraindication(s) or intolerance to buprenorphine/naloxone;

E. If request is for a dose increase, request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 6 months**

**Workflow Document**

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buprenorphine and

**Background**

**Description/Mechanism of Action**

Buprenorphine is a partial opioid agonist that binds to the mu receptor, reinitiating opioid activity in the brain producing less euphoria than a full opioid agonist but sufficient activity to suppress withdrawal and cravings. Naloxone is a potent antagonist at mu-opioid receptors and produces opiate withdrawal signs and symptoms when administered parenterally to individuals physically dependent on opioid agonists. The naloxone component is included to discourage diversion and misuse. Naloxone has very limited bioavailability when administered sublingually, as intended. In the absence of an opioid, the antagonist has no effect.

**FDA Approved Indications**

Buprenorphine, buprenorphine/naloxone, Suboxone, Bunavail, and Zubsolv are indicated for the treatment of opioid dependence.

**References**

2. Substance Abuse and Mental Health Services Administration. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Available at:
**Clinical Policy**
buprenorphine and buprenorphine/naloxone
(Bunavail™, Suboxone®, Zubsolv®)


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<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
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<tbody>
<tr>
<td>Policy created.</td>
<td>04/15</td>
<td>06/15</td>
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<tr>
<td>Updated to new template (converted algorithm to bulleted criteria, added background and references). Removed branded product Subutex from policy as it has been discontinued by the manufacturer.</td>
<td>07/16</td>
<td>09/16</td>
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