Clinical Policy: Buprenorphine-Naloxone (Bunavail, Suboxone, Zubsolv)
Reference Number: OH.PHAR.PPA.17
Effective Date: 01.01.19
Last Review Date: 12.18
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Buprenorphine-naloxone (Bunavail®, Suboxone®, and Zubsolv®) is a partial opioid agonist.

FDA Approved Indication(s)
Bunavail, Suboxone, and Zubsolv are indicated for the treatment of opioid dependence.

Policy/Criteria
Short acting buprenorphine products are covered without prior authorization as long as the dose does not exceed 16 mg per day (of buprenorphine equivalent) after the initial 90 days of fill. Prior authorization will be required for those doses exceeding 16 mg per day of buprenorphine equivalent after the initial 90 day period.

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Bunavail, Suboxone, and Zubsolv are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Opioid Dependence (must meet all):
      1. Diagnosis of opioid dependence;
      2. Age ≥ 16 years;
      3. Dose does not exceed:
         a. Bunavail: 8.4 mg per day
         b. Suboxone: 16 mg per day
         c. Zubsolv: 11.4 mg per day
      4. If request is for dose exceeding those stated in criteria 4 above, all of the following must be met (a, b, c, and d):
         a. Dose does not exceed the following: Bunavail (12.6 mg per day), Suboxone (24 mg per day), or Zubsolv (17.1 mg per day)
         b. Prescriber has X DEA number
         c. Prescriber submits documentation with rationale for dose increase
         d. Prescriber submits a taper plan
      Approval duration: 12 months
   B. Other diagnoses/indications
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1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. **Continued Therapy**

A. **Opioid Dependence** (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. Member is responding positively to therapy;
   3. One of the following conditions is met (a or b):
      a. Member has NOT received an opioid analgesic since last approval;
      b. Prescriber submits documentation acknowledging that the use of opioid during the last approval period was due to legitimate diagnosis of pain;
   4. If request is for a dose increase, new dose does not exceed:
      a. Bunavail: 8.4mg per day
      b. Suboxone 16 mg per day
      c. Zubsolv: 11.4 mg per day
   5. If request is for dose exceeding those stated in criteria 4 above, all of the following must be met (a, b, c, and d):
      a. Dose does not exceed the following: Bunavail (12.6 mg per day), Suboxone (24 mg per day), or Zubsolv (17.1 mg per day)
      b. Member is seen by an addictionologist (i.e. prescriber has X DEA number)
      c. Prescriber submits documentation with rationale for dose increase
      d. Prescriber submits a taper plan

   **Approval duration: 12 months**

B. **Other diagnoses/indications** (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      **Approval duration: Duration of request or 12 months (whichever is less); or**
   2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. **Diagnoses/Indications for which coverage is NOT authorized:**

A. Pain management;

B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. **Appendices/General Information**

   *Appendix A: Abbreviation/Acronym Key*
   FDA: Food and Drug Administration

   *Appendix B: Therapeutic Alternatives*
   N/A
### V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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</table>
| Buprenorphine-naloxone (Suboxone) sublingual (SL) or buccal dissolving film | **Induction**: Titrate to 8 mg/2 mg SL on Day 1 and 16 mg/4 mg SL on Day 2; then start maintenance treatment  
**Maintenance**: Target dose: buprenorphine 16 mg/naloxone 4 mg once daily; dosage should be adjusted in increments or decrements of 2 mg/0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day | 24 mg/6 mg per day |
| Buprenorphine-naloxone (Bunavail) buccal film      | **Maintenance**: Target dose: buprenorphine 8.4 mg/naloxone 1.4 mg once daily; dosage should be adjusted in increments or decrements of 2.1 mg/0.3 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.1 mg/0.3 mg to 12.6 mg/2.1 mg per day | 12.6 mg/2.1 mg per day |
| Buprenorphine-naloxone SL tablet                    | **Maintenance**: Target dose: buprenorphine 16 mg/naloxone 4 mg SL once daily; dosage should be adjusted in increments or decrements of 2 mg/0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day | 24 mg/6 mg per day |
| Buprenorphine-naloxone (Zubsolv) SL tablet         | **Induction**: Titrate to 5.7 mg/1.4 mg SL on Day 1 and 11.4 mg/2.9 mg SL on Day 2; then start maintenance treatment  
**Maintenance**: Target dose: buprenorphine 11.4 mg/naloxone 2.9 mg once daily; dosage should be adjusted in increments or decrements of 2.9 mg/0.71 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.9 mg/0.71 mg to 17.2 mg/4.2 mg per day | 17.1 mg/4.2 mg per day |

### VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine-naloxone (Suboxone)</td>
<td>Sublingual film: buprenorphine/naloxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg</td>
</tr>
<tr>
<td>Buprenorphine-naloxone (Bunavail)</td>
<td>Buccal film: buprenorphine/naloxone 2.1 mg/0.3 mg; 4.2 mg/0.7 mg, 6.3 mg/1 mg</td>
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Buprenorphine-Naloxone

<table>
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<tr>
<th>Drug Name</th>
<th>Availability</th>
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<tbody>
<tr>
<td>Buprenorphine-naloxone</td>
<td>Sublingual tablet: buprenorphine/naloxone 2 mg/0.5 mg, 8 mg/2 mg</td>
</tr>
<tr>
<td>Buprenorphine-naloxone</td>
<td>Sublingual tablet: buprenorphine/naloxone 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg</td>
</tr>
</tbody>
</table>

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tr>
<td>Policy created.</td>
<td>12.18</td>
<td>01.19</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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