BUPRENORPHINE FOR OPIOID DEPENDENCE

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suboxone</td>
<td>buprenorphine/naloxone</td>
<td>Per Medical Guidelines</td>
</tr>
<tr>
<td>Subutex</td>
<td>buprenorphine</td>
<td>Per Medical Guidelines</td>
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<tr>
<td>Zubsolv</td>
<td>buprenorphine/naloxone</td>
<td>Per Medical Guidelines</td>
</tr>
<tr>
<td>Bunavail</td>
<td>buprenorphine/naloxone</td>
<td>Per Medical Guidelines</td>
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</tbody>
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Suboxone/Zubsolv/Bunavail Approvable Criteria:

I. Is therapy being initiated as a ‘condition of employment’?
   • If no, continue to II.
   • If yes, do not approve.

II. Is the request for Suboxone Tablet?
   • If no, continue to III.
   • If yes, members must have documented intolerance/contraindication to Suboxone Film. Must send for secondary review.

III. Does the member have a diagnosis of Opioid Dependence (304.00)?
    • If yes, continue to IV.
    • If no, do not approve.

IV. Is the practitioner DATA 2000 certified? (The only practitioners who are certified to prescribe buprenorphine products are those who have been granted a special DEA waiver and prefix code, X DEA number.)
   • If yes, continue to V.
   • If no, do not approve.

V. Does the member have a co-occurring dependence on high doses of benzodiazepines or other central nervous system depressants including alcohol?
   • If no, continue to VI.
   • If yes, do not approve.

VI. Does the member have co-occurring mental health conditions that may undermine the member’s ability to participate in treatment or otherwise indicate the need for treatment in a higher level of care?
   • If no, continue to VII.
   • If yes, do not approve.

VII. Does the member have a prior history of poor response to well-conducted episodes of buprenorphine treatment or has member relapsed from previous therapy?
   • If no, continue to VIII.
   • If yes, do not approve. Refer member to Optum Health Behavioral Solutions (OHBS) for a higher level of care.

Continued on the following page...
BUPRENORPHINE FOR OPIOID DEPENDENCE

VIII. Please acquire chart notes for review. Is documentation provided confirming member participation in a psychosocial support program including counseling, substance-abuse specific support, or treatment that incorporates treatment planning, relapse prevention, coping skills, and positive lifestyle adjustments?

- If no, do not approve.
- If yes and this request is initial therapy with BFH, approve for 9 months.

BFH does not cover maintenance use of Buprenorphine/Naloxone

QUANTITY LIMITS

Suboxone/Zubsolv/Subutex = 90 x 30 DAYS; 9 MONTHS PER LIFETIME

Bunavail = 60 x 30 DAYS; 9 MONTHS PER LIFETIME

If a member is denied therapy and wishes to be evaluated further for treatment, refer member to Optum Health Behavioral Solutions (OHBS) at 1-877-369-2201. OHBS will conduct a full clinical assessment and make recommendations to BFH accordingly.

Subutex Approvable Criteria:

I. Does the member meet criteria for Suboxone/Zubsolv/Bunavail?
   - If yes, continue to II.
   - If no, do not approve.

II. Is the member medically contraindicated (e.g., documented allergy to naloxone) or is the member pregnant?
   - If yes, approve for a total of 9 months as outline in Suboxone/Zubsolv/Bunavail criteria.
   - If no, do not approve.

Induction Phase of Treatment:

Induction is initiated in the physician’s office with daily administration of increasing dosages of buprenorphine until a therapeutic dose is achieved. The usual duration of the induction phase is approximately one week.

Stabilization Phase of Treatment:

During the stabilization phase the member’s withdrawal symptoms lessen, there are minimal or no side effects, and the member’s cravings for the opioid of abuse diminish. The usual duration of the stabilization phase is approximately two months.

Continued on the following page...
BUPRENORPHINE FOR OPIOID DEPENDENCE

Maintenance Phase of Treatment:
The maintenance phase begins when the member no longer experiences withdrawal, has no side effects, and no longer has uncontrollable cravings for opioids of abuse. The duration of the maintenance phase depends on the severity and complexity of the member’s condition as well as the member’s response to treatment and stage of readiness. The following are indications for discontinuing maintenance treatment:

- The member has achieved the goals outlined in the treatment plan, medically-monitored withdrawal from buprenorphine has been completed, and an adequate discharge plan has been developed with the member.
- The need for a higher level of behavioral health care is suggested by either a poor response to treatment, no improvement in the member’s stage of readiness, or by a worsening co-occurring mental health condition.

*References:
- Adapted from ‘Management of Office-based Treatment of Opioid Dependence’ provided by Optum Health. 03/2014 and ‘Appropriate use Recommendations for Suboxone and Subutex’ provided by Reckitt Benckiser Pharmaceuticals, Inc. 04/2014.