**SUBOXONE® SUBLINGUAL FILM, SUBOXONE® SUBLINGUAL TABLET, AND SUBUTEX® SUBLINGUAL TABLET APPROPRIATE USE CHECKLIST:**

This checklist is a useful reminder of the safe use conditions and monitoring requirements for prescribing SUBOXONE (buprenorphine and naloxone) sublingual film CIII, SUBOXONE (buprenorphine and naloxone) sublingual tablets CIII, or SUBUTEX (buprenorphine) sublingual tablets CIII for opioid dependence.

Requirements to address during each patient’s appointment include:

- Understanding and reinforcement of safe use conditions
- The importance of psychosocial counseling
- Screening and monitoring patients to determine progress towards treatment goals

If a patient continues to abuse various drugs or is unresponsive to treatment, including psychosocial intervention, it is important that you assess the need to refer the patient to a specialist and/or a more intensive behavioral treatment environment.

Additional resource: Physician Clinical Support System: www.pcssmat.org

This checklist may be used during the induction period and filed in patient’s medical record to document safe use conditions. Once a maintenance dose has been established, use the maintenance checklist.

<table>
<thead>
<tr>
<th>Measurement to Ensure Appropriate Use</th>
<th>NOTES:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>Induction</td>
<td></td>
</tr>
<tr>
<td>☐ Verified patient meets diagnostic criteria for opioid dependence</td>
<td></td>
</tr>
<tr>
<td>☐ Discussed risks described in professional labeling and Medication Guide with patient</td>
<td></td>
</tr>
<tr>
<td>☐ Explained or reviewed conditions of safe storage of medication</td>
<td></td>
</tr>
<tr>
<td>☐ Provided induction doses under appropriate supervision</td>
<td></td>
</tr>
<tr>
<td>☐ Prescribed limited amount of medication at first visit</td>
<td></td>
</tr>
</tbody>
</table>
| ☐ Scheduled next visit at interval commensurate with patient stability  
  • Weekly or more frequent visits recommended for the first month |        |

Reference ID: 3822165
SUBOXONE®, SUBLINGUAL FILM, SUBOXONE® SUBLINGUAL TABLET, AND SUBUTEX® SUBLINGUAL TABLET APPROPRIATE USE CHECKLIST:

This checklist may be used for visits following the induction period and filed in patient’s medical record to document safe use conditions.

<table>
<thead>
<tr>
<th>Measurement to Ensure Appropriate Use</th>
<th>NOTES:</th>
</tr>
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<tbody>
<tr>
<td><strong>Date:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Visit #:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td></td>
</tr>
<tr>
<td>○ Assessed and encouraged patient to take medication as prescribed</td>
<td></td>
</tr>
<tr>
<td>▶ Consider pill/film count/dose reconciliation</td>
<td></td>
</tr>
<tr>
<td>○ Assessed appropriateness of dosage</td>
<td></td>
</tr>
<tr>
<td>▶ Buprenorphine combined with naloxone is recommended for maintenance:</td>
<td></td>
</tr>
<tr>
<td>— SUBOXONE sublingual film and SUBOXONE sublingual tablets and generic formulations: 16 mg/4 mg is</td>
<td></td>
</tr>
<tr>
<td>the recommended dose for maintenance</td>
<td></td>
</tr>
<tr>
<td>— Zubsolv® sublingual tablets: a target dose of 11.4 mg buprenorphine is recommended for</td>
<td></td>
</tr>
<tr>
<td>maintenance</td>
<td></td>
</tr>
<tr>
<td>— Bunavalli™ buccal film: a target dose of 8.4 mg of buprenorphine is</td>
<td></td>
</tr>
<tr>
<td>recommended for maintenance</td>
<td></td>
</tr>
<tr>
<td>— SUBUTEX sublingual tablets and generic formulations may be appropriate</td>
<td></td>
</tr>
<tr>
<td>for maintenance for some patients (e.g., pregnancy, liver disease):</td>
<td></td>
</tr>
<tr>
<td>4 mg to 24 mg is the recommended dose range for maintenance</td>
<td></td>
</tr>
<tr>
<td>Doses higher than this should be an exception</td>
<td></td>
</tr>
<tr>
<td>▶ The need for higher dose should be carefully evaluated</td>
<td></td>
</tr>
<tr>
<td>○ Conduct urine drug screens as appropriate to assess use of illicit substances</td>
<td></td>
</tr>
<tr>
<td>○ Assessed participation in professional counseling and support services</td>
<td></td>
</tr>
<tr>
<td>○ Assessed whether benefits of treatment with buprenorphine-containing products outweigh risks</td>
<td></td>
</tr>
<tr>
<td>associated with buprenorphine-containing products</td>
<td></td>
</tr>
<tr>
<td>○ Assessed whether patient is making adequate progress toward treatment goals</td>
<td></td>
</tr>
<tr>
<td>▶ Considered results of urine drug screens as part of the evidence of the patient</td>
<td></td>
</tr>
<tr>
<td>complying with the treatment program</td>
<td></td>
</tr>
<tr>
<td>▶ Consider referral to more intensive forms of treatment for patients</td>
<td></td>
</tr>
<tr>
<td>not making progress</td>
<td></td>
</tr>
<tr>
<td>○ Scheduled next visit at interval commensurate with patient stability</td>
<td></td>
</tr>
<tr>
<td>▶ Weekly, or more frequent visits are recommended for the first month</td>
<td></td>
</tr>
</tbody>
</table>

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SUBUTEX® is a registered trademark of Indivior UK Limited
Zubsolv® is a registered trademark of Otsuka US, Inc.
Bunavalli™ is a trademark owned by BioDelivery Sciences International, Inc.

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