

## Commercial/Healthcare Exchange PA Criteria

*Effective: February 2016*

**Prior Authorization:** Belbuca

**Products Affected:** Belbuca (buprenorphine hydrochloride) buccal films

**Medication Description:** Buprenorphine, a mixed agonist-antagonist agent, exerts analgesic effects by binding to CNS opiate receptors. It produces partial agonistic effect at the mu-opioid receptors and an antagonistic effect at kappa-opioid receptors.

**Covered Uses:** Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options (e.g., non-opioid analgesics or immediate-release opioids) treatment options are inadequate.

**Exclusion Criteria:**

1. Known hypersensitivity to buprenorphine
2. Use as an as-needed (prn) analgesic
3. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
4. Known or suspected gastrointestinal obstruction, including paralytic ileus
5. Significant respiratory depression

**Required Medical Information:**

1. Diagnosis
2. Previous medications tried/failed

**Age Restrictions:** 18 years of age and older

**Prescriber Restrictions:** Prescribed by, or in consultation with, a pain management specialist.

**Coverage Duration:** 12 months

**Other Criteria:**

- A. Patient has a diagnosis of pain severe enough to require daily, around-the-clock, long-term opioid treatment; AND
- B. Patient has had an intolerance to or treatment failure with alternative options to treat their pain (e.g., non-opioid analgesics or immediate-release opioids).

**References:**

1. Product Information: BELBUCA(TM) buccal film, buprenorphine buccal film. Endo Pharmaceuticals Inc. (per FDA), Malvern, PA, 2016

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	02/2016
2	Update	<p>Moved to updated template;                      Removed LA opioid trials and updated criteria to include other qualifiers;</p> <p>CCI P&amp;T History Review: 2/16, 8/16, 2/17, 1/18</p> <p>CCI Revision History: 8/16 (Pain management criteria added)</p>	All	02/03/2020
3	Update	<p>Removed following criteria: A. Patient has had a documented intolerance to, or treatment failure with, an adequate trial of buprenorphine sublingual tablets to comply with FDA approved indication</p> <p>Removed the following: Requests for continuation of treatment must be accompanied by rationale for why the patient is not being transitioned to Buprenorphine/Naloxone tablets or films AND updated Coverage duration to 12 months</p>	<p>Other Criteria</p> <p>Coverage Duration</p>	08/11/2021