

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: 3 months

Requests for continuation of treatment must be accompanied by rationale for why the patient is not being transitioned to Buprenorphine/Naloxone tablets or films.

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); AND
- C. Patient has had a documented intolerance to, or treatment failure with, an adequate trial of buprenorphine sublingual tablets.

References:

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

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|-------|----------------|--|-------------------|------------|
| 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&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 |