

PHARMACY POLICY STATEMENT Kentucky Medicaid								
DRUG NAME	Bunavail (buprenorphine and naloxone) buccal film							
BILLING CODE	Must use valid NDC code							
BENEFIT TYPE	Pharmacy							
SITE OF SERVICE ALLOWED	Home							
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include generic buprenorphine/naloxone sublingual tablets							
	QUANTITY LIMIT— 30-day supply at a time only							
	<table border="1"> <thead> <tr> <th>Strength</th> <th>Quantity Limit</th> </tr> </thead> <tbody> <tr> <td>2.1 mg – 0.3 mg</td> <td>1 film per day</td> </tr> <tr> <td>4.2 mg – 0.7 mg</td> <td>2 films per day</td> </tr> <tr> <td>6.3 mg – 1 mg</td> <td>2 films per day</td> </tr> </tbody> </table>	Strength	Quantity Limit	2.1 mg – 0.3 mg	1 film per day	4.2 mg – 0.7 mg	2 films per day	6.3 mg – 1 mg
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LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>							

Bunavail (buprenorphine and naloxone) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### OPIOID DEPENDENCE

For **initial** authorization:

1. All of the following:
  - a) The individual has failed an adequate trial of the preferred generic buprenorphine/naloxone sublingual tablets within the previous 120 days (*Note: Adequate trial is defined as at least 28 days of treatment*); AND
  - b) One of the following:
    - i) The member experienced therapeutic failure with the preferred generic buprenorphine/naloxone sublingual tablets (*Note: Brand and non-preferred buprenorphine agents will not be approved for members who report lesser efficacy as compared to the preferred generic buprenorphine sublingual tablets unless it would be clinically inappropriate to address efficacy with dose adjustment*); OR
    - ii) Generic sublingual tablets caused adverse outcome; AND
  - c) The prescriber has provided a copy and confirmation of a MedWatch form submission to the FDA documenting the therapeutic failure or adverse outcome experienced by the member (*Note: The MedWatch form is available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>*)

**OR**

2. Both of the following:
  - a) The individual has a hypersensitivity reaction to an inactive ingredient in the preferred generic buprenorphine sublingual tablets; AND
  - b) The hypersensitivity reaction(s) is clearly documented in the member's medical record.

3. **Dosage allowed:** The maintenance dose of Bunavail buccal film is generally in the range of 2.1/0.3 mg buprenorphine/naloxone to 12.6/2.1 mg buprenorphine/naloxone per day. Dosages higher than this have not been demonstrated to provide any clinical advantage.

**Additional Notes:**

- GI upset or irritation is not generally considered an allergy or failed treatment. Members should be referred to their physician or pharmacist for advice on dose adjustment, and/or other options to reduce GI upset/irritation.
- Common documented side effects attributed to the drug (i.e., headache, nausea, blurred vision, fatigue, muscle aches) are not considered an allergy and would be expected to occur at the same level in both the generic and brand agent.
- Drug hypersensitivity symptoms may include skin rash, hives, itching, fever, swelling, shortness of breath, wheezing, runny nose, itchy and/or watery eyes, and in severe cases, anaphylaxis.

***If member meets all the requirements listed above, the medication will be approved for lifetime.***

**CareSource considers Bunavail (buprenorphine and naloxone) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
03/04/2019	New policy for Bunavail created.

References:

1. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at <http://www.fda.gov/safety/medwatch/default.htm>.
2. Bunavail [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; 2002.

Effective date: TBD

Revised date: 03/04/2019