

PHARMACY POLICY STATEMENT North Carolina Marketplace	
DRUG NAME	Subutex (buprenorphine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) with some exceptions QUANTITY LIMIT— up to 16 mg/day
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Subutex (buprenorphine) is a will only be considered for coverage 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. Medication will **not** be authorized if one of the following criteria met:
 - a) Member is 15 years of age or younger; OR
 - b) Members who are 16 to 44 years old and not pregnant receiving short acting buprenorphine without naloxone for longer than 9 months; OR
 - c) Dosages requested are greater than 16 mg/day; OR
 - d) Member has claims for concurrent use of opioids (including Medication Assisted Treatments) and benzodiazepines; OR
 - e) Members who are male or female 45 years of age or older receiving short acting <u>buprenorphine</u> without naloxone.
 - *Exception: if member requests buprenorphine without naloxone than must meets all of the following criteria with Prior Authorization request:
 - i) Member has documented trial of buprenorphine/naloxone combination product supported by claims history (at least one claim in the last 120 days); AND
 - ii) Member has documented allergic hypersensitivity reaction to buprenorphine/naloxone combination product, supported by chart notes; OR
 - iii) Member has documented clinically significant adverse drug reaction in response to buprenorphine/naloxone combination product, and the prescriber has provided a copy and confirmation of a MedWatch form submission to the FDA.

If member meets all the requirements listed above and:

- Member is pregnant, the medication will be approved for 12 months, OR
- Member is male or non-pregnant, the medication will be approved for lifetime.

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



DATE	ACTION/DESCRIPTION
04/03/2019	New policy for Subutex created.
03/11/2021	Annual review, no changes
01/01/2022	Initial implementation for NC Marketplace.

References:

- 1. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at http://www.fda.gov/safety/medwatch/default.htm.
- 2. Subutex [prescribing information]. Richmond, VA: Indivior Inc; September 2017.

Effective date: 01/01/2023 Revised date: 03/11/2021