

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Zubsolv (buprenorphine and naloxone) sublingual tablets for sublingual administration	
BILLING CODE	Must use valid NDC code	
BENEFIT TYPE	Pharmacy	
SITE OF SERVICE ALLOWED	Home	
COVERAGE REQUIREMENTS	No Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 30-day supply at a time only	
	Strength	Quantity Limit
	0.7 mg - 0.18 mg	1 tab per day
	2.9 mg - 0.7 mg	1 tab per day
	11.4 mg - 2.9 mg	1 tab per day
	1.4 mg - 0.36 mg	1 tab per day
	5.7 mg - 1.4 mg	1 tab per day
	8.6 mg - 2.1 mg	1 tab per day
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here	

Zubsolv (buprenorphine and naloxone) is a **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. 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 male and receiving short acting buprenorphine without naloxone; OR
 - c) Members who are female of reproductive age (15 to 44 years old) and receiving short acting buprenorphine without naloxone for longer than 9 months; OR
 - d) Dosages requested are greater than 24 mg/day; OR
 - e) Dosages requested are over 16 mg/day beginning 90 days after the initial fill; OR
 - f) Member has claims for concurrent use of opioids (including Medication Assisted Treatments) and benzodiazepines.

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

DATE	ACTION/DESCRIPTION
06/21/2018	Generic buprenorphine-naloxone products prior authorization suspended and brand name formulations can be approved when criteria listed above are met.
10/08/2018	Previously used phrase “preferred generic buprenorphine/naloxone agent” clarified and applies only to generic buprenorphine/naloxone sublingual tablet. Clarifications entered.
11/28/2018	Prior Authorization is no longer required. Policy revised based on Ohio Department of Medicaid requirements for Point-of-Sale Safety Edits and Drug Utilization Review Criteria of single preferred drug list.



References:

1. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at <http://www.fda.gov/safety/medwatch/default.htm>. Accessed November 30, 2017.
2. Zubsolv [package insert]. Morristown, NJ: Orexo US, Inc.; September, 2017.

Effective date: 01/01/2019

Revised date: 11/27/2018