CareSource

PHARMACY POLICY STATEMENT
Georgia 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	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include generic buprenorphine/naloxone sublingual tablets QUANTITY LIMIT— 30-day supply at a time only
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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	2 tabs per day

Zubsolv (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 Zubsolv sublingual tablet is generally in the range of 2.9 mg/0.71 mg buprenorphine/naloxone to 17.2 mg/4.2 mg buprenorphine/naloxone per day. The recommended target dose is 11.4 mg/2.9 mg as a single daily dose. Dosages higher than 17.2 mg/4.2 mg buprenorphine/naloxone 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 Zubsolv (buprenorphine and naloxone) 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 Zubsolv created.

References:

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

Effective date: 07/01/2019
Revised date: 04/03/2019