CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Suboxone (buprenorphine and naloxone sublingual film), Zubsolv (buprenorphine and naloxone sublingual tablets)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Suboxone and Zubsolv are mixed opioid agonist-antagonists, containing buprenorphine, a partial opioid agonist, and naloxone, an opioid antagonist. They were initially approved by the FDA in 2002 and indicated for the treatment of opioid dependence. Suboxone and Zubsolv should be used as part of a complete treatment plan that includes counseling and psychosocial support.

Suboxone, Zubsolv (buprenorphine and naloxone) will be considered for coverage when the following criteria are met:

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
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/Quantity limit:**
   a) Suboxone: The maintenance dose of Suboxone is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day. The recommended target dosage during maintenance is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose. Dosages higher than 24 mg/6 mg daily have not been demonstrated to provide a clinical advantage. Quantity limit: 30 day supply at a time only.

Strength	Quantity Limit

2 mg – 0.5 mg	1 film per day
4 mg – 1 mg	1 film per day
8 mg – 2 mg	2 films per day
12 mg – 3 mg	2 films per day

b) Zubsolv: 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. 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	2 tabs per day

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 all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes must document positive response to therapy (i.e. urine samples negative for opioids, no signs of opioid dependence-relapse)

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Suboxone, Zubsolv (buprenorphine and naloxone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/03/2019	New policy for Suboxone and Zubsolv created.
08/24/2022	Annual Review. Transferred to new template. Updated references. Updated approval duration to 12 months. Combined Suboxone and Zubsolv policies.

References:

1. Suboxone [package insert]. Richmond, VA: Indivior Inc.; June 2022.
2. Zubsolv [package insert]. Morristown, NJ: Orexo US, Inc.; June, 2022.

3. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Available at http://www.fda.gov/safety/medwatch/default.htm.
4. White L, et al. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91.
5. Center for Substance Abuse Treatment. Clinical guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

Effective date: 01/01/2023
Revised date: 08/24/2022