Clinical Policy: Buprenorphine/Naloxone (Suboxone, Zubsolv)

Reference Number: CP.PMN.81
Effective Date: 09.01.17
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Buprenorphine/naloxone (Suboxone® and Zubsolv®) is a partial opioid agonist.

FDA Approved Indication(s)

Suboxone and Zubsolv are indicated for the treatment of opioid dependence.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Suboxone and Zubsolv are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

*For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.

A. Opioid Dependence (must meet all)**:**

1. Diagnosis of opioid dependence;
2. Member must use generic buprenorphine/naloxone sublingual tablets or film;
   **For Illinois HIM requests, the step therapy requirements above do not apply for Zubsolv as of 1/1/2026 per IL HB 5395*
3. One of the following (a or b):
   a. Dose does not exceed any of the following (i or ii):
      i. Suboxone: 32 mg/8 mg per day;
      ii. Zubsolv: 22.8mg/5.8 mg per day;
   b. If requested dose of buprenorphine component exceeds 32 mg per day for Suboxone or 22.8 mg per day for Zubsolv, medical justification supports use of high-dose buprenorphine (e.g., fentanyl use, pregnancy).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

*For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.

A. Opioid Dependence (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. One of the following conditions is met (a or b):
   a. Member has NOT received an opioid analgesic since last approval;
   b. Prescriber submits documentation acknowledging that the use of opioid during the last approval period was due to a diagnosis of acute pain;

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, CP.PMN.53 for Medicaid, or evidence of coverage documents;

B. Pain management.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

SL: sublingual

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
buprenorphine/ naloxone sublingual (SL) tablets	Maintenance: buprenorphine 16 mg/naloxone 4 mg SL once daily, dosing should be further adjusted based on the individual patient and clinical response; dosage should be adjusted in increments or decrements of 2 mg/ 0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	Based on clinical response
buprenorphine/ naloxone SL film	• DAY 1 DOSING: First induction dose buprenorphine; naloxone 2 mg/0.5 mg or 4 mg/1 mg SL film; may titrate in 2 or 4 mg increments of buprenorphine, at approximately 2-hour increments, under supervision, up to a total dose of buprenorphine/naloxone 8 mg/2 mg SL film. • DAY 2 DOSING: A single daily dose of buprenorphine; naloxone up to 16 mg/4 mg SL film is recommended. • DAY 3 DOSING AND BEYOND: Progressively adjust dose in increments or decrements of 2 mg/0.5 mg or 4 mg/1 mg to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms.	Based on clinical response

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to buprenorphine or naloxone
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
buprenorphine/ naloxone (Suboxone) SL or buccal dissolving film	Induction: Titrate to 8 mg/2 mg SL on Day 1 and 16 mg/4 mg SL on Day 2; then start maintenance treatment Maintenance:: buprenorphine 16 mg/naloxone 4 mg once daily, dosing should be further adjusted based on the individual patient and clinical response; dosage should be adjusted in increments or decrements of 2 mg/0.5 mg or 4 mg/1 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 4 mg/1 mg to 24 mg/6 mg per day	Based on clinical response
buprenorphine/ naloxone (Zubsolv) SL tablet	Induction: Titrate to 5.7 mg/1.4 mg SL on Day 1 and 11.4 mg/2.9 mg SL on Day 2; then start maintenance treatment Maintenance: buprenorphine 11.4 mg/naloxone 2.9 mg once daily, dosing should be further adjusted based on the individual patient and clinical response; dosage should be adjusted in increments or decrements of 2.9 mg/ 0.71 mg to a level that maintains treatment and suppresses opioid withdrawal symptoms; usual range: 2.9 mg/0.71 mg to 17.2 mg/4.2 mg per day	Based on clinical response

VI. Product Availability

Drug Name	Availability
buprenorphine/naloxone (Suboxone)	Sublingual film: buprenorphine/naloxone 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg
buprenorphine/naloxone (Zubsolv)	Sublingual tablet: buprenorphine/naloxone 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg /0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg

VII. References

1. Suboxone Sublingual Film Prescribing Information. North Chesterfield, VA: Indivior Inc.; May 2025. Available at: https://www.suboxone.com/. Accessed November 6, 2025.
2. Zubsolv Prescribing Information. Morristown, NJ: Orexo US, Inc.; May 2025. Available at: https://www.zubsolv.com/. Accessed November 6, 2025.

3. Center for Substance Abuse Treatment. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2004. (Treatment Improvement Protocol (TIP) Series, No. 40.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK64245/. Accessed: November 6, 2025.
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6. Center for Substance Abuse Treatment. Detoxification and substance abuse treatment. Treatment improvement protocol (TIP) series, No. 45. HHS Publication No. (SMA) 15-4131. Rockville, MD: Center for Substance Abuse Treatment, 2006. Available at: Available at: https://store.samhsa.gov/product/TIP-45-Detoxification-and-Substance-Abuse-Treatment/SMA15-4131. Accessed November 6, 2025.
7. Kampman K and Jarvis M. American society of addiction medicine (ASAM): national practice guideline for the use of medications in the treatment of addiction involving opioid use. *J Addict Med.* 2015 Oct; 9(5):358-367. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4605275/. Accessed November 6, 2025.
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9. FDA.gov. FDA recommends changes to labeling for transmucosal buprenorphine products indicated to treat opioid use disorder. Updated December 26, 2024. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-changes-labeling-transmucosal-buprenorphine-products-indicated-treat-opioid-use. Accessed December 2, 2025.
10. Federalregister.gov. Modifications to labeling of buprenorphine-containing transmucosal products for the treatment of opioid dependence. December 27, 2024. Available at: https://www.federalregister.gov/documents/2024/12/27/2024-30776/modifications-to-labeling-of-buprenorphine-containing-transmucosal-products-for-the-treatment-of#print. Accessed December 2, 2205.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.16.22	02.23
1Q 2024 annual review: no significant changes; removed references to Bunavail and cassipa due to product discontinuation; references reviewed and updated.	10.19.23	02.24
Added disclaimer that medical management techniques, including quantity management, beyond step therapy is not allowed for members in NV per SB 439.	05.30.24	
1Q 2025 annual review: no significant changes; references reviewed and updated.	11.01.24	02.25
1Q 2026 annual review: revised maximum dose limitation to 32 mg/8 mg for suboxone and 22.8 mg/5.8 mg for Zubsolv with option for usage exceeding 32 mg per day or 22.8 mg per day (buprenorphine component) for Suboxone or Zubsolv, respectively, with medical justification; added step therapy bypass for IL HIM per IL HB 5395 for Zubsolv; references reviewed and updated.	11.06.25	02.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.