

buprenorphine (sublingual)

Policy # 00516

Original Effective Date: 01/01/2017

Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider sublingual buprenorphine to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for sublingual buprenorphine when the following criteria are met:

- Patient has a diagnosis of opioid dependence; AND
- One of the following:
 - Patient is being treated for induction therapy; OR
 - Patient has moderate to severe hepatic impairment; OR
 - Patient is being treated for maintenance therapy because she is pregnant or breastfeeding; OR
 - There is evidence that a buprenorphine/naloxone product was tried AND documentation is present in the medical record of severe naloxone intolerance (e.g., vomiting and/or debilitating headaches lasting several hours).

*(Note: The above four bullet points are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of sublingual buprenorphine for purposes other than induction therapy, unless the patient has moderate to severe hepatic impairment OR unless the patient is pregnant or breastfeeding OR unless there is evidence that a buprenorphine/naloxone product was tried and documentation is present in the medical record of severe naloxone intolerance (e.g., vomiting and/or debilitating headaches lasting several hours), to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of sublingual buprenorphine for purposes other than the treatment of opioid dependence to be **investigational**.*

Background/Overview

Sublingual buprenorphine may be better recognized as Subutex, however Subutex is no longer manufactured. Only the generic version, sublingual buprenorphine, is currently available. Sublingual buprenorphine is indicated for the treatment of opioid dependence and is preferred for induction therapy. There are instances where this drug can be used beyond induction therapy. These instances include those with severe hepatic impairment OR females that are being treated, but are pregnant or breastfeeding OR when a buprenorphine/naloxone product was tried AND documentation is present in the medical record of severe naloxone intolerance (e.g., vomiting and/or debilitating headaches lasting several hours). Other treatment options for induction and maintenance therapy include buprenorphine/naloxone containing products, such as the generic tablets (maintenance), brand and generic Suboxone^{®‡} Film (induction and maintenance), Zubsolv^{®‡} (induction and maintenance), and Bunavail^{™‡} (maintenance). Buprenorphine is a drug that has the potential to be used off-label; therefore it is important to determine the intended use of this medication on the prescription benefit.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Sublingual buprenorphine is indicated for the treatment of opioid dependence and is preferred for induction therapy.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The purpose of this policy is to ensure that sublingual buprenorphine is being used in accordance with its labeled indication as well as in accordance with nationally accepted guidelines for the treatment of opioid dependence.

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References

1. Subutex [package insert]. Reckitt Benckiser Pharmaceuticals. Updated December 2014.
2. Suboxone Film [package insert]. Indivior, Inc. Updated December 2016.
3. Bunavail [package insert]. Biodelivery Sciences International, Inc. Updated 2016.
4. Zubsolv [package insert]. Orexo, US, Inc. Morristown, New Jersey. Updated December 2016.
5. Jarvis M, Kampman K. American Society of Addiction Medicine National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use. J Addict Med. 2015; 9:1-10.

Policy History

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08/03/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. New policy.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. No changes to coverage.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. No changes to coverage.
04/04/2019	Medical Policy Committee review
04/24/2019	Medical Policy Implementation Committee approval. Added an exception for the use of sublingual buprenorphine (e.g. severe naloxone intolerance). Updated background information to reflect the change.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. No change to coverage.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. No change to coverage.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.