



Louisiana

buprenorphine (sublingual)

Policy # 00516

Original Effective Date: 01/01/2017

Current Effective Date: 08/15/2018

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:
 - The patient is being treated for induction therapy; OR
 - The patient has moderate to severe hepatic impairment; OR
 - The patient is being treated for maintenance therapy because she is pregnant or breastfeeding
*(Note: The above three 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, to be **not medically necessary.****

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.

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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. Other treatment options for induction and maintenance therapy include buprenorphine/naloxone containing products, such as the generic tablets (maintenance), 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

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.

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

Original Effective Date: 01/01/2017

Current Effective Date: 08/15/2018

08/0/2016 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.

Next Scheduled Review Date: 08/2019

**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

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- 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.

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