Select buprenorphine/naloxone Combination Products

Policy # 00355
Original Effective Date: 06/25/2013
Current Effective Date: 10/14/2024

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 the following buprenorphine/naloxone combination products: generic buprenorphine/naloxone tablets (generic Suboxone) and brand Suboxone Film to be **eligible for coverage**** when the patient selection criteria are met:

Patient Selection Criterion

Coverage eligibility will be considered for generic buprenorphine/naloxone tablets (generic Suboxone) or brand Suboxone Film when the following criteria are met:

- Patient has opioid dependence; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) BOTH generic buprenorphine/naloxone film and Zubsolv unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Note that generic buprenorphine/naloxone film and Zubsolv are NOT subject to this medical policy

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of generic buprenorphine/naloxone tablets (generic Suboxone) and brand Suboxone Film when the patient has NOT tried and failed BOTH generic buprenorphine/naloxone film and Zubsolv 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 generic buprenorphine/naloxone tablets (generic Suboxone) and brand Suboxone Film for non-FDA approved indications to be **investigational.***

Background/Overview

Buprenorphine/naloxone combination products are indicated for the treatment of opioid dependence.

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.

Buprenorphine/naloxone combination products have the potential to be used off label for various indications, including pain management. The purpose of this policy is to limit the use of buprenorphine/naloxone combination products to those patients with opioid dependence. The purpose of the criteria for the medications targeted in this policy is to drive to the use of preferred products. Patient selection criteria are based on information collected in a review of the available data.

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References

1. Suboxone tablets [package insert]. Warren, NJ: Reckitt Benckiser Pharmaceuticals, Inc.; 2011.
2. Bunavail [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc. 2014.

Policy History

Original Effective Date: 06/25/2013
Current Effective Date: 10/14/2024

06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. New policy.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Changed title from "buprenorphine/naloxone (Suboxone) Products" to "buprenorphine/naloxone Combination Products" due to a new product on the market. Added Zubsolv as an example of a drug that falls under generic buprenorphine/naloxone combination products.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. Added new product Bunavail to policy.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. No change to coverage
04/05/2018	Medical Policy Committee review
04/18/2018	Medical Policy Implementation Committee approval. Removed Suboxone Film and Zubsolv from the policy.
04/04/2019	Medical Policy Committee review
04/24/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021	Medical Policy Committee review

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01/13/2021	Medical Policy Implementation Committee approval. Modified the policy to reflect the difference in formulary and non-formulary request criteria. No change in coverage.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Changed the open formulary criteria to match the closed formulary criteria and removed references to the formulary.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Removed brand Suboxone tablets and Bunavail from policy as these products have been discontinued.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2025

*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.

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.