



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

buprenorphine/naloxone Combination Products

Policy # 00355

Original Effective Date: 06/25/2013

Current Effective Date: 06/18/2014

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 brand or generic buprenorphine/naloxone combination products (including, but not limited to Suboxone[®] tablets, Suboxone[®] Film, and Zubsolv[®])[‡] to be **eligible for coverage** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand or generic buprenorphine/naloxone combination products when the following criterion is met:

- The patient has opioid dependence

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 brand or generic buprenorphine/naloxone combination products when patient selection criteria are not met to be **investigational**.*

Background/Overview

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

Rationale/Source

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. Patient selection criteria are based on information collected in a review of the available data.

References

1. Suboxone tablets [package insert]. Warren, NJ: Reckitt Benckiser Pharmaceuticals, Inc.; 2011.
2. Suboxone Film [package insert]. Warren, NJ: Reckitt Benckiser Pharmaceuticals, Inc.; 2014.
3. Zubsolv [package insert]. Wilmington, NC: Orexa US, Inc; 2013.



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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.
Next Scheduled Review Date: 06/2015

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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: 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.