



## Branded Bupropion Products

Policy # 00517

Original Effective Date: 01/01/2017

Current Effective Date: 02/12/2024

*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 branded bupropion products for depression, including, but not limited to Aplenzin<sup>®</sup>†, Forfivo XL<sup>®</sup>†, Wellbutrin SR<sup>®</sup>†, Wellbutrin XL<sup>®</sup>†, and branded Bupropion XL to be **eligible for coverage\*\*** when the below patient selection criterion is met.

### Patient Selection Criteria

Coverage eligibility will be considered for branded bupropion products for depression, including, but not limited to Aplenzin, Forfivo XL, Wellbutrin SR, Wellbutrin XL, or branded Bupropion XL when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of generically available oral bupropion will be/was ineffective or will/did cause an adverse reaction to the patient.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of branded bupropion products for depression, including, but not limited to Aplenzin, Forfivo XL, Wellbutrin SR, Wellbutrin XL, or branded Bupropion XL WITHOUT clinical evidence or patient history that suggests the use of generically available oral bupropion will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.\*\***

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## **Background/Overview**

Aplenzin and Wellbutrin XL are both indicated for the treatment of major depressive disorder, and also for the prevention of seasonal affective disorder. Forfivo XL, branded Bupropion XL, and Wellbutrin SR are indicated for the treatment of major depressive disorder. Both Wellbutrin SR and Wellbutrin XL have generic equivalents. As of September 2018, there is a branded Bupropion XL product with similar dosage and formulation as Forfivo XL. Although Forfivo XL, branded Bupropion XL, and Aplenzin do not have a generic equivalent, there were no independent trials that demonstrated the antidepressant effectiveness of these products. The approvals were based on pharmacokinetic data demonstrating bioequivalence to various versions of bupropion. Given the clinical information regarding the branded bupropion products and the availability of generic alternatives, the use of the alternative generic products is a clinically and economically sensible option.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Aplenzin (approved in April of 2008) and Wellbutrin XL (approved in August of 2003) are both indicated for the treatment of major depressive disorder, and also for the prevention of seasonal affective disorder. Forfivo XL (approved in November of 2011), branded Bupropion XL (approved in September of 2018), and Wellbutrin SR (approved in October of 1996) are indicated for the treatment of major depressive disorder. Generic bupropion products have been available for quite some time and are a more economical option for patients that provide equal or similar clinical outcomes.

## **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 patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of generically available oral bupropion will be/was ineffective

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or will/did cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using branded bupropion products for depression, including, but not limited to Aplenzin, Forfivo XL, Wellbutrin SR, Wellbutrin XL, or branded Bupropion XL over generically available oral bupropion.

## **References**

1. Aplenzin [package insert]. Valeant. Bridgewater, New Jersey. Updated November 2015.
2. Forfivo XL [package insert]. Edgemont Pharmaceuticals. Austin, Texas. Updated January 2015.
3. Wellbutrin SR [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated April 2016.
4. Wellbutrin XL [package insert]. Veleant Pharmaceuticals. Bridgewater, New Jersey. Updated December 2014.
5. Bupropion XL [package insert]. Alvogen, Inc. Pine Brook, New Jersey. Updated September 2018.

## **Policy History**

Original Effective Date: 01/01/2017

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08/04/2016	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. Coverage eligibility unchanged.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. Added branded bupropion XL to the policy.
01/03/2020	Medical Policy Committee review
01/08/2020	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. Coverage eligibility unchanged.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2024	Medical Policy Committee review
01/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2025

**\*\*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.

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**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.

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