



Louisiana

Branded Bupropion Products

Policy # 00517

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 branded bupropion products for depression, including, but not limited to Aplenzin^{®‡}, Forfivo XL^{®‡}, Wellbutrin SR^{®‡}, and Wellbutrin XL^{®‡}, to be **eligible for coverage** when the below patient selection criterion is met:

Patient Selection Criterion

Coverage eligibility will be considered for branded bupropion products for depression, including, but not limited to Aplenzin, Forfivo XL, Wellbutrin SR, or Wellbutrin 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, or Wellbutrin 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.****

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 and Wellbutrin SR are both indicated for the treatment of major depressive disorder. Both Wellbutrin SR and Wellbutrin XL have generic equivalents. Although Forfivo XL and Aplenzin do not have a generic equivalent, there were no independent trials that demonstrated the antidepressant effectiveness of these two 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) and Wellbutrin SR (approved in October of 1996) are both

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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

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 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, or Wellbutrin 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]. Valeant Pharmaceuticals. Bridgewater, New Jersey. Updated December 2014.

Policy History

Original Effective Date: 01/01/2017
 Current Effective Date: 08/15/2018
 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.
 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
- 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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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.

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