Pharmacy Policy Bulletin: J-0002 Wellbutrin (bupropion) Products - Commercial	
Number: J-0002	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☐ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial (1.):** 1. Wellbutrin = Yes w/ Prior Authorization
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0002-024	**Original Date:** 03/01/1999
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Aplenzin (bupropion hydrobromide) • bupropion • bupropion extended-release (SR) • bupropion extended-release (XL) • Forfivo XL (bupropion XL) • Wellbutrin SR (bupropion SR) • Wellbutrin XL (bupropion XL)
FDA-Approved Indication(s):	• Treatment of Major Depressive Disorder (MDD) • Seasonal Affective Disorder (SAD) – Wellbutrin XL (prevention) and Aplenzin (treatment) only

Background:	• Bupropion is an oral antidepressant agent available in immediate-release, sustained-release, and extended-release dosage forms; please see above for FDA approved diagnosis information. • Bupropion is also available under the proprietary name Zyban which is an oral sustained-release formulation indicated only as an aid to smoking cessation treatment. Zyban does not carry FDA approved indications for MDD or SAD. Many groups do not include smoking cessation therapy as part of their prescription drug benefit. To prevent the use of bupropion-containing products for smoking cessation therapy when there is no coverage under the prescription drug benefit, groups may choose to require prior authorization on any bupropion-containing product to ensure that it is being used for non-smoking cessation purposes. • Prescribing Considerations: o Bupropion products are contraindicated in patients with a current diagnosis or history of seizures, bulimia, or anorexia nervosa. o When initiating therapy with a bupropion product, increase the dose gradually to reduce seizure risk. o Due to a dose-related risk of seizures, the maximum daily dose of bupropion hydrochloride is 450 mg. o 522 mg of Aplenzin (bupropion hydrobromide) is equivalent to 450 mg of bupropion hydrochloride. The maximum daily dose of Aplenzin is 522 mg.

	o Forfivo XL is only available in a 450 mg tablet; do not initiate treatment with Forfivo XL. Another bupropion product should be used for initial dose titration.

Approval Criteria

I. Approval Criteria
When a benefit, coverage of bupropion products may be approved when the following criterion is met **(A.)**:
A. Bupropion products (listed above) are being used for any FDA-approved indication with the exception of smoking cessation therapy.

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support their effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Wellbutrin [package insert]. Durham, NC: GlaxoSmithKline; April 2024.
2. Wellbutrin SR [package insert]. Durham, NC: GlaxoSmithKline; April 2024.
3. Wellbutrin XL [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.
4. Aplenzin [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.
5. Forfivo XL [package insert]. Paramus, NJ: TWi Pharmaceuticals USA, Inc.; May 2024.
6. Zyban [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.