

## STEP THERAPY POLICY

- POLICY:** Antidepressants – Bupropion Long-Acting Step Therapy Policy
- Aplenzin<sup>®</sup> (bupropion hydrobromide extended-release tablets – Bausch Health)
  - Forfivo XL (bupropion hydrochloride extended-release tablets – Almatica)
  - Wellbutrin SR<sup>®</sup> (bupropion hydrochloride sustained-release tablets – GlaxoSmithKline, generic)
  - Wellbutrin XL<sup>®</sup> (bupropion hydrochloride extended-release tablets – Bausch Health, generic)

**REVIEW DATE:** 03/23/2022

---

### OVERVIEW

Aplenzin, Forfivo XL, bupropion hydrochloride (HCl) sustained-release (SR) tablets, and bupropion HCl extended-release (ER) tablets are indicated for the **treatment of depression**.<sup>1-5</sup> Bupropion HCl ER tablets and Aplenzin are also indicated for the prevention of seasonal major depressive episodes in patients with seasonal affective disorder.<sup>3,4</sup>

Aplenzin contains bupropion hydrobromide (HBr). Of note, 174 mg/day of bupropion HBr is equivalent to 150 mg/day of bupropion HCl.<sup>4</sup> Therefore, when switching patients from bupropion HCl SR or ER tablets to Aplenzin (or vice versa), it is possible to give equivalent daily doses. Aplenzin is bioequivalent to bupropion HCl ER tablets, which has been demonstrated to have similar bioavailability to both the immediate-release and the sustained-release formulations of bupropion. Forfivo XL is available as 450 mg extended-release tablets, while the other bupropion HCl ER tablets are available as 150 mg or 300 mg.<sup>3,5</sup>

Zyban<sup>®</sup> (bupropion HCl SR, generic) contains the same active ingredient as bupropion HCl SR and ER tablets and Forfivo XL; however, Zyban is indicated as an aid to smoking cessation treatment.<sup>6</sup> Because of the different indication for use, Zyban is not included in this policy.

**Table 1. Available Long-Acting Bupropion-Containing Products.**<sup>1,3,5</sup>

Brand/Generic name	Formulation	Strengths	Notes
Aplenzin <sup>®</sup> (bupropion HBr)	ER tablets	174, 348, 522 mg	Strengths are equivalent to 150, 300, and 450 mg of bupropion HCl, respectively.
Forfivo XL (bupropion HCl)	ER tablets	450 mg	Use another bupropion formulation for initial dose titration. Patients being treated with other bupropion products at 450 mg/day can be switched to equivalent dose of Forfivo XL once daily.
Wellbutrin SR <sup>®</sup> (bupropion HCl), generic	SR tablets	100, 150, 200 mg	Available generically.
Wellbutrin XL <sup>®</sup> (bupropion HCl), generic	ER tablets	150, 300 mg	Available generically.

HBr – Hydrobromide; HCl – Hydrochloride; ER – Extended-release; SR – Sustained-release.

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 3 years in duration.

**Automation:** A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

**Step 1:** generic bupropion extended-release tablets, generic bupropion sustained-release tablets

**Step 2:** Aplenzin, Forfivo XL, Wellbutrin SR, Wellbutrin XL

### CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

Note: If the patient has tried bupropion immediate-release tablets, they must still try a generic sustained- or extended-release tablet before receiving authorization for a Step 2 Product.

2. No other exceptions are recommended.

### REFERENCES

1. Wellbutrin SR<sup>®</sup> sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
2. Wellbutrin<sup>®</sup> tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
3. Wellbutrin XL<sup>®</sup> extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2022.
4. Aplenzin<sup>®</sup> extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2022.
5. Forfivo XL extended-release tablets [prescribing information]. Pine Brook, NJ: Almatica; December 2019.
6. Zyban<sup>®</sup> sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.
7. FDA Update: bupropion hydrochloride extended-release 300 mg bioequivalence studies. U.S. Food and Drug Administration Web site. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm322161.htm>  
Accessed on March 21, 2022.