

STEP THERAPY POLICY

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

REVIEW DATE: 03/24/2021

OVERVIEW

Aplenzin, Forfivo XL, Wellbutrin, Wellbutrin SR, and Wellbutrin XL are indicated for the treatment of **depression**.¹⁻⁵ Wellbutrin XL and Aplenzin are also indicated for the prevention of seasonal major depressive episodes in patients with seasonal affective disorder.^{3,4}

Aplenzin contains bupropion hydrobromide (HBr). Of note, 174 mg/day of bupropion HBr is equivalent to 150 mg/day of bupropion hydrochloride (HCl).⁴ Therefore, when switching patients from Wellbutrin or Wellbutrin SR/XL to Aplenzin (or vice versa), it is possible to give equivalent daily doses. Aplenzin is bioequivalent to Wellbutrin XL, 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 hydrochloride extended-release tablets are available as 150 mg or 300 mg.^{3,5}

Zyban® (bupropion hydrochloride sustained-release, generics) contains the same active ingredient as Wellbutrin SR/XL and Forfivo XL; however, Zyban is indicated as an aid to smoking cessation treatment.⁶ Because of the different indication for use, Zyban is not included in this policy.

Table 1. Available ER Bupropion-Containing Products.^{1,3,5}

Brand/Generic name	Formulation	Strengths	Notes
Aplenzin® (bupropion hydrobromide)	ER tablets	174, 348, 522 mg	Strengths are equivalent to 150, 300, and 450 mg of bupropion hydrochloride, respectively.
Forfivo XL (bupropion hydrochloride)	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® (bupropion hydrochloride), generics	SR tablets	100, 150, 200 mg	Available generically.
Wellbutrin XL® (bupropion hydrochloride), generics	ER tablets	150, 300 mg	Available generically.

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 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[®] sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
2. Wellbutrin[®] tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
3. Wellbutrin XL[®] extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; November 2019.
4. Aplenzin[®] [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; May 2020.
5. Forfivo XL extended-release tablets [prescribing information]. Pine Brook, NJ: Almatica Pharma, Inc.; December 2019.
6. Zyban[®] 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>
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