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Bupropion Extended-Release Products

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Related Coverage Resources

[Brands with Bioequivalent Generics – \(IP0011\)](#)

INSTRUCTIONS FOR USE

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Overview

This policy supports medical necessity review for the following non-covered bupropion extended-release products:

- **Aplenzin[®]** (bupropion hydrobromide extended-release tablets)
- **bupropion hydrochloride 450 mg** extended-release tablets
- **Forfivo XL[®]** (bupropion hydrochloride extended-release tablets)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Non-Covered Product	Criteria
Aplenzin (bupropion hydrobromide 174 mg, 348 mg, and 522	Aplenzin is considered medically necessary when there is documentation of failure, contraindication, or intolerance to bupropion extended-release tablets (generic Wellbutrin XL)

Non-Covered Product	Criteria
mg extended-release tablets)	
bupropion hydrochloride 450 mg extended-release tablets	Bupropion hydrochloride 450 mg extended-release tablets are considered medically necessary when there is documentation of failure, contraindication, or intolerance to bupropion extended-release tablets (generic Wellbutrin XL)
Forfivo XL (bupropion hydrochloride 450 mg extended-release tablets)	Forfivo XL is considered medically necessary when there is documentation of failure, contraindication, or intolerance to bupropion extended-release tablets (generic Wellbutrin XL)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of non-covered bupropion extended-release products are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Background

OVERVIEW

Aplenzin, Auvelity, Forfivo XL, bupropion hydrochloride (HCl) sustained-release (SR) tablets, and bupropion HCl extended-release (ER) tablets are indicated for the **treatment of depression**.¹⁻⁵ Bupropion HCl ER tablets and Aplenzin are also indicated for the prevention of seasonal major depressive episodes in patients with seasonal affective disorder.^{2,3}

Aplenzin contains bupropion hydrobromide (HBr). Of note, 174 mg/day of bupropion HBr is equivalent to 150 mg/day of bupropion HCl.³ 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 SR formulations of bupropion. Forfivo XL is available as 450 mg ER tablets, while the other bupropion HCl ER tablets are available as 150 mg or 300 mg.^{2,4}

Zyban® (bupropion HCl SR, generic only) 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.⁶ Because of the different indication for use, Zyban is not included in this policy.

Table 1. Available Long-Acting Bupropion-Containing Products.¹⁻⁵

Brand / Generic name	Formulation	Strengths	Notes
Aplenzin® (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

Brand / Generic name	Formulation	Strengths	Notes
			products at 450 mg/day can be switched to equivalent dose of Forfivo XL once daily.
Wellbutrin SR® (bupropion HCl), generic	SR tablets	100, 150, 200 mg	Available generically.
Wellbutrin XL® (bupropion HCl), generic	ER tablets	150, 300 mg	Available generically.

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

References

1. Wellbutrin SR® sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2022.
2. Wellbutrin XL® extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2022.
3. Aplenzin® extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2022.
4. Forfivo XL extended-release tablets [prescribing information]. Pine Brook, NJ: Almatica; December 2019.
5. Auvelity™ extended-release tablets [prescribing information]. New York, NY: Axsome; August 2022.
6. Zyban® sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; March 2021.

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