

DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Antidepressants – Bupropion Drug Quantity Management Policy – Per Rx
- Aplenzin[®] (bupropion hydrobromide extended-release tablets – Bausch Health)
 - Forfivo XL[®] (bupropion hydrochloride extended-release tablets – Pillar5Pharma/Almatica)
 - Wellbutrin SR[®] (bupropion hydrochloride sustained-release tablets – GlaxoSmithKline, generic)
 - Wellbutrin XL[®] (bupropion hydrochloride extended-release tablets – Bausch Health, generic)

REVIEW DATE: 06/22/2022

OVERVIEW

The FDA-approved indications of the bupropion antidepressants are in Table 1.

Table 1. FDA-Approved Indications of the Bupropion Products.¹⁻⁴

Brand (generic)	Major Depressive Disorder	Seasonal Affective Disorder*
Aplenzin [®] (bupropion hydrobromide extended-release tablets)	X	X
Forfivo XL [®] (bupropion hydrochloride extended-release tablets)	X	
Wellbutrin SR [®] (bupropion hydrochloride sustained-release tablets, generic)	X	
Wellbutrin XL [®] (bupropion hydrochloride extended-release tablets, generic)	X	X

* Indicated for prevention of seasonal affective disorder.

Dosing

Aplenzin

Major Depressive Disorder

- Starting dose: 174 mg once daily (QD) [equivalent to 150 mg bupropion HCl]. After 4 days, may increase the dose to 348 mg QD.
- Usual target dose: 348 mg QD (equivalent to 300 mg bupropion HCl). The dose should not exceed 522 mg QD (equivalent to 450 mg bupropion HCl).

Seasonal Affective Disorder

- Aplenzin should be initiated in the fall, prior to the onset of seasonal depressive symptoms.
- Starting dose: 174 mg QD (equivalent to 150 mg bupropion HCl). After 1 week, may increase the dose to 348 mg QD.
- Usual target dose: 348 mg QD (equivalent to 300 mg bupropion HCl). Treatment should continue through the winter season. The dose should not exceed 522 mg QD (equivalent to 450 mg bupropion HCl).

Dose Reductions

- Moderate to severe hepatic impairment: maximum dose of 174 mg every other day.
- Mild hepatic impairment or renal impairment: consider a dose and/or frequency reduction.

Forfivo XL

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Major Depressive Disorder

- As the 450 mg tablet is the only available dose, treatment should not be initiated with Forfivo XL. Another bupropion formulation should be used for initial dose titration.
- Forfivo XL may be used in patients who are receiving 300 mg/day of another bupropion formulation for ≥ 2 weeks and who require a dose of 450 mg/day.
- The recommended dose of Forfivo XL is 450 mg QD without regard to meals. Do not crush, divide, or chew Forfivo XL; swallow tablets whole.
- Periodically, reassess the dose and need for maintenance treatment.
- Use of Forfivo XL is not recommended in patients with hepatic or renal impairment.

Bupropion sustained-release tablets (Wellbutrin SR, generic)

Major Depressive Disorder

- Starting dose: 150 mg/day. After 3 days, may increase the dose to 300 mg/day, given as 150 mg twice daily (BID) at an interval of at least 8 hours.
- Usual target dose: 300 mg/day as 150 mg BID. If the patient does not respond to 300 mg/day, the dose may be increased. However, the dose should not exceed 400 mg/day, given as 200 mg BID.
- Periodically, reassess the dose and need for maintenance treatment.

Dose Reductions

- Moderate to severe hepatic impairment: 100 mg daily or 150 mg every other day.
- Mild hepatic impairment or renal impairment: consider a dose and/or frequency reduction.

Bupropion extended-release tablets (Wellbutrin XL, generic)

Major Depressive Disorder

- Starting dose: 150 mg QD. After 4 days, may increase the dose to 300 mg QD.
- Usual target dose: 300 mg QD. The dose should not exceed 450 mg QD.

Seasonal Affective Disorder

- Bupropion extended-release tablets should be initiated in the fall, prior to the onset of seasonal depressive symptoms.
- Starting dose: 150 mg QD. After 1 week, may increase the dose to 300 mg QD.
- Usual target dose: 300 mg QD. Treatment should continue through the winter season. The dose should not exceed 450 mg QD.

Dose Reductions

- Moderate to severe hepatic impairment: 150 mg every other day.
- Mild hepatic impairment or renal impairment: consider a dose and/or frequency reduction.

Availability

Aplenzin is available as 174 mg, 348 mg, and 522 mg extended-release tablets.¹ Forfivo XL is available as a 450 mg extended-release tablet.² Sustained-release bupropion (Wellbutrin SR, generic) is available as 100 mg, 150 mg, and 200 mg tablets.³ Extended-release bupropion (Wellbutrin XL, generic) is available as 150 mg and 300 mg tablets.⁴

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of bupropion. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Product	Strength/Form	Maximum Quantity per Rx
Aplenzin® (bupropion hydrobromide extended-release tablets)	174 mg tablets	30 tablets
	348 mg tablets	
	522 mg tablets	
Forfivo XL® (bupropion hydrochloride extended-release tablets)	450 mg tablets	30 tablets
Wellbutrin SR® (bupropion hydrochloride sustained-release tablets, generic)	100 mg tablets	60 tablets
	150 mg tablets	60 tablets
	200 mg tablets	60 tablets
Wellbutrin XL® (bupropion hydrochloride extended-release tablets, generic)	150 mg tablets	30 tablets
	300 mg tablets	30 tablets

CRITERIA

Aplenzin 174 mg, 348 mg, and 522 mg tablets

No overrides recommended.

Forfivo XL 450 mg

No overrides recommended.

Bupropion HCl 100 mg sustained-release tablets (Wellbutrin SR, generic)

1. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used), approve a quantity sufficient to allow for a 30-day supply per dispensing, not to exceed 120 tablets per dispensing.

Note: An example of this situation is a patient taking 200 mg in the morning and 100 mg in the evening. The patient would require a quantity of 3 tablets per day, for a total of 90 tablets per dispensing.

Bupropion HCl 150 mg sustained-release tablets (Wellbutrin SR, generic)

1. If the patient requires a dose of 450 mg per day, approve 90 tablets per dispensing.

Bupropion HCl 200 mg sustained-release tablets (Wellbutrin SR, generic)

No overrides recommended.

Bupropion HCL 150 mg extended-release tablets (Wellbutrin XL, generic)

1. If the patient requires a dose of 450 mg per day, approve 90 tablets per dispensing.

Bupropion HCL 300 mg extended-release tablets (Wellbutrin XL, generic)
No overrides recommended.

REFERENCES

1. Aplenzin[®] extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2022.
2. Forfivo XL[®] extended-release tablets [prescribing information]. Pine Brook, NJ: Almatica; December 2019.
3. Wellbutrin SR[®] sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
4. Wellbutrin XL[®] extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2022.