DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Antidepressants – Bupropion Long-Acting Drug Quantity Management Policy – Per Rx

- Aplenzin® (bupropion hydrobromide extended-release tablets – Bausch Health)
- Forfivo XL® (bupropion hydrochloride extended-release tablets – Pillar5Pharma/Almatica, generic)
- Wellbutrin SR® (bupropion hydrochloride sustained-release tablets – GlaxoSmithKline, generic)
- Wellbutrin XL® (bupropion hydrochloride extended-release tablets – Bausch Health, generic)

REVIEW DATE: 07/17/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

Table 1. FDA-Approved Indications of the Bupropion Long-Acting 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, authorized generic)	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 (authorized generic)

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 QD 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 (authorized generic) 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.

Drug Quantity Limits

Product	Strength/Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Aplenzin® (bupropion hydrobromide extended-release tablets)	174 mg tablets	30 tablets	90 tablets
	348 mg tablets	30 tablets	90 tablets
	522 mg tablets	30 tablets	90 tablets
Forfivo XL® (bupropion hydrochloride extended-release tablets, authorized generic)	450 mg tablets	30 tablets	90 tablets
Wellbutrin SR® (bupropion hydrochloride sustained-release tablets, generic)	100 mg tablets	60 tablets	180 tablets
	150 mg tablets	60 tablets	180 tablets
	200 mg tablets	60 tablets	180 tablets
Wellbutrin XL® (bupropion hydrochloride extended-release tablets, generic)	150 mg tablets	30 tablets	90 tablets
	300 mg tablets	30 tablets	90 tablets

Antidepressants – Bupropion Long-Acting Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Aplenzin 174 mg, 348 mg, and 522 mg tablets
No overrides recommended.

Forfivo XL 450 mg (authorized generic)
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 at retail or 360 tablets per dispensing at home delivery.
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 at retail or 270 tablets per dispensing at home delivery.

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 at retail or 270 tablets per dispensing at home deliver.

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 at retail or 270 tablets per dispensing at home delivery.

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 2024.
2. Forfivo XL® extended-release tablets [prescribing information]. Pine Brook, NJ: Almatica; May 2024.
3. Wellbutrin SR® sustained-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; May 2024.
4. Wellbutrin XL® extended-release tablets [prescribing information]. Bridgewater, NJ: Bausch Health; March 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	06/26/2023
Annual Revision	Authorized generic to Forfivo XL 450 mg extended-release tablets added to the policy. The same quantity limits apply to the authorized generic as to the brand product. No clinical overrides apply.	07/17/2024