

Policies Repository



Policy Title Bupropion hydrobromide extended-release (Aplenzin®)

Policy Number FS.CLIN.25

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Bupropion hydrobromide, extended-release (Aplenzin)** is indicated for Major Depressive Disorder (MDD) in patients 18 years and older.

The use of bupropion hydrobromide, extended-release (Aplenzin®) requires Prior Authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Bupropion hydrobromide, extended-release (Aplenzin)** is a norepinephrine and dopamine reuptake Inhibitor. The mechanism of action of bupropion is unknown; however, it is presumed that this action is mediated by noradrenergic and/or dopaminergic mechanisms. Bupropion hydrobromide, extended-release was approved based on clinical efficacy and safety studies conducted with bupropion HCl. No human studies have been done to prove a clinical advantage of the hydrobromide salt.

Policy Guideline Inclusion **Bupropion hydrobromide, extended-release (Aplenzin)** is approved when there is a documentation of a diagnosis of major depressive disorder (MDD) in patients 18 years and older and **one** of the following:

- Documentation of a trial and failure with a bupropion-containing product
- Documentation of stabilization from an institutional setting
- Documentation of current stabilization for over four weeks with corresponding dates

Policy Guideline Exclusion **Bupropion hydrobromide, extended-release (Aplenzin)** is denied when **any** of the following are present:

- No documentation of a diagnosis of major depressive disorder (MDD) in patients 18 years and older
- No documentation of one of the following:

- No documentation of a trial and failure with a bupropion-containing product

- No documentation of stabilization from an institutional setting
- No documentation of current stabilization for over four weeks with corresponding dates

Policy List of Applicable Drugs

Brand Name	Generic Name
Aplenzin	bupropion hydrobromide, extended-release

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Product information for Aplenzin. Sanofi-aventis pharmaceuticals. Bridgewater, NJ 08807. October 2008.

New Dosage Form: Aplenzin (bupropion hydrobromide extended-release). Pharmacist's Letter/Prescriber's Letter 2009; 25(5): 250518.

Policy Link to Related Policies**Printed**

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