



AmeriHealth.

Policy Title Bupropion hydrobromide extended-release (Aplenzin®)

Policy Number FS.CLIN. 25

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification and age, gender or quantity restrictions. Individual member benefits must be verified.

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	<p>Bupropion hydrobromide, extended-release (Aplenzin) is indicated for Major Depressive Disorder (MDD) in patients 18 years and older.</p> <p>The use of bupropion hydrobromide, extended-release (Aplenzin®) requires Prior Authorization (ie, clinical pharmacy and/or Medical Director review).</p>
Policy description	<p>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.</p>
Policy guideline inclusion	<p>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:</p> <ul style="list-style-type: none">• Documentation of a trial and failure with a bupropion-containing product• Documentation of continuous therapy with Bupropion hydrobromide, extended-release (Aplenzin)
Policy guideline exclusion	<p>Bupropion hydrobromide, extended-release (Aplenzin) is denied when both of the following exclusion criteria are present:</p> <ul style="list-style-type: none">• No documentation of a diagnosis of major depressive disorder (MDD) in patients 18 years and older with documentation of a trial and failure with a bupropion-containing product• No documentation of a diagnosis of major depressive disorder (MDD) in patients 18 years and older with documentation of continuous therapy with Bupropion hydrobromide, extended-release (Aplenzin)

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 for each specific agent.	
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		
Version effective date	October 1, 2011	

The Policy Bulletins on this web site were developed to assist AmeriHealth in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an AmeriHealth member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. AmeriHealth does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of AmeriHealth. If you have a specific medical condition, please consult with your doctor. AmeriHealth reserves the right at any time to change or update its Policy Bulletins. ©2011 AmeriHealth, Inc. All Rights Reserved.