Reference number(s)
7569-A

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	☑
Advanced Control Formulary Chart (ACFC)	☐
Advanced Control – Choice (ACCF)	☐
Basic Control (BC)	☐
Basic Control Chart (BCC)	☐
Standard Control (SF)	☑
Standard Control Formulary Chart (SFC)	☐
Standard Control – Choice (SCCF)	☐
Value (VF)	☐
Value Formulary Chart (VFC)	☐

Formulary	Applies
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Aetna Fully Insured Advanced Control Formulary (Aetna FI ACF)	☐
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	☐
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	☐

Exception Criteria

Aplenzin

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aplenzin	bupropion hydrobromide

Indications

FDA-approved Indications

Aplenzin

Major Depressive Disorder

Aplenzin (bupropion hydrobromide) extended-release tablets are indicated for the treatment of major depressive disorder (MDD), as defined by the Diagnostic and Statistical Manual (DSM). The efficacy of the

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immediate-release formulation of bupropion was established in two 4-week controlled inpatient trials and one 6-week controlled outpatient trial of adult patients with MDD. The efficacy of the sustained-release formulation of bupropion in the maintenance treatment of MDD was established in a long-term (up to 44 weeks), placebo-controlled trial in patients who had responded to bupropion in an 8-week study of acute treatment.

Seasonal Affective Disorder

Aplenzin is indicated for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD). The efficacy of bupropion hydrochloride extended-release tablets in the prevention of seasonal major depressive episodes was established in 3 placebo-controlled trials in adult outpatients with a history of MDD with an autumn-winter seasonal pattern as defined in the DSM.

Coverage Criteria

Major Depressive Disorder/Seasonal Affective Disorder

Authorization may be granted when the requested drug is being prescribed for the treatment of major depressive disorder (MDD) or the prevention of seasonal major depressive episodes in a patient with a diagnosis of seasonal affective disorder (SAD) [ACTION REQUIRED: Documentation is required for approval] when ALL of the following criteria are met:

- The patient CANNOT be treated with a formulary alternative (Available Formulary Alternatives: generic bupropion extended-release).
- The patient has experienced an inadequate treatment response or intolerance or has a clinical reason to avoid a trial of AT LEAST ONE generic bupropion extended-release product. [ACTION REQUIRED: Documentation is required for approval]

Duration of Approval (DOA)

- 7569-A: 12 months

References

1. Aplenzin [package insert]. Bridgewater, NJ: Bausch Health Companies Inc.; November 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2026. https://online.lexi.com. Accessed August 07, 2026.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 08/07/2026).

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