Aplenzin® bupropion HBr 174 mg 348 mg 522 mg extended-release tablets

NAVIGATING PRESCRIPTION COVERAGE REQUIREMENTS

So your patients may access APLENZIN® (bupropion hydrobromide) extended-release tablets

Your APLENZIN Field Reimbursement Manager will PROVIDE LIVE SUPPORT AND EDUCATION REGARDING:

- Prior authorization (PA) process
- Requirements for a streamlined PA process
- How to avoid PA denials

INDICATION

APLENZIN® (bupropion hydrobromide) extended-release tablets is indicated for the treatment of major depressive disorder (MDD), and for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD). Periodically reevaluate long-term usefulness for the individual patient.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

SUICIDALITY AND ANTIDEPRESSANT DRUGS:

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in subjects aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

Contraindications

APLENZIN is contraindicated in:

- patients with a seizure disorder
- patients with a current or prior diagnosis of bulimia or anorexia nervosa, due to a higher incidence of seizures
- patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs
- patients taking other bupropion products, including Zyban
- patients taking a monoamine oxidase inhibitor (MAOIs) or within 14 days discontinuing MAOI treatment due to an increased risk of hypertensive reactions. Starting APLENZIN in a patient treated with reversible MAOIs such as linezolid or intravenous methylene blue is contraindicated.
- patients with hypersensitivity to bupropion or other ingredients of APLENZIN.

Please click here for full Prescribing Information for APLENZIN, including Boxed Warning regarding suicidal thoughts and behaviors.

Links to: https://www.aplenzin.com/siteassets/pdfs/Aplenzin-PI.pdf

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Steps to Get a Prior Authorization (PA) Correct the First Time

Start It

- Obtain PA form through patient's health plan website, pharmacy, or CoverMyMeds (additional information regarding CoverMyMeds available on last page)
- Fill out PA form detailing the necessity of APLENZIN
- Verify information is accurate and complete, including chart documentation

Submit It

- Submit PA form to patient's insurance plan for review
- Follow up with plan if you have not received a PA approval or denial in a timely manner
  - Electronic submission review may be immediate or take 2-3 days
  - Faxed submission review may take 10-14 days

Monitor It

- Contact your local Field Reimbursement Manager for help reviewing the PA outcome and next steps
- Inform the patient's pharmacy when the PA is approved
- Make sure eligible* patients enroll in the APLENZIN savings program and use the copay card when filling their prescription

For additional resources to help you navigate the PA process, contact your local Field Reimbursement Manager

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*This offer is not valid for patients covered by Medicare, Medicaid, or any other federal or state funded healthcare program or where prohibited by law. Please see full eligibility criteria at https://www.aplenzin.com/savings-access/

IMPORTANT SAFETY INFORMATION (cont)

Links to: https://www.aplenzin.com/savings-access/

Warnings and Precautions

- APLENZIN is not approved for smoking cessation treatment; however, bupropion HCl sustained-release is approved for this use. Postmarketing reports of serious or clinically significant neuropsychiatric adverse events with smoking cessation treatment have included changes in mood (including depression and mania), psychosis, hallucinations, paranoia, delusions, homicidal ideation, aggression, hostility, agitation, anxiety, and panic, as well as suicidal ideation, suicide attempt, and completed suicide. Observe patients attempting to quit smoking with APLENZIN for the occurrence of such symptoms and instruct them to discontinue APLENZIN and contact a healthcare provider if they experience such adverse events.
- Bupropion is associated with a dose-related risk of seizures. The dose should not exceed 522 mg once daily. Increase the dose gradually. Discontinue APLENZIN and do not restart treatment if the patient experiences a seizure. Use with extreme caution in patients with a history of seizure or cranial trauma, or in patients treated with other medications that lower the seizure threshold.

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Streamline PA Process

- **Check Specific Payer Requirements:**
  - PA criteria can differ between health plans—always verify patient's insurance requirements
- **Clearly document the following:**
  - Appropriate ICD-10 code for major depressive disorder (MDD) or seasonal affective disorder (SAD).*
  - Previous antidepressant therapies, including drug name, duration on therapy, and outcomes
  - Prescribed dosing for APLENZIN is a once-daily, single tablet available in 174 mg, 348 mg, and 522 mg strengths.[1]

Avoid Common Reasons for PA Denial

- PA not completed or incorrect
- Dosing does not match indication
- Invalid or inaccurate diagnosis (ICD-10) code
- Patient did not try and fail on formulary alternative
- APLENZIN is not covered by patient's formulary
- For PA renewals, missing documentation of clinical improvement

ICD-10 Code for MDD or SAD[2]*

F33 Major depressive disorder, recurrent	
Includes:	recurrent episodes of seasonal affective disorder recurrent episodes of seasonal depressive disorder
F33.0	**Major depressive disorder, recurrent, mild**
F33.1	**Major depressive disorder, recurrent, moderate**
F33.2	**Major depressive disorder, recurrent, severe without psychotic features**
F33.3	**Major depressive disorder, recurrent, severe with psychotic symptoms**
F33.4	**Major depressive disorder, recurrent, in remission**
F33.8	**Other recurrent depressive disorders**
F33.9	**Major depressive disorder, recurrent, unspecified**

As of October 2022, seasonal affective disorder is a recognized diagnosis in the CMS tabular index, enabling healthcare professionals to further clarify a SAD diagnosis and send all SAD diagnoses to one simple code: F33.

***Disclaimer:** The ICD-10 codes are for informational purposes only. They represent no statement, promise, or guarantee by Bausch Health Companies Inc. concerning coverage and/or levels of reimbursement, payment, or charge, and are not intended to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for service provided to their patient.

IMPORTANT SAFETY INFORMATION (cont)

Warnings and Precautions (cont)

- Treatment with APLENZIN can result in elevated blood pressure and hypertension. Assess blood pressure before initiating treatment with APLENZIN and monitor periodically during treatment.
- Antidepressant treatment can precipitate a manic, mixed, or hypomanic manic episode. Prior to initiating APLENZIN, screen patients for a history of bipolar disorder and the presence of risk factors for bipolar disorder (e.g., family history of bipolar disorder, suicide, or depression). APLENZIN is not approved for the treatment of bipolar depression.
- Depressed patients treated with bupropion have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. Some of these patients had a diagnosis of bipolar disorder. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment. Discontinue APLENZIN if these reactions occur.
- The pupillary dilation that occurs following use of many antidepressant drugs including APLENZIN may trigger an angle closure attack (Angle-Closure Glaucoma) in a patient with anatomically narrow angles who does not have a patent iridectomy.
- Anaphylactoid/anaphylactic reactions have occurred during clinical trials with bupropion, as well as rare, postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock associated with bupropion.

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covermymeds®

Through an online platform and robust network integrations with leading EHRs, more than 950,000 providers use CoverMyMeds to electronically submit PA requests to every health plan.[3]

- Submit requests for any medication and all plans
- Renew previously submitted PA requests
- Receive faster PA determinations, often in real time
- Automatically notify patients of PA determination

GET STARTED IN 3 EASY STEPS

01 **Create an account with CoverMyMeds**, or log into your existing account at covermymeds.com.

02 **Start a PA request** or access a pharmacy-initiated request. **Complete PA fields** including option, with consent, to enable auto-share of PA determination with your patient.

03 **Electronically submit the request** to any plan for determination.

Need help getting started?
1-866-452-5017 | go.covermymeds.com/help

IMPORTANT SAFETY INFORMATION (cont)

Warnings and Precautions (cont'd)

Adverse Reactions

- The most common adverse reactions that occurred in at least 5% of patients treated with bupropion HCl sustained-release (300 mg and 400 mg per day) and at a rate at least twice the placebo rate were: anorexia, dry mouth, nausea, insomnia, dizziness, pharyngitis, abdominal pain, agitation, anxiety, tremor, palpitation, sweating, tinnitus, myalgia, urinary frequency, and rash.

Drug Interactions

- An increased dose of bupropion may be necessary if co-administered with CYP2B6 inducers based on clinical exposure but should not exceed the maximum recommended dose. Bupropion inhibits CYP2D6 and can increase concentrations of: antidepressants, antipsychotics, beta-blockers, and Type 1C antiarrhythmics. Consider dose reduction when using with bupropion. Dose bupropion with caution when used with drugs that lower seizure threshold. CNS toxicity can occur when bupropion is used concomitantly with dopaminergic drugs.
- APLENZIN can cause false-positive urine test results for amphetamines.

Use in Special Populations

- Pregnancy: Use only if benefit outweighs potential risk to the fetus. Healthcare providers are encouraged to register patients in the Pregnancy Exposure Registry by calling 1-844-405-6185 or visiting https://womensmentalhealth.org/research/pregnancyregistry/.
- In patients with moderate to severe hepatic impairment (Child-Pugh score: 7 to 15), the maximum dose is **174 mg every other day**. In patients with mild hepatic impairment (Child-Pugh score: 5 to 6) or renal impairment (glomerular filtration rate <90 mL/min), consider reducing the dose and/or frequency of dosing.
- Advise patients to read the FDA-approved patient labeling (Medication Guide).

To report SUSPECTED ADVERSE REACTIONS, contact Bausch Health at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for full Prescribing Information for APLENZIN, including Boxed Warning regarding suicidal thoughts and behaviors.

EHR, electronic health records.

References: 1. APLENZIN. Prescribing Information. Bausch Health Companies Inc. **2.** ICD10Data.com. Major depressive disorder, recurrent F33-. https://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F33-. Accessed March 20, 2025. **3.** CoverMyMeds Data on File. Bausch Health; 2025.

Links to: https://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F33-

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