

APLENZIN

Prior Authorization (PA) Guide



Graphic representation of APLENZIN tablets. Not actual size.

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.

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
- The concomitant use of MAOIs (intended to treat psychiatric disorders) and APLENZIN, or within 14 days of each other, is contraindicated 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.
- APLENZIN is contraindicated in patients with known hypersensitivity to bupropion or other ingredients of APLENZIN. Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported.

Please see additional Important Safety Information throughout. [Click here](#) for full Prescribing Information, including Boxed Warning.

Steps to Complete a PA for APLENZIN

For the treatment of **major depressive disorder (MDD)** and prevention of **seasonal affective disorder (SAD)**



STEP 1 Provide patient and insurance information

STEP 2 Include prescriber information

(eg, practice name, your name, NPI #, DEA/License #)

STEP 3 Provide accurate information, including:

- **Age, diagnosis, dosing**
Patient age, MDD or SAD, APLENZIN, once daily, 30 tablets
- **ICD-10 code**
(eg, F33.9 major depressive disorder, recurrent, unspecified)
- **Previous therapies tried and failed**
- **Rationale for prescribing APLENZIN**

STEP 4 Remember your signature and the date

~80% of PA requests submitted through CoverMyMeds[®] receive a determination in a 24-hour timeframe.¹

SELECTING THE APPROPRIATE 2024 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 codes are for informational purposes only. It represents no statement, promise, or guarantee by Bausch Health Companies Inc. concerning coverage and/or levels of reimbursement, payment, or charge and is 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 his or her patient.

IMPORTANT SAFETY INFORMATION (cont)

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.

Please see additional Important Safety Information throughout. [Click here](#) for full Prescribing Information, including **Boxed Warning** regarding suicidal thoughts and behaviors.

Double Check Top Reasons for PA Denials Before Submitting

| REASON FOR DENIAL | CONSIDERATIONS FOR AVOIDING DENIAL |
|--|---|
| PA not completed | Confirm PA, fill in missing information, and resubmit |
| Dosing does not match indication | Confirm dosing for MDD or SAD <ul style="list-style-type: none"> • APLENZIN is a once-daily, single tablet and is available in 174 mg, 348 mg, and 522 mg strengths |
| Invalid diagnosis code | Confirm ICD-10 code and resubmit <ul style="list-style-type: none"> • See previous page for possible ICD-10 codes |
| Did not try/fail formulary alternative | Include information on why APLENZIN is necessary and how you expect it to help the patient |
| Product is a plan exclusion | Confirm coverage; Medicare excludes certain kinds of drugs, but APLENZIN is not in those categories |

A Letter of Medical Necessity may be needed. If so, it is important to:



- Keep it concise
- Submit on practice letterhead
- Include patient name
- Include name of medication (eg, APLENZIN 174 mg)
- Specify diagnosis
- State your treatment rationale
- Include your name, signature, and date

[Click here for a sample Letter of Medical Necessity.](#)



<< Access **additional support** and **downloadable resources** for you and your patients

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.

Please see additional Important Safety Information throughout. [Click here](#) for full Prescribing Information, including **Boxed Warning** regarding suicidal thoughts and behaviors.

Complete a PA With **CoverMyMeds** in 3 Easy Steps

- **STEP 1** Create an account with CoverMyMeds, or log in to your existing account at covermymeds.com
- **STEP 2** Shorten time to therapy by **creating a PA request** required for treatment, or complete a pharmacy-initiated request
- **STEP 3** Fill in **medical details** and then click one button to electronically submit the request to any plan for determination

GET SIGNED UP! CoverMyMeds offers individual training to offices to assist in the PA submission process.



**Live Chat/Request Training for
a Sponsored Brand:** covermymeds.com

Phone: 1-866-452-5017

Resources: go.covermymeds.com/help

covermymeds[®]

IMPORTANT SAFETY INFORMATION (cont)

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). Inform patients, their families, and their caregivers about the benefits and risks associated with treatment with APLENZIN and counsel them in its appropriate use.

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 see additional Important Safety Information throughout. [Click here](#) for full Prescribing Information, including Boxed Warning regarding suicidal thoughts and behaviors.

References: 1. Data on File. Bausch Health Companies Inc. or its affiliates. 2023. 2. ICD10Data.com. Major depressive disorder, recurrent F33-. <https://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F33->. Accessed November 8, 2023.

APLENZIN is a trademark of Bausch Health Companies Inc. or its affiliates.

CoverMyMeds is a registered trademark of CoverMyMeds LLC.

Any other product/brand names and/or logos are trademarks of the respective owners.

© 2023 Bausch Health Companies Inc. or its affiliates.

APL.0115.USA.23