APL.0018.USA.25 - Neurology Aplenzin Med D

From: {{sender name and email}}

To: {{recipient name and email}}

Subject:

1. See the latest Medicare Part D updates for 2025
2. Discover important changes to Medicare Part D

Full Prescribing Information, including **Boxed Warning** regarding suicidal thoughts and behaviors.

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

Links to: https://www.aplenzin.com/

2025 CHANGES TO MEDICARE PART D

A note from {{UserName}}, your APLENZIN representative

{{customText[Hello|Hi|Dear]}} {{customText[DrlMr|MrsIMs]}}, {{accLname}},

Staying up-to-date with Medicare Part D changes can be challenging, so I wanted to share the latest updates. As of January 2025, patients now have a maximum out-of-pocket cost of $2,000 for prescription medications, along with 0% patient co-insurance responsibility in the catastrophic phase.

Learn more about these changes to Medicare Part D benefits below.

▼ ▼ ▼ PLEASE CONTINUE READING ▼ ▼ ▼

INDICATION

APLENZIN 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 SAD. Periodically reevaluate long-term usefulness for the individual patient.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL IDEATION AND BEHAVIOR

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.

Please see additional Important Safety Information below.

UNDERSTANDING THE EVOLUTION OF MEDICARE PART D BENEFITS IN 2025

Applies to branded and generic therapies[1]

	2024[2]	2025[1]
Patient Out-of-Pocket Spending Maximum/Responsibility	~$3,400*	~$2,000
Patient Co-Insurance Responsibility in Catastrophic Phase	0%	0%

*Assumes mostly name brand drugs

FOR THE FIRST TIME:

New option for

Medicare Prescription Payment Plan

Links to: https://www.medicare.gov/prescription-payment-plan

This option allows for select patients to manage their drug costs over time by paying a monthly amount.

▼ ▼ ▼ PLEASE CONTINUE READING ▼ ▼ ▼

IMPORTANT SAFETY INFORMATION (continued)

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.

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.
- 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.

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 Specific 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).

Links to: https://womensmentalhealth.org/research/pregnancyregistry/

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.

Links to: https://www.fda.gov/MedWatch

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Make sure to keep your patients informed of these important updates and help them maximize their Medicare Part D benefits. If you have any questions or need additional information, feel free to reach out.

{{customText[Warm regards,|Thank you,]}}

{{userName}}

{{User.Phone}}

{{userEmailAddress}}

References: 1. Costs in the coverage gap. Medicare.gov. https://www.medicare.gov/health-drug-plans/part-d/basics/costs. Accessed February 19, 2025. 2. Data on file. 2024 Med D Cost Changes. Bausch Health Companies Inc., Bridgewater, NJ.

BAUSCH+ Health

Links to: https://www.bauschhealth.com

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Links to: https://go.bauschhealth.com/Neurology-Preferences-HCP-Existing.html

Links to: https://www.bauschhealth.com/privacy

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