Date: <Insert Date>

Attn: <Department>

<Name of health plan> <Case ID Number if available>

Payer Address: <Insert plan address(es)> **Payer Fax Number:** <Insert plan fax number(s)>

To Whom It May Concern:

I understand that the <Insert plan name> has decided not to provide coverage for APLENZIN® (bupropion hydrobromide) extended-release tablets. However, I believe that <Insert patient name> requires APLENZIN without restriction due to clinical and medical circumstances. Please see below for details about the medical history and treatment rationale that supports the claim for this medical exception request.

Patient Information:

Patient's Name		Date of Birth
Patient's Address		
City	State	Zip Code
Member ID #	Policy or Group #	

☐ I need approval for a drug that is not on the plan's list of covered drugs

☐ I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year

Medication:

☐ **APLENZIN (bupropion hydrobromide) extended-release tablets:** 174 mg once daily

☐ **APLENZIN (bupropion hydrobromide) extended-release tablets:** 348 mg once daily

☐ **APLENZIN (bupropion hydrobromide) extended-release tablets:** 522 mg once daily

Date Started:	Expected Length of Therapy:

Diagnosis – Please list all diagnoses being treated with requested drug and corresponding ICD-10 codes

□ F33 Major depressive disorder, recurrent (includes recurrent episodes of seasonal affective disorder and 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 features

□ F33.4 Major depressive disorder, recurrent, in remission

□ F33.8 Other recurrent depressive disorders

□ F33.9 Major depressive disorder, recurrent, unspecified

Drug History: (for treatment of the condition(s) requiring the requested drug)

Previous Drug Tried	Dates of Drug Trials	Results of previous drug trials
1._____	1._____	1._____
2._____	2._____	2._____
3._____	3._____	3._____
4._____	4._____	4._____

JUSTIFICATION FOR REQUEST FOR MEDICAL EXCEPTION

☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome**

☐Therapeutic Failure

☐Adverse Events

☐Sexual Dysfunction

☐Anxiety

☐Suicidal Ideation

☐Other _____

☐ **Patient is stable on APLENZIN; high risk of significant adverse clinical outcome with medication change**

☐ APLENZIN 174 mg once daily; duration _____

☐ APLENZIN 348 mg once daily; duration _____

☐ APLENZIN 522 mg once daily; duration _____

Based on the above, I hope that you agree APLENZIN® (bupropion hydrobromide) extended-release tablets is an appropriate choice for my patient. A timely approval would be greatly appreciated by myself and my patient.

Please contact me at <Insert phone number> if you need more information to approve this medical exception.

Sincerely

<Insert Healthcare Provider Name>

<Insert Signature>

Enclosures: Consider including patient medical history, relevant state therapy legislation, notes and product prescribing information which can be found at www.aplenzin.com/hcp/

State Therapy Law Information (www.steptherapy.com)_____

_____

_____

FOR THE PRESCRIBERS BACKGROUND INFORMATION:

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.

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).

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.

Click here for full Prescribing Information including Boxed Warning regarding suicidal thoughts and behaviors.