BAUSCH Health

# Seasonal Affective Disorder (SAD) Is Now a Recognized Diagnosis in the CMS Tabular Index, Accessible to Prescribers Oct. 1, 2022

October 05, 2022

***CMS Issues New Clarification on ICD-10 Coding for SAD***

LAVAL, QC, Oct. 5, 2022 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) ("Bausch Health") is continuing its commitment to improving lives with the announcement of modifications within the Tabular Index, specifically for the prevention and treatment of SAD from the Centers for Medicare & Medicaid Services (CMS). Now, all appropriate codes have been combined into a bundle for SAD which allows healthcare professionals to further clarify a diagnosis in an easy-to-understand index tab and send all diagnoses for SAD to one simple code: F33. This achievement helps further define SAD as a recognizable condition that may be diagnosed and appropriately treated.

More than 16 million people suffer from SAD in the United States alone.[1,2] While the symptoms of SAD can be the same as those of Major Depressive Disorder (MDD), many people with SAD may experience these symptoms more frequently during the fall or winter months and may benefit from a treatment that does not need to be taken year-round.[3-6]

Prior to this important modification of the Tabular Index, it is believed that SAD has been underdiagnosed[7] and the ICD-10 is used to properly classify a disease and diagnosis. As of Oct. 1, 2022, healthcare professionals will have access to a new instructional note for SAD at F33 in the Tabular Index and with that, sufferers may be more appropriately identified and prescribed an FDA-approved treatment for SAD.

To learn more about the Federal Register announcement, please visit here: https://www.cdc.gov/nchs/icd/comprehensive-listing-of-icd-10-cm-files.htm

**About APLENZIN**
APLENZIN (bupropion hydrobromide) is an antidepressant indicated for the treatment of MDD and prevention of SAD. APLENZIN is the **only FDA-approved** bupropion hydrobromide indicated for the prevention of SAD and offers more than 20 years of combined clinical experience in MDD and SAD.[6,8-10] APLENZIN is a once-daily, single tablet available in 3 dosage strengths, with no generic substitute.[6,10] Recommended dosing for patients with SAD includes initiating treatment in the fall and discontinuing in early spring, as prescribed by a healthcare professional. For more information, visit www.aplenzin.com
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**About Bausch Health**
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global diversified pharmaceutical company whose mission is to improve people's lives with our healthcare products. We develop, manufacture, and market a range of products primarily in gastroenterology, hepatology, neurology, dermatology, international pharmaceuticals, and eye health through our approximately 88.7% ownership of Bausch + Lomb Corporation. With our leading durable

brands, we are delivering on our commitments as we build an innovative company dedicated to advancing global health. For more information, visit www.bauschhealth.com and connect with us on Twitter and LinkedIn.

**Forward-looking Statements**

This news release may contain forward-looking statements about Bausch Health, which may generally be identified by the use of the words "anticipates," "hopes," "expects," "intends," "plans," "should," "could," "would," "may," "believes," "subject to," and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In addition, actual results are subject to other risks and uncertainties that relate more broadly to Bausch Health's overall business, including those more fully described in Bausch Health's filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

**INDICATION**

APLENZIN® (bupropion hydrobromide extended-release tablets) is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder, and for the prevention of autumn-winter seasonal depression (seasonal affective disorder).

**IMPORTANT SAFETY INFORMATION**

**WARNING: CHANGES IN THINKING AND BEHAVIOR, DEPRESSION, AND SUICIDAL THOUGHTS OR ACTIONS**

**Suicidal Thoughts or Actions and Antidepressant Drugs**

**Antidepressants may increase the risk of suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment. Depression or other serious mental illnesses are the most important causes of suicidal thoughts and actions. People who have (or have a family history of) bipolar illness or suicidal thoughts or actions may have a particularly high risk. Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. Call your healthcare provider right away if symptoms such as anxiety, irritability, impulsivity, trouble sleeping, aggressive behavior or suicidal thoughts are new, worse or worry you. APLENZIN has not been evaluated for use in patients under the age of 18.**

**Call your healthcare provider right away if you or your family member has any of**

**the following symptoms, especially if they are new, worse, or worry you:**

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

Although APLENZIN is not a treatment for quitting smoking, it contains the same active ingredient (bupropion) as ZYBAN, which is used to help patients quit smoking.

Some people have had serious side effects while taking bupropion to help them quit smoking, including:

**New or worse mental health problems, such as changes in behavior or thinking, aggression, hostility, agitation, depression, or suicidal thoughts or actions.** Some people had these symptoms when they began taking bupropion, and others developed them after several weeks of treatment, or after stopping bupropion. These symptoms happened more often in people who had a history of mental health problems before taking bupropion than in people without a history of mental health problems.

**Stop taking APLENZIN and call your healthcare provider right away if you, your family, or caregiver notice any of these symptoms.** Work with your healthcare provider to decide whether you should continue to take APLENZIN. In many people, these symptoms went away after stopping APLENZIN, but in some people, symptoms continued after stopping APLENZIN. It is important for you to follow-up with your healthcare provider until your symptoms go away.

**Before taking APLENZIN,** tell your healthcare provider if you have ever had depression or other mental health problems. You should also tell your healthcare provider about any symptoms you had during other times you tried to quit smoking, with or without bupropion.

**What Other Important Information Should I Know About APLENZIN?**

- **Seizures**: **There is a chance of having a seizure (convulsion, fit) with APLENZIN, especially in people with certain medical problems or who take certain medicines. Do not take any other medicines while you are taking APLENZIN unless your healthcare provider has said it is okay to take them. If you have a seizure while taking APLENZIN, stop taking the tablets and call your healthcare provider right away.**
- **High blood pressure (hypertension)**: Some people get high blood pressure that can be severe while taking APLENZIN.
- **Manic episodes**: Some people may have periods of mania while taking APLENZIN. If you have any of the following symptoms of mania, call your healthcare provider:
  - greatly increased energy
  - severe trouble sleeping

- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

- **Unusual thoughts or behaviors:** Some patients may have unusual thoughts or behaviors while taking APLENZIN, including delusions (e.g., believe you are someone else), hallucinations (seeing or hearing things that are not there), paranoia (feeling that people are against you), or feeling confused. If this happens to you, call your healthcare provider.
- **Visual problems:** Some people are at risk of glaucoma which can present as: eye pain, changes in vision, or swelling and redness around the eye if they take APLENZIN. You should see an eye doctor to determine whether you are at risk prior to starting therapy.
- **Severe allergic reactions: Some patients have severe allergic reactions to APLENZIN. Stop taking APLENZIN and call your healthcare provider right away** if you get a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious allergic reaction.

**Do not take APLENZIN if you:**

- have or had a seizure disorder or epilepsy
- have or had an eating disorder such as anorexia nervosa or bulimia
- **are taking any other medicines that contain bupropion, including WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, ZYBAN, or FORFIVO XL.** Bupropion is the same active ingredient that is in APLENZIN
- drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these make you sleepy), benzodiazepines, or anti-seizure medicines, and you stop using them all of a sudden
- take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid
  - **do not take an MAOI within 2 weeks of stopping APLENZIN unless directed to do so by your healthcare provider**
  - **do not start APLENZIN if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider**
- are allergic to the active ingredient in APLENZIN, bupropion, or to any of the inactive ingredients

**Although APLENZIN is not a treatment for quitting smoking, it contains the same active ingredient (bupropion) as ZYBAN, which is used to help patients quit smoking. Before taking APLENZIN, tell your healthcare provider if you have ever had depression, suicidal thoughts or actions, or other mental health problems or any symptoms you had during other times you tried to quit smoking with or without bupropion. Also, tell your healthcare provider about your other medical conditions, including if you:**

- have liver problems, especially cirrhosis of the liver
- have kidney problems
- have, or have had, an eating disorder such as anorexia nervosa or bulimia
- have had a head injury
- have had a seizure (convulsion, fit)
- have a tumor in your nervous system (brain or spine)
- have had a heart attack, heart problems, or high blood pressure
- are a diabetic taking insulin or other medicines to control your blood sugar

- drink alcohol
- abuse prescription medicines or street drugs
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risk to your unborn baby if you take APLENZIN during pregnancy, and about registering with the National Pregnancy Registry by calling 1-844-405-6185
- are breastfeeding. APLENZIN passes into your milk in small amounts

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Many medicines increase your chances of having seizures or cause other serious side effects if you take them while you are using APLENZIN.

**The most common side effects of APLENZIN include:** trouble sleeping, stuffy nose, dry mouth, dizziness, feeling anxious, nausea, constipation, and joint aches.

Click here
to read the Medication Guide carefully before you start using APLENZIN. If you have any questions about APLENZIN, ask your healthcare provider or pharmacist.

Click here
for full Prescribing Information, including Medication Guide and **Boxed Warning** regarding suicidal thoughts and actions.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch
or call 1-800-FDA-1088. You may also contact Bausch Health Customer Service at 1-800-321-4576.

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