Date:

PATIENT NAME: <Patient Name>

<Prior Authorization/Appeals Department>

DATE OF BIRTH: <Patient Date of Birth>

<Payer/Health Plan Name>

POLICY ID NUMBER: <Patient Policy ID Number>

<Payer Address>

PROVIDER ID NUMBER: <Provider ID Number>

<Optional: Claim rejection number>

REGARDING: Denied Claim for WELLBUTRIN XL® (bupropion hydrochloride) extended-release tablets

Dear <Health Plan Contact Name>

I am writing to appeal the denied claim for WELLBUTRIN XL for my patient, <Patient Name> , for which the reason for denial was <quote the specific reason for denial in denial letter>
I have prescribed WELLBUTRIN XL because this patient has been diagnosed with <Major Depressive Disorder (MDD) or Seasonal Affective Disorder SAD> . Attached to this request are clinical notes regarding this patient's disease state and the WELLBUTRIN XL package insert.

WELLBUTRIN XL 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.

The following is the medical history of <Patient Name> and the rationale for treatment with WELLBUTRIN XL.

Date of Diagnosis			
Diagnosis (ICD-10 Code)	□ 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		
Summary of clinical symptoms			
Previous and current treatment regimens	Previous/Current Drug Tried	Date of Drug Trials	Results of previous drug trials
	1. _____	1. _____	1. _____
	2. _____	2. _____	2. _____
	3. _____	3. _____	3. _____
	4. _____	4. _____	4. _____

Please see full Prescribing Information including Boxed Warning regarding suicidal thoughts and behaviors on following pages.

Other Information	☐ **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 WELLBUTRIN XL; high risk of significant adverse clinical outcome with medication change** ☐ WELLBUTRIN XL 150 mg once daily; duration _____ ☐ WELLBUTRIN XL 300 mg once daily; duration _____

<Restate the denial reason and your clinical rationale for why the denial should be overturned and why WELLBUTRIN XL is medically necessary for this patient.>

Based on the evidence provided, I hope you agree with my clinical opinion that treatment with WELLBUTRIN XL® (bupropion hydrochloride) is appropriate. We appreciate your prompt review and reconsideration of this case. If you need additional information for a timely approval please contact my office at <Office Number>

Sincerely,

<Physician Name> <Physician Contact Info>

Enclosures: Consider including patient medical history, relevant state therapy legislation, notes and product prescribing information which can be found at https://www.wellbutrinxl.com/for-prescribers/

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

FOR THE PRESCRIBERS BACKGROUND INFORMATION:

INDICATION

WELLBUTRIN XL® (bupropion hydrochloride) 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

WELLBUTRIN XL 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 (MAOI) or within 14 days of discontinuing MAOI treatment due to an increased risk of hypertensive reactions. Starting WELLBUTRIN XL 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 WELLBUTRIN XL

Warnings and Precautions

- WELLBUTRIN XL 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 WELLBUTRIN XL for the occurrence of such symptoms and instruct them to discontinue WELLBUTRIN XL 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 300 mg once daily. Increase the dose gradually. Discontinue WELLBUTRIN XL 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 WELLBUTRIN XL can result in elevated blood pressure and hypertension. Assess blood pressure before initiating treatment with WELLBUTRIN XL and monitor periodically during treatment.
- Antidepressant treatment can precipitate a manic, mixed, or hypomanic manic episode. Prior to initiating WELLBUTRIN XL, 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). WELLBUTRIN XL is not approved for the treatment of bipolar depression.

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- 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 WELLBUTRIN XL if these reactions occur.
- The pupillary dilation that occurs following use of many antidepressant drugs including WELLBUTRIN XL 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.
- WELLBUTRIN XL 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 **150 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.

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