Checklist for a Prior Authorization (PA) for CONTRAVE®

Use the following worksheet to ensure that all relevant information is captured before submitting a PA for CONTRAVE®. All services must be medically appropriate and properly supported in the patient medical record.

Key PA criteria (required by the majority of plans or providers for approval)

Patient's current weight	
Patient's BMI	
Presence of any weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)	

Additional information (may be required by a few plans or providers for approval)

Additional information, if needed	Do you have it? (Check all that apply)
Different therapies they have tried	☐
Medication list for any weight-related comorbidity (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)	☐
Patient's baseline blood pressure with date measured	☐
Patient's baseline HbA1C with date measured	☐
Patient's baseline lipid panel with date measured	☐
Patient's last weight before the diet and exercise plan was started with date measured	☐
Dietician's notes from the past 2 years	☐
A copy of the patient's current registration with a weight-loss program (eg, Weight Watchers®)	☐

Indication

CONTRAVE is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)

Limitations of Use

The effect of CONTRAVE on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of CONTRAVE in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Please see Important Safety Information for CONTRAVE on the following pages.

Contrave®
(naltrexone HCl/bupropion HCl)
8 mg/90 mg • Extended-Release Tablets

Important Safety Information for CONTRAVE

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Suicidality and Antidepressant Drugs

CONTRAVE® is not approved for use in the treatment of major depressive disorder or other psychiatric disorders. CONTRAVE contains bupropion, the same active ingredient as some other antidepressant medications (including, but not limited to, WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, and APLENZIN). 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 over age 24; there was a reduction in risk with antidepressant use in subjects aged 65 and older. In patients of all ages who are started on CONTRAVE, monitor closely for worsening, and for the emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. CONTRAVE is not approved for use in pediatric patients.

Contraindications

CONTRAVE is contraindicated in: uncontrolled hypertension; seizure disorder or a history of seizures; use of other bupropion-containing products; bulimia or anorexia nervosa, which increase the risk for seizure; chronic opioid or opiate agonist (eg, methadone) or partial agonist (eg, buprenorphine) use, or acute opiate withdrawal; patients undergoing an abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs; use during/within 14 days following treatment with monoamine oxidase inhibitors (MAOIs), as there is an increased risk of hypertensive reactions when CONTRAVE is used concomitantly with MAOIs, including reversible MAOIs such as linezolid or intravenous methylene blue; known allergy to any component of CONTRAVE, as anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported; and pregnancy.

WARNINGS AND PRECAUTIONS

Suicidal Behavior and Ideation

All patients being treated with antidepressants for any indication should be monitored and observed for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes.

Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of suicidality, anxiety, agitation, irritability, unusual changes in behavior, and other symptoms, and to report such symptoms immediately to healthcare providers.

Neuropsychiatric Adverse Events and Suicide Risk in Smoking Cessation Treatment

CONTRAVE is not approved for smoking cessation. Serious neuropsychiatric adverse events have been reported in patients taking bupropion for smoking cessation. These postmarketing reports 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.

Some patients who stopped smoking may have been experiencing symptoms of nicotine withdrawal, including depressed mood. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these adverse events occurred in patients taking bupropion who continued to smoke.

Neuropsychiatric adverse events occurred in patients without and with pre-existing psychiatric disease; some patients experienced worsening of their psychiatric illnesses. Observe patients for the occurrence of neuropsychiatric adverse events. Advise patients and caregivers that the patient should stop taking CONTRAVE and contact a healthcare provider immediately if agitation, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed, or if the patient develops suicidal ideation or suicidal behavior. In many postmarketing cases, resolution of symptoms after discontinuation of bupropion was reported. However, the symptoms persisted in some cases, therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

Depression, suicide, attempted suicide, and suicidal ideation have been reported in the postmarketing experience with naltrexone used in the treatment of opioid dependence. No causal relationship has been demonstrated.

Seizures

The risk of seizure is dose-related. Discontinue treatment and do not restart CONTRAVE in patients who experience a seizure. Use caution when prescribing CONTRAVE to patients with an elevated risk of seizure, including: history of head trauma or prior seizure, severe stroke, arteriovenous malformation, central nervous system tumor or infection, or metabolic disorders (eg, hypoglycemia, hyponatremia, severe hepatic impairment, and hypoxia); excessive use of alcohol or sedatives, addiction to cocaine or stimulants, or withdrawal from sedatives; patients with diabetes treated with insulin and/or oral diabetic medications (sulfonylureas and meglitinides) that may cause hypoglycemia; concomitant administration of medications that may lower the seizure threshold, including other bupropion products, antipsychotics, tricyclic antidepressants, theophylline, and systemic steroids.

Clinical experience with bupropion suggests that the risk of seizure may be minimized by adhering to the recommended dosing recommendations, including the avoidance of high-fat meals while taking CONTRAVE.

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Patients Receiving Opioid Analgesics

CONTRAVE should not be administered to patients receiving chronic opioids. If chronic opiate therapy is required, CONTRAVE treatment should be stopped. In patients requiring intermittent opiate treatment, CONTRAVE therapy should be temporarily discontinued and lower doses of opioids may be needed. Patients should be alerted that they may be more sensitive to opioids, even at lower doses, after CONTRAVE treatment is discontinued.

An opioid-free interval of a minimum of 7 to 10 days is recommended for patients previously dependent on short-acting opioids, and those patients transitioning from buprenorphine or methadone may need as long as two weeks. Patients should be made aware of the risks associated with precipitated withdrawal and encouraged to give an accurate account of last opioid use.

Increase in Blood Pressure (BP) and Heart Rate (HR)

CONTRAVE can cause an increase in systolic BP, diastolic BP, and/or resting HR. These events were observed in both patients with and without evidence of preexisting hypertension. In clinical practice with other bupropion-containing products, hypertension, in some cases severe and requiring acute treatment, has been reported. Blood pressure and pulse should be monitored at regular intervals.

Allergic Reactions

Anaphylactoid/anaphylactic reactions and symptoms suggestive of delayed hypersensitivity have been reported with bupropion, as well as rare spontaneous reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock. Instruct patients to discontinue CONTRAVE and consult a healthcare provider if they develop an allergic or anaphylactoid/anaphylactic reaction.

Hepatotoxicity

Cases of hepatitis, clinically significant liver dysfunction, and transient asymptomatic hepatic transaminase elevations have been observed with naltrexone exposure. Warn patients of the risk of hepatic injury and advise them to discontinue CONTRAVE if they experience symptoms of acute hepatitis.

Activation of Mania

CONTRAVE treatment can precipitate a manic, mixed, or hypomanic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating CONTRAVE, screen patients for history of bipolar disorder and the presence of risk factors for bipolar disorder (eg, family history of bipolar disorder, suicide, or depression). CONTRAVE is not approved for use in treating bipolar depression.

Angle-Closure Glaucoma

The pupillary dilation that occurs following use of many antidepressant drugs, including bupropion, may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

Hypoglycemia with Use of Antidiabetic Medications

Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus treated with insulin and/or insulin secretagogues (eg, sulfonylureas). Measurement of blood glucose levels prior to starting CONTRAVE and during CONTRAVE treatment is recommended in patients with type 2 diabetes. Decreases in medication doses for antidiabetic medications that are non-glucose-dependent should be considered to mitigate the risk of hypoglycemia.

Adverse Reactions

Most common adverse reactions (≥5%) include: nausea (32.5%), constipation (19.2%), headache (17.6%), vomiting (10.7%), dizziness (9.9%), insomnia (9.2%), dry mouth (8.1%), and diarrhea (7.1%).

Drug Interactions

Use caution when prescribing CONTRAVE concomitantly with dopaminergic drugs (levodopa and amantadine), drugs metabolized by CYP2D6, or drugs that lower the seizure threshold. Avoid concomitant use with MAOIs and CYP2B6 inducers. Reduce CONTRAVE dose when taken with CYP2B6 inhibitors. CONTRAVE can cause false positive urine test results for amphetamines.

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Please see accompanying Full Prescribing Information for complete Boxed Warning and Medication Guide for CONTRAVE.

OREXIGEN®

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