Naltrexone/Bupropion (CONTRAVE)
Criteria for Use
August 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive naltrexone/bupropion.

- ☐ Pregnancy ^1
- ☐ Lactating ^2
- ☐ Uncontrolled hypertension
- ☐ History of seizure disorder, bulimia, or anorexia nervosa
- ☐ Concurrent opioid use or use of opioids within the last 7 to 10 days
- ☐ Undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- ☐ Major depressive disorder especially in patients 24 years of age or younger ^3 (unless a mental health consultation supports benefits of naltrexone/bupropion in patients at risk for suicidal thoughts or behaviors)

1. Weight loss offers no potential benefit to a pregnant patient and may result in fetal harm; refer to product information
2. Lactating patients excluded from clinical trials for weight management; in general, weight management should focus on healthy nutrition, behavioral modification and exercise, as well as take into consideration the energy requirements for breastfeeding. Consider risk vs. benefit in individual patients and the breastfed infant.
3. Per a Boxed Warning in the product information due to the component bupropion, an antidepressant; antidepressants increased the risk of suicidal thoughts and behaviors in patients 24 years of age or younger

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Verifiable participation in a comprehensive lifestyle intervention (CLI) that targets all three aspects of weight management: diet, physical activity, behavioral changes ^4
- ☐ BMI is greater than or equal to 30 kg/m^2 **OR** BMI is greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity ^5,6

4. Participation in a CLI is an essential component to overall weight management. Use of weight management medications should be prescribed in conjunction with CLI.
5. Examples of weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, nonalcoholic fatty liver disease (aka metabolic dysfunction-associated steatotic liver disease)
6. If clinically appropriate, consider discontinuing medications that may precipitate weight gain. Refer to Sidebar 2. Select Medications and their Potential Effects on Weight in the VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity at: https://www.healthquality.va.gov/guidelines/CD/obesity/VADoDObesityCPGFinal5087242020.pdf

Additional Inclusion Criteria *(Select if applicable)*

☐ For patients who can become pregnant: Pregnancy should be excluded prior to receiving naltrexone/bupropion and the patient provided contraceptive counseling on potential risks vs. benefits of treatment if the patient were to become pregnant

Supplemental Information

Refer to PBM-MAP-VPE Clinical Guidance: Weight Management Medications for Chronic Use Guidance for Treatment Selection at: PBM Formulary Management - Clinical Recommendations - All Documents (sharepoint.com)

11/2016; Revised 3/2020, 10/2021, 6/2023, 8/2024
Contact person: Natasha Antonovich, PharmD, BCPS National PBM Clinical Pharmacy Program Manager, Formulary Management, VA Pharmacy Benefits Management Services (12PBM)