



## Medication Audit Criteria and Guidelines

### Bupropion (Wellbutrin®, Budeprion®, Zyban®)

PEFC Approved: January 2023

#### Indications

This document lists only FDA-approved indications from the product labeling. The PEFC acknowledges that there are off-label indications for use that have supporting evidence for efficacy. If a medication is prescribed for an off-label indication, documentation in the patient chart is recommended.

- Seasonal Affective Disorder (24 hour extended release)
- Major Depressive Disorder
- Smoking cessation (12 hour extended release)

#### Black Box Warning

Increased risk of suicidal thinking and behavior in children, adolescents and young adults ( $\leq 24$  years) taking antidepressants. Monitor for worsening and emergence of suicidal thoughts and behaviors.

#### Contraindications

Absolute

- Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, antiepileptics
- Co-administration with an MAOI, including linezolid or IV methylene blue, or use within 14 days of discontinuing an MAOI
- Current or prior diagnosis of bulimia or anorexia nervosa
- Diagnosis of a seizure disorder or history of seizures
- History of anaphylactic reaction or similarly severe significant hypersensitivity to the medication prescribed

Relative

- Pregnancy/nursing mothers

#### Warnings and Precautions

- Angle-closure glaucoma

- Bipolar disorder in the absence of a mood stabilizer, activation of mania/hypomania
- Concomitant use with agents that lower seizure threshold (e.g., excessive alcohol, sedatives, antipsychotics, antidepressants, etc.)
- Discontinuation syndrome
- Head trauma or history of seizures, conditions that increase the risk of seizures (CNS tumor, abrupt benzodiazepine withdrawal, etc.)
- Hypersensitivity reactions
- Hypertension – new onset or worsening hypertension
- Recent history of acute myocardial infarction or unstable cardiac disease
- Neuropsychiatric adverse events and suicide risks in smoking cessation treatment
- Psychosis and other neuropsychiatric reactions
- Suicidal thoughts and behaviors in children, adolescents, and young adults ( $\leq 24$  years)

### **Adverse Reactions**

#### Side Effects Which Require Medical Attention

- Hypersensitivity reactions
- Angle-closure glaucoma
- Cardiac dysrhythmia
- Hypertension
- Seizure
- Suicidal thoughts and behaviors in children, adolescents and young adults
- Activation of mania or hypomania
- Psychosis or neuropsychiatric events
- CNS stimulation including increased energy, insomnia, anxiety

### **Drug Interactions of Major Significance**

See: [Indiana Univ Drug Interaction Table](#)

See: Lexicomp, Micromedex for more information

### **Special Populations**

- Pediatrics/Adolescents: Safety and efficacy have not been established in children younger than 18 years.
- Geriatric: Use with caution in elderly patients; may be at greater risk of drug accumulation during chronic dosing. Consider a reduction in dose.
- Renal: Consider a reduced dose and/or dosing frequency in patients with renal impairment (GFR < 90 mL per min).

- Hepatic: In mild hepatic impairment (Child-Pugh score: 5 to 6), consider reducing the dose and/or frequency of dosing. In moderate to severe hepatic impairment (Child-Pugh score: 7 to 15), maximum dose is:
  - ▶ Bupropion immediate release: 75 mg once daily
  - ▶ Bupropion sustained release: 100 mg once daily or 150 mg every other day
  - ▶ Bupropion extended release: 150 mg every other day
- Hemodialysis: Use of an alternative agent may be preferred, use with caution. Maximum dose 150mg/day.
- Pregnancy and Breastfeeding
  - ▶ See Contraindications, Warnings and Precautions, Black Box Warning.
  - ▶ Review product-specific labeling. Consider risks/benefits in reviewing medication-specific labeling.

### **Patient Monitoring Parameters**

#### Baseline Tests:

- Blood pressure and heart rate
- CBC
- Hepatic and renal function panels
- Pregnancy test (females)
- Weight

#### Ongoing Tests:

- Blood pressure and heart rate – as clinically indicated
- CBC – as clinically indicated
- ECG – as clinically indicated
- Hepatic function – as clinically indicated
- Emergence of suicidal ideation or behavior – as clinically indicated, particularly during the first two months of therapy/after dosage adjustments
- Neuropsychiatric reactions if using for smoking cessation
- Pregnancy test – as clinically indicated
- Renal function – as clinically indicated

### **Dosing**

- See HHSC Psychiatric Drug Formulary for dosage guidelines.
- Exceptions to maximum dosage must be justified as per medication rule.