

## Pharmacy Policy Bulletin

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**Title:** Smoking Cessation Agents

**Policy #:** Rx.01.139

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

### ▸ Intent:

The intent of this policy is to communicate the medical necessity criteria for **bupropion (Zyban®), varenicline (Chantix®) and nicotine replacements (nicotine gum, patches, inhalers, and spray)** as provided under the member's pharmacy benefit.

### ▸ Description:

**Bupropion (Zyban®), Varenicline (Chantix®) and nicotine replacements (nicotine gum, patches, inhalers, and spray)** are indicated as aids to smoking cessation treatment.

**Bupropion (Zyban®)**, a nonnicotine aid to smoking cessation, is a relatively weak inhibitor of the neuronal uptake of norepinephrine and dopamine and does not inhibit monoamine oxidase (MAO) or the reuptake of serotonin. While the mechanism of action of bupropion as an antidepressant or as a smoking deterrent is unknown, it is presumed that this action is mediated by noradrenergic and/or dopaminergic mechanisms.

**Varenicline (Chantix®)** is a partial neuronal alpha-4-beta-2 nicotinic receptor agonist. It prevents nicotine stimulation of mesolimbic dopamine system associated with nicotine addiction. It also binds to 5-hydroxytryptamine 3 receptor (significance not determined) with moderate affinity. Varenicline stimulates dopamine activity but to a much smaller degree than nicotine does, resulting in decreased craving and withdrawal symptoms.

### ▸ Policy:

**Bupropion (Zyban), Varenicline (Chantix) and Nicotine Replacements (Nicotine gum, patches, inhalers, and spray)** are approved when BOTH of the following inclusion criteria are met:

1. Member is 18 years of age or older; and
2. Member is currently a smoker.

The following combinations can be approved:

1. Nicotine patch and Nicotine gum
2. Nicotine patch and Nicotine inhaler
3. Nicotine patch and Nicotine spray
4. Nicotine patch and Zyban

**Reauthorization Criteria: Bupropion (Zyban), Varenicline (Chantix) and Nicotine Replacements (Nicotine gum, patches, inhalers, and spray)** are re-approved when all the following inclusion criteria are met:

1. One month has passed since last failure
2. Member is enrolled in a Smoking Cessation Program (in person or online)
3. Member is currently a smoker

**Authorization length:** 6 months

▸ **Black Box Warning:**

**Zyban®**

Cessation treatment:

Wellbutrin, Wellbutrin SR, and Wellbutrin XL are not approved for smoking cessation treatment, but bupropion under the name Zyban is approved for this use. Serious neuropsychiatric events, including but not limited to depression, suicidal ideation, suicide attempt, and completed suicide, have been reported in patients taking Zyban for smoking cessation. Some cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking Zyban who continued to smoke.

Observe all patients being treated with Zyban for neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of pre-existing psychiatric illness and completed suicide, have been reported in some patients attempting to quit smoking while taking Zyban in the postmarketing experience. When symptoms were reported, most were during treatment with Zyban, but some were following discontinuation of treatment with Zyban. These events have occurred in patients with and without pre-existing psychiatric disease; some have experienced worsening of their psychiatric illnesses. Patients with serious psychiatric illness, such as schizophrenia, bipolar disorder, and MDD, did not participate in the premarketing studies of Zyban.

Advise patients and caregivers to instruct the patient to stop taking Zyban and contact a health care provider immediately if agitation, hostility, depressed mood, or changes in thinking or behavior 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 Zyban was reported, although in some cases the symptoms persisted; therefore, provide ongoing monitoring and supportive care until symptoms resolve.

Weigh the risks of bupropion against the benefits of its use. Zyban has been demonstrated to increase the likelihood of abstinence from smoking for as long as 6 months compared with treatment with placebo. The health benefits of quitting smoking are immediate and substantial.

**Chantix®**

Serious neuropsychiatric events:

Serious neuropsychiatric events including but not limited to, depression, suicidal ideation, suicide attempt, and completed suicide have been reported in patients taking varenicline. Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including

suicidal ideation, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking varenicline who continued to smoke.

Observe all patients being treated with varenicline for neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, and suicide-related events, including ideation, behavior, and attempted suicide. These symptoms, as well as worsening of preexisting psychiatric illness and completed suicide, have been reported in some patients attempting to quit smoking while taking varenicline in the postmarketing experience. When symptoms were reported, most were during varenicline treatment, but some were following discontinuation of varenicline therapy.

These events have occurred in patients with and without preexisting psychiatric disease. Patients with serious psychiatric illness, such as schizophrenia, bipolar disorder, and major depressive disorder, did not participate in the premarketing studies of varenicline, and safety and efficacy of varenicline in these patients have not been established.

Advise patients and caregivers that the patient should stop taking varenicline and contact a health care provider immediately if agitation, hostility, 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 varenicline was reported, although in some cases the symptoms persisted; therefore, provide ongoing monitoring and supportive care until symptoms resolve.

Weigh the risks of varenicline against the benefits of its use. Varenicline has been demonstrated to increase the likelihood of abstinence from smoking for as long as 1 year compared with treatment with placebo. The health benefits of quitting smoking are immediate and substantial.

#### ▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

## **BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

#### ▸ References:

American Cancer Society. American Cancer Society, Inc. Available at: <http://www.cancer.org/>. Accessed August 26, 2014.

Chantix. Pfizer Inc. Available at: <http://www.chantix.com>. Accessed August 26, 2014.

Chantix (Varenicline) In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed August 26, 2014.

Nicoderm CQ. GlaxoSmithKline Consumer Healthcare. Available at: <http://www.nicodermcq.com>. Accessed August 26, 2014.

Nicorette. GlaxoSmithKline Consumer Healthcare. Available at: <http://www.nicorette.com/>. Accessed August 26, 2014.

NicotrollInhaler. Pfizer Inc. Available at: <http://www.nicotrol.com/>. Accessed August 26, 2014.

Zyban (Bupropion) In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed August 26, 2014.

**Applicable Drugs:**

**i** Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Zyban	Bupropion
Chantix	Varenicline
Various names (i.e. Commit Lozenge, Nicoderm)	Nicotine replacement

**Cross References:**

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