

**Kaiser Permanente Colorado Region-Denver/Boulder Local Area Market  
Tobacco: Guideline for the use of Medications for Tobacco Cessation**

**Date:** July 1999

**Review Dates**      August 2001  
                                 July 2003  
                                 July 2005  
**Next Review:**      July 2007

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**Approval:**

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These guidelines are informational only and are not intended or designed to substitute for the reasonable exercise of independent clinical judgment by providers in any particular set of circumstances for each patient encounter. The guidelines are flexible and are intended to be used as a resource for integration with sound exercise of clinical judgment. They can be used to create an approach to care that is unique to the needs of each individual patient.

The implementation of this guideline is not intended to conflict with any agreed upon health plan benefits nor is it intended to prevent access to care that the provider believes is warranted based on clinical judgment.

**Rationale for the Guideline:**

Bupropion SR (also known as Wellbutrin SR or Zyban) and Nortriptyline (also known as Pamelor) have been found to reduce withdrawal symptoms in individuals who are quitting tobacco use **when used in conjunction with** tobacco cessation education and behavior change support.

Results of a meta-analysis of randomized controlled trials demonstrated a 30% quit rate in smokers, which is statistically significant over placebo (1) (*Strength of evidence: United States Preventive Services Task Force Rating 1: Evidence obtained from at least one properly designed randomized controlled trial*). The literature does not demonstrate a difference in the long-term efficacy of 150 mg q day vs. 150 mg BID dosing (2, 3). Nortriptyline has been shown to produce quit rates equivalent to those of Bupropion SR (4).

**Target Population:**

Bupropion SR and Nortriptyline are appropriate for use in adults 18 and over who use tobacco. There are no large studies yet that relate to use in people under 18. Any tobacco user who is interested in quitting and is enrolled in an approved behavioral counseling program should be offered pharmacology aids as assistance in quitting.

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# Guideline overview:

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## Pharmacy Benefit

Evidence suggests that patients achieve greater success when they combine medication and a behavior change program. Therefore:

**Bupropion SR may be prescribed for tobacco cessation and covered by the member's drug benefit only when:**

1. **written by a hospitalist** (4-week "pre-education" prescription, no refill); **or**
2. **the member enrolls in an approved tobacco cessation program.**

<p><b>Note:</b> In order to have prescriptions for Bupropion SR filled for their pharmacy co-pay, <b>patients must present a certificate</b> of program enrollment from Health Education.</p>
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**Nortriptyline may be prescribed for tobacco cessation and covered by the member's drug benefit. Enrollment in an approved tobacco cessation program is strongly encouraged.**

## Approved tobacco cessation programs:

- Stop Smoking Basics,
- Freedom From Cigarettes,
- Cardiac Rehabilitation Program,
- State of Colorado Quit Line, and
- equivalent programs approved by Eric France, MD or Juanita Redfield, MD

## Intended audience for this guideline:

This guideline may be used by:

- **Providers with Prescriptive Authority**  
(See appendix 1: "Procedures for Providers with Prescriptive Authority prescribing **Bupropion SR**")  
(See appendix 2: "Procedures for Providers with Prescriptive Authority prescribing **Nortriptyline**")
- **Hospitalists**  
(See appendix 3: "Procedures for Hospitalists prescribing Bupropion SR....")
- **Health Educators** (in collaboration with Clinical Pharmacists and Physicians)  
(See appendix 4: "Protocol for Health Educators initiating orders for **Bupropion SR**")  
(See appendix 5: "Protocol for Health Educators initiating orders for **Nortriptyline**")

## Guidelines for prescribing Bupropion SR:

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### Contraindications to use of Bupropion SR

Bupropion SR cannot be given to members with any of the following:

- History of seizure disorder
- Allergy to Bupropion or Wellbutrin
- Patients with an eating disorder

- Alcohol consumption > 14 drinks per week
- Undergoing abrupt withdrawal of ethanol or sedatives, including benzodiazepines
- Taking an MAO inhibitor.

## Cautions for use of Bupropion SR

- Extreme caution should be used in patients under 18 years of age. Consult Mental Health prior to starting Bupropion SR to discuss follow up.
- Bupropion alone, or, particularly, in combination with nicotine from any source (whether nicotine replacement therapy or continued tobacco use) can increase blood pressure. This effect has been observed in patients with and without baseline hypertension. The increase in blood pressure can be mild, or quite severe in rare patients. Patients receiving Bupropion SR in combination with nicotine replacement who also continue to smoke are at greater risk for rises in blood pressure.
- Use with caution in patients with renal or hepatic insufficiency.
- Use with caution in pregnant or breastfeeding patients (No drug has been proven safe in pregnancy. Weigh the known risks of smoking against the risks of using Bupropion SR to assist in quitting smoking.)
- Use with caution in patients with a recent history of head injury.
- Use with caution in patients concurrently taking SSRIs.
- Use with caution in bipolar patients.
- Use with caution in patients concurrently taking St. Johns Wort.

## Side Effects and Warnings for use of Bupropion SR:

The following side effects may occur:

More common:

- insomnia, dry mouth, dizziness, runny nose.

Less common:

- loss of concentration, nausea, constipation, anxiety,
- **allergic reaction** (rash, itching, hives, swelling, difficulty breathing),  
**(One of every 3,000 users has an allergic-like reaction, accompanied by itching, shortness of breath and difficulty breathing).**
- **elevated blood pressure**  
(patients with a history of hypertension and those taking Bupropion SR *and* NRT)

**Patients combining NRT with Bupropion SR should be instructed to check their blood pressure one week after being on both medications and every two weeks during treatment.**

If their systolic value exceeds 160 or diastolic value exceeds 100 they should stop the nicotine replacement and the Bupropion SR and contact their physician before taking any more of these medications.

- **seizure**  
**(One of every 1,000 people taking Bupropion SR has a seizure).**  
Conditions that may increase the risk of seizure are :
  - history of past seizure,
  - head trauma,
  - tumor of the brain or spine;
  - use of antipsychotics, antidepressants or theophylline,

- history of diabetes with frequent hypoglycemia,
- excessive use of alcohol,
- abrupt withdrawal from alcohol or sedatives,
- current addiction to opiates, cocaine, or stimulants,
- use of over-the-counter stimulants and anorectics.

**Instruct patients to notify their doctor immediately, or to call 911 if they believe they are experiencing an emergency situation, if they experience:**

- **Seizure.**
- **Itching, swelling, shortness of breath, difficulty breathing**  
(possible allergic reaction)

## Summary of prescribing instructions for Bupropion SR:

**Note: Clinicians who do not wish to screen patients and counsel them about tobacco cessation medications may have them enroll in a stop smoking program by calling health education at 344-7255.**

Patients who enroll in a stop smoking program will receive medication education and be screened under protocol by Health Education and Clinical Pharmacy as described below and in appendix 4:

A pharmacist and health educator will:

- Check to see that the patient meets guideline requirements for Bupropion SR
- Provide education about the proper use of Bupropion SR
- Initiate an order for Bupropion SR and send it to the patient's physician for signature.
- Issue a certificate enabling the patient to receive Bupropion SR for his/her drug co-pay.
- Order a follow-up prescription and issue a second certificate for patients who continue to participate in an approved tobacco cessation program.

**Hospitalists:** 4-week introductory prescriptions, ***no certificate required for in-patients***

(Paper prescriptions:)

(See appendix 3 for detailed prescribing procedures)

- **Bupropion SR 150 mg once a day in the AM for four weeks (28 pills). Discontinue tobacco use one week after starting medication.**
- Patients should be advised to call health education at 303-344-7255 to enroll in a tobacco cessation program after they have been discharged.
- Only patients who receive a certificate of enrollment in a tobacco cessation program from Health Education can receive a follow-up prescription of Bupropion SR for their pharmacy co-pay.

**Providers with Prescriptive Authority, 8-week *initial prescription***

(Smartset: Tobacco Cessation Bupropion SR 1)

(See appendix 1 for detailed prescribing procedures)

- **Bupropion SR 150 mg once a day in the AM for eight weeks (56 pills). Discontinue tobacco use one week after starting medication.**
  - Patients may choose nicotine replacement therapy (NRT) along with Bupropion SR.
  - After being on Bupropion SR for one week the member can start using NRT, upon quitting smoking or chewing, for up to six weeks according to the NRT guidelines.
  - Patients should be advised to call health education at 303-344-7255 to enroll in a tobacco cessation program.

- Only patients who receive a certificate of enrollment in a tobacco cessation program from Health Education can receive a follow-up prescription of Bupropion SR for their pharmacy co-pay.

**Providers with Prescriptive Authority, 4-week *follow-up prescription*:**

(Smartset: Tobacco Cessation Bupropion SR 2)

(See appendix 1 for detailed prescribing procedures)

- **Bupropion SR 150 mg once day in the AM for four weeks (28 pills).**  
The following patients may be at increased risk of elevated blood pressure:
  - Patients combining Bupropion SR and nicotine replacement therapy.
  - Patients continuing to smoke more than 10 cigarettes per day.
  - Patients with uncontrolled hypertension before starting Bupropion SR.
- Patients may call health education at 303-344-7305 to request a follow-up prescription.
- Only patients who receive an additional certificate of enrollment indicating continued participation in a tobacco cessation program can receive a follow-up prescription of Bupropion SR for their pharmacy co-pay.

## **Bupropion SR orders initiated by a health educator.**

Health educators approved by Eric France, MD or Juanita Redfield, MD may initiate a Bupropion SR order for patients who enroll in an approved tobacco cessation program.

Per protocol, health educators may send a new medication order for Bupropion SR to the patient's physician for signature if the following conditions are met.

- **The patient has received education about the correct use of Bupropion SR** for tobacco cessation.
- **The patient has completed an “informed consent” form** (see appendix 6) acknowledging the risk of seizure, allergic reaction or increased blood pressure.

Patients whose responses on the consent form leave it unclear whether Bupropion SR is appropriate will be referred to their physician for review and recommendations.

- **The member has a blood pressure reading documented in the medical record**

Self-reported measurements based on readings taken using an automated blood pressure cuff will satisfy this requirement.

- **A clinical pharmacist has reviewed the consent and medical record** and confirms that the patient meets guideline criteria for Bupropion SR.

**Where consent or medical record reveals stage 2 hypertension (>160/100) no medication order will be initiated. The pharmacist will request review by the member's physician.**

Per protocol, health educators may order a follow-up prescription for Bupropion SR and send it to the patient's physician for co-signature if the patient continues to participate in an approved tobacco cessation program and indicates progress in his or her attempts to quit tobacco (patients at risk for blood pressure elevations must report a current blood pressure reading of less than 160/100).

## **Guidelines for prescribing Nortriptyline:**

### **Contraindications to use of Nortriptyline**

Nortriptyline cannot be given to members with any of the following:

- Allergy to Nortriptyline

- Narrow angle glaucoma
- MAOI use within 14 days
- Acute recovery period following an MI (one month)
- Pregnant women and nursing mothers

## Cautions for use of Nortriptyline

- Extreme caution should be used in patients under 18 years of age. Consult Mental Health prior to starting Nortriptyline to discuss follow up.
- Use with caution in patients with cardiac conduction disturbances.
- Use with caution in patients with history of hyperthyroidism.
- Use with caution in patients with history of urinary retention.
- Use with caution in patients with patients with history of bowel obstruction.
- Use with caution in patients with history of schizophrenia, psychosis, or bipolar disorder. Mental Health consultation recommended.
- Monitor levels with use of SSRIs and Bupropion.

## Side Effects and Warnings for use of Nortriptyline:

The following side effects may occur:

More common:

- Dry mouth, constipation, dizziness, drowsiness, headache, increased appetite, nausea, unpleasant taste, and photosensitivity.

Less common:

- **Hypo or hypertension**
- **allergic reaction** (rash, itching, hives, swelling, difficulty breathing),

## Summary of prescribing instructions for Nortriptyline:

**Note:** Clinicians who do not wish to screen patients and counsel them about tobacco cessation medications may have them enroll in a stop smoking program by calling health education at 344-7255.

Patients who enroll in a stop smoking program will receive medication education and be screened under protocol by Health Education and Clinical Pharmacy as described below and in appendix 4:

A pharmacist and health educator will:

- Check to see that the patient meets guideline requirements for Nortriptyline
- Provide education about the proper use of Nortriptyline
- Initiate an order for Nortriptyline and send it to the patient's physician for signature.
- Order a follow-up prescription for patients who continue to participate in an approved tobacco cessation program.

**Providers with Prescriptive Authority**, 8-week initial prescription  
(Smartset: Tobacco Cessation Nortriptyline 1)  
(See appendix 2 for detailed prescribing procedures)

- Nortriptyline 25 mg once a day at HS for four days, 50 mg once a day at HS for four days, then 75 mg once a day at HS (156 pills). Discontinue tobacco use 10 – 14 days after starting medication.
  - Patients may choose nicotine replacement therapy (NRT) along with Nortriptyline.
  - After being on Nortriptyline for 10 – 14 days, the member can start using NRT, upon quitting smoking or chewing, for up to six weeks according to the NRT guidelines.
  - Patients should be advised to call health education at 303-344-7255 to enroll in a tobacco cessation program.

**Providers with Prescriptive Authority**, 4-week follow-up prescription:

(Smartset: Tobacco Cessation Nortriptyline 2)

(See appendix 2 for detailed prescribing procedures)

- Nortriptyline 75 mg once daily at HS for four weeks (28 pills).
- Patients may call health education at 303-344-7305 to request a follow-up prescription.

## Nortriptyline orders initiated by a health educator

**Health educators** approved by Eric France, MD or Juanita Redfield, MD may initiate a Nortriptyline order for patients who enroll in an approved tobacco cessation program.

Per protocol, health educators may send a new medication order to the patient’s physician for signature if the following conditions are met.

- **The patient has received education about the correct use of Nortriptyline** for tobacco cessation.
- **The patient has completed an “informed consent” form** (see appendix 7) acknowledging the risk of allergic reaction or side effects.

Patients whose responses on the consent form leave it unclear whether Nortriptyline is appropriate will be referred to their physician for review and recommendations.

- **A clinical pharmacist has reviewed the consent and medical record** and confirms that the patient meets guideline criteria for Nortriptyline.

Per protocol, health educators may order a follow-up prescription for Nortriptyline and send it to the patient’s physician for co-signature if the patient continues to participate in an approved tobacco cessation program and indicates progress in his or her attempts to quit tobacco.

## Sources of evidence

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1. Ferry, L., Johnston, J.A. “Efficacy and Safety of Nortriptyline for Smoking Cessation: Data from Clinical Trials and Five Years of Post marketing Experience”, *IJCP* 2003 Vol. 57 Number 3 pg.224-230.
2. Hurt, R.D., Sachs, David, et. al. A Comparison of Sustained-Release Nortriptyline and Placebo for Smoking Cessation. *New England Journal of Medicine* 1997 Vol. 337 Number 17 pg. 1195-1202.
3. McAfee, T., France, E. Letter to the Editor “Sustained-Release Nortriptyline for Smoking Cessation”. *New England Journal of Medicine* 1998 Vol. 338 Number 9 pg. 619-620.
4. Hughes, J.R., Stead, L. F., Lancaster, T. Antidepressants for Smoking Cessation. *Cochrane Database of Systemic Reviews* 1, 2005.

## **Appendix 1: Procedures for Providers with Prescriptive Authority Prescribing Bupropion SR (Wellbutrin SR, Zyban) for Tobacco Cessation**

### **BACKGROUND**

The effectiveness of Bupropion SR for tobacco cessation is greatly enhanced when paired with behavior change counseling. **To receive Bupropion SR for tobacco cessation for their generic medication co-pay, KP patients must participate in an approved tobacco cessation program, and the prescription must be written in a very specific manner.**

#### **OPTION 1: Health Educator Initiates Order after a Clinical Pharmacist Screens for Contraindications**

Patients who enroll in an approved tobacco cessation program (see p. 2) and then request a prescription for Bupropion SR will be screened under protocol by Health Education and Clinical Pharmacy. A health educator will then send a note to the patient's physician with the initial prescription for Bupropion SR as a pending order.

**Please sign these pending prescriptions within 48 hours.** If you would like to document, do so in a Quick Note.

**NOTE:** This RX must be signed by a provider with prescriptive authority.

#### **OPTION 2: Provider Initiates Medication Order and Screens for Contraindications**

If a patient requests Bupropion SR for smoking cessation, providers may refer the patient to an approved smoking cessation program for screening and education as described in option 1, above (Members call 303-344-7255).

Alternatively, providers with prescriptive authority may order the medication per the procedures described below. Providers should be aware that their patients will pay full price for these prescriptions unless the patient brings a certificate of class attendance from health education to the pharmacy. Patients who enroll in the Colorado Quit Line rather than attending a class may call Health Education at 303-344-7305 to request a certificate.

### **PRESCRIPTION PARAMETERS**

**The prescription must be written as follows and the patient must have a certificate from Health Education indicating that they are participating in an approved behavioral counseling program:**

**Bupropion SR 150 mg**  
**1 po qd for tobacco cessation**  
**#56, No Refills**  
**(Follow-up Rx: #28, No Refills)**

#### **Key points:**

1. Once daily dosing, in A.M.
2. Indication of tobacco cessation
3. Eight week initial supply, no refills
4. Four week, follow-up Rx, no refills
5. Typically the patient discontinues tobacco seven days after starting the medication.
6. Patients may call Health Education for refills. These may be generated per protocol by a Health Educator.

Two HealthConnect SmartSets are available to help you screen for and order Bupropion SR for Tobacco Cessation:

SmartSet for initiating Bupropion SR (8-week supply): **Tobacco Cessation Bupropion SR 1.**

SmartSet for follow-up prescriptions (4-week supply): **Tobacco Cessation Bupropion SR 2.**

**Please see the back of this sheet for a list of approved tobacco cessation programs, talking points, Bupropion SR contraindications and cautions.**



## APPROVED TOBACCO CESSATION PROGRAMS

To receive Bupropion SR at their generic medication co-pay, patients must receive a certificate from Health Education indicating they are participating in one of the following programs

- **Stop Smoking Basics**
  - A one time, two-hour class taught by KP Health Educators and CPCRS clinical pharmacists.
- **Freedom From Cigarettes**
  - 10 sessions, held over 2 months, taught through KP Health Education.
- **The Colorado State Quit Line**
  - Five one-on-one calls with a tobacco counselor. Calls can be made from the comfort of the member's home.
  - You may refer your patient to this program by placing the dot phrase: .tobformcql in a note, printing it out, and faxing it to the number printed on the form. Once patients are enrolled in the Colorado Quit line program, they should call Health Education for their certificate.
- Other Tobacco Cessation Programs Approved by a Kaiser Permanente Health Educator

**Health Education will supply educational certificates to participants in all approved tobacco cessation programs. Members may be referred to (303) 344-7255 to enroll in a tobacco cessation program.**

## PATIENTS WHO SHOULD NOT TAKE BUPROPION

1. History of seizure disorder
2. Alcohol consumption > 14 drinks per week
3. Allergy to Bupropion or Wellbutrin
4. Undergoing abrupt withdrawal of ethanol or sedatives, including benzodiazepines.
5. Patients with an eating disorder
6. Taking an MAOI or St. John's Wort

## CAUTIONS

- Extreme caution should be used in patients under 18 years of age due to reports of suicidal ideation and attempts. Consult Mental Health prior to starting Bupropion SR to discuss follow up.
- Bupropion alone, or, particularly, in combination with nicotine from any source (whether nicotine replacement therapy or continued tobacco use) can increase blood pressure. This effect has been observed in patients with and without baseline hypertension. The increase in blood pressure can be mild, or quite severe in rare patients. Patients receiving Bupropion SR in combination with nicotine replacement who also continue to smoke are at greater risk for rises in blood pressure.
- Use with caution in patients with renal or hepatic insufficiency.
- Use with caution in pregnant or breastfeeding patients (No drug has been proven safe in pregnancy. Weigh the known risks of smoking against the risks of using Bupropion SR to assist in quitting smoking.)
- Use with caution in patients with a recent history of head injury.
- Use with caution in patients concurrently taking SSRIs.
- Use with caution in bipolar patients.

## TALKING POINTS

- ◆ Congratulations on your decision to quit using tobacco! This is one of the best things you can do for your health! We want to help you be as successful as possible in your quit attempt. Participating in one of our tobacco cessation programs can double your chances of quitting for good.
- ◆ When you participate in one of our approved tobacco cessation programs (such as Stop Smoking Basics, Freedom From Cigarettes, or the Colorado Quitline) you will receive a program certificate from Health Education. This certificate will allow you to obtain Bupropion SR at your generic medication co-pay. If you choose not to participate in a tobacco cessation program, you will be asked to pay full price at the pharmacy.
- ◆ Bupropion SR takes seven days to reach its full strength. If you are still smoking or chewing during this time, discontinue all tobacco use by day eight.
- ◆ If you have never tried to quit using Bupropion SR, we recommend you try Bupropion SR alone and not add nicotine replacement products such as "the patch" or nicotine gum. If you *do* plan to use these medications together, the combination could raise your blood pressure. To be safe, check your blood pressure every two weeks, and never smoke or chew while taking both Bupropion SR and nicotine replacement.
- ◆ Some people are able to quit with an 8-week supply of this medication. Others use the medication for 12 weeks. If you would like an additional prescription, please be sure to contact Health Education at (303) 344-7305 at least one week before your prescription runs out.

## Appendix 2: Procedures for providers with Prescriptive Authority Prescribing Nortriptyline for Tobacco Cessation

### BACKGROUND

The effectiveness of Nortriptyline for tobacco cessation is greatly enhanced when paired with behavior change counseling.

#### OPTION 1: Health Educator Initiates Order after a Clinical Pharmacist Screens for Contraindications

Patients who enroll in an approved tobacco cessation program (see p. 2) and then request a prescription for Nortriptyline will be screened under protocol by Health Education and Clinical Pharmacy. A health educator will then send a note to the patient's physician with the initial prescription for Nortriptyline as a pending order.

**Please sign these pending prescriptions within 48 hours.** If you would like to document, do so in a Quick Note.

**NOTE:** This RX must be signed by a provider with prescriptive authority.

#### OPTION 2: Provider Initiates Medication Order and Screens for Contraindications

If a patient requests Nortriptyline for smoking cessation, providers may refer the patient to an approved smoking cessation program for screening and education as described in option 1, above (Members call 303-344-7255).

Alternatively, providers with prescriptive authority may order the medication per the procedures described below.

#### PRESCRIPTION PARAMETERS

The prescription should be written as follows:

**Nortriptyline 25 mg**

**1 po q HS for 4 days, 2 po q HS for 4 days, then 3 po q HS for tobacco cessation**

**#156, No Refills**

**(Follow-up Rx: #84, No Refills)**

#### Key points:

1. Once daily dosing, at H. S.
2. Indication of tobacco cessation
3. Eight week initial supply, no refills
4. Four week, follow-up Rx, no refills
5. Typically the patient discontinues tobacco 10 – 14 days after starting the medication.
6. Patients may call Health Education for refills. These may be generated per protocol by a Health Educator.

Two HealthConnect SmartSets are available to help you screen for and order Nortriptyline for Tobacco Cessation:

SmartSet for initiating Nortriptyline (8-week supply): **Tobacco Cessation Nortriptyline 1.**

SmartSet for follow-up prescriptions (4-week supply): **Tobacco Cessation Nortriptyline 2.**

**Please see the back of this sheet for a list of approved tobacco cessation programs, talking points, Nortriptyline contraindications and cautions.**

## APPROVED TOBACCO CESSATION PROGRAMS

- *Stop Smoking Basics*
  - A one time, two-hour class taught by KP Health Educators and CPCRS clinical pharmacists.
- *Freedom From Cigarettes*
  - 10 sessions, held over 2 months, taught through KP Health Education.
- *The Colorado State Quit Line*
  - Five one-on-one calls with a tobacco counselor. Calls can be made from the comfort of the member's home.
  - You may refer your patient to this program by placing the dot phrase: .tobformcql in a note, printing it out, and faxing it to the number printed on the form. Once patients are enrolled in the Colorado Quit line program, they should call Health Education for their certificate.
- Other Tobacco Cessation Programs Approved by a Kaiser Permanente Health Educator

Members may be referred to (303) 344-7255 to enroll in a tobacco cessation program.

## PATIENTS WHO SHOULD NOT TAKE NORTRIPTYLINE

1. Allergy to Nortriptyline
2. MAOI use within 14 days
3. Narrow angle glaucoma
4. Acute recovery period following an MI (one month)
5. Pregnant or nursing women

## CAUTIONS

- Extreme caution should be used in patients under 18 years of age. Consult Mental Health prior to starting Nortriptyline to discuss follow up.
- Use with caution in patients with cardiac conduction disturbances.
- Use with caution in patients with history of hyperthyroidism
- Use with caution in patients with history of urinary retention.
- Use with caution in patients with history of bowel obstruction.
- Use with caution in patients with history of schizophrenia, psychosis, or bipolar disorder. Mental Health consultation recommended.
- Monitor levels with use of SSRIs and Bupropion.

## TALKING POINTS

- ◆ Congratulations on your decision to quit using tobacco! This is one of the best things you can do for your health! We want to help you be as successful as possible in your quit attempt. Participating in one of our tobacco cessation programs can double your chances of quitting for good.
- ◆ Nortriptyline takes ten days to reach its full strength. If you are still smoking or chewing during this time, discontinue all tobacco use by day ten.
- ◆ If you have never tried to quit using Nortriptyline, we recommend you try Nortriptyline alone and not add nicotine replacement products such as “the patch” or nicotine gum.
- ◆ Some people are able to quit with an 8-week supply of this medication. Others use the medication for 12 weeks. If you would like an additional prescription, please be sure to contact Health Education at (303) 344-7305 at least one week before your prescription runs out.
- ◆ The most common side effects of Nortriptyline include dry mouth and sedation, which usually get better with time (normally in a couple of weeks). Other side effects may include headache, dizziness, and skin sensitivity to sunlight. Side effects, which are rare, include blurred vision, trouble urinating, and palpitations. Call your physician if you experience any of these side effects.

Once you are taking Nortriptyline, if you have any concerns, please contact your physician. If you get a rash, hives, or swelling call (303) 338-4545 to contact your doctor. You could be having an allergic reaction to the nortriptyline. For emergencies, such as difficulty breathing or needing an ambulance, call 911.

### Appendix 3: Procedures for Hospitalists Writing Prescriptions for Bupropion SR (Wellbutrin SR, Zyban) for Tobacco Cessation for Kaiser Permanente Patients

#### BACKGROUND:

The effectiveness of Bupropion SR for tobacco cessation is greatly enhanced when paired with behavior change counseling. Therefore:

- In order for Kaiser Permanente in-patients to receive Bupropion SR for tobacco cessation for their generic medication co-pay, their *initial* prescriptions must be written in a very specific manner.
- Discharged patients must participate in an approved tobacco cessation program in order to fill a *follow-up* prescription for Bupropion SR for tobacco cessation for their generic medication co-pay.

#### INITIAL PRESCRIPTION PARAMETERS:

- The initial prescription for in-patients must be written as follows:

<p style="text-align: center;"><b>Bupropion SR 150 mg</b></p> <p style="text-align: center;"><b>1 po qd for tobacco cessation</b></p> <p style="text-align: center;"><b>#28, No Refills</b></p>
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- **Key points:**

- |                                    |   |
|------------------------------------|---|
| 1. Once daily dosing, in A.M.      | 4. No refills   |
| 2. Indication of tobacco cessation | 5. Typically the patient discontinues tobacco seven days after starting the medication. |
| 3. Four week supply                |   |

#### FOLLOW-UP PRESCRIPTIONS AND APPROVED TOBACCO CESSATION PROGRAMS

To receive additional Bupropion SR at their generic medication co-pay, patients must present a certificate from Health Education indicating they are participating in one of the following programs

- ***Stop Smoking Basics***

- A one time, two-hour class taught by KP Health Educators and CPCRS clinical pharmacists.  
Call 303-344-7255 to enroll.

- ***Freedom From Cigarettes***

- 10 sessions, held over 2 months, taught through KP Health Education.  
Call 303-344-7255 to enroll.

- ***The Colorado State Quit Line***

- Five one-on-one calls with a tobacco counselor.
- Call 303-639-7848 or use the dot phrase **.tobformcql** to print a faxable enrollment form.
- **NOTE:** Once patients are enrolled in the Colorado Quit line, they should call Health Education at 303-344-7305 to request their follow-up prescription for Bupropion SR and a certificate that will allow them to fill this prescription for their generic pharmacy co pay.

- ***Cardiac Rehab Program***

- One-on-one tobacco cessation counseling from Cardiac Rehab nurses.

## **PATIENTS WHO SHOULD NOT TAKE BUPROPION**

1. History of seizure disorder
2. Allergy to Bupropion or Wellbutrin
3. Patients with an eating disorder
4. Alcohol consumption > 14 drinks per week
5. Undergoing abrupt withdrawal of ethanol or sedatives, including benzodiazepines.
6. Taking an MAO-I or St. John's Wort

## **CAUTIONS**

- Extreme caution should be used in patients under 18 years of age. Consult Mental Health prior to starting Bupropion SR to discuss follow up.
- Bupropion alone, or, particularly, in combination with nicotine from any source (whether nicotine replacement therapy or continued tobacco use) can increase blood pressure. This effect has been observed in patients with and without baseline hypertension. The increase in blood pressure can be mild, or quite severe in rare patients. Patients receiving Bupropion SR in combination with nicotine replacement who also continue to smoke are at greater risk for rises in blood pressure.
- Use with caution in in-patients with renal or hepatic insufficiency.
- Use with caution in pregnant or breastfeeding patients (pregnancy category B, excreted into breast milk).
- Use with caution in patients with a recent history of head injury.
- Use with caution in patients concurrently taking SSRIs.
- Use with caution in bipolar patients.

## **TALKING POINTS**

- This medication takes seven days to reach its full strength. If you are still smoking or chewing during this time, discontinue all tobacco use by day eight.
- Congratulations on your decision to quit using tobacco! This is one of the best things you can do for your health! We want to help you be as successful as possible in your quit attempt. Participating in one of our behavioral counseling programs can increase your success.
- If you have never tried to quit using Bupropion SR, we recommend you try Bupropion SR alone and not add any nicotine replacement (NRT) products. If you do plan to use these medications together, this combination could raise your blood pressure. Therefore, check your blood pressure every two weeks. Never smoke or chew while taking both Bupropion SR and nicotine replacement.
- Some people are able to quit with a 4 week supply of this medication. Others use the medication for 8- 12 weeks. If you would like an additional prescription beyond your first 4 weeks, contact Health Education at (303) 344-7305.

**Appendix 4: Protocol for Health Educators initiating orders for Bupropion SR for Tobacco Cessation and ordering refills of Bupropion SR as a delegated medical function.**

**Initial Prescriptions**

**Tobacco counselors approved by Eric France, MD or Juanita Redfield, MD will initiate orders for an 8-week prescription for Bupropion SR, and forward this order to the patient’s physician if the following criteria are met:**

**a. The member completes and returns an informed consent form; AND**

Where a patient reports the intention to continue to use alcohol in excess of 14 drinks per week, a health educator will notify the patient’s physician before initiating an order.

**b. Member enrolls in an approved tobacco cessation program\* \*\*; AND**

<b>Approved Programs</b>	<b>Approved for:</b>
Stop Smoking Basics Freedom From Cigarettes	All members
Cardiac Rehab Tobacco Cessation Program	Patients enrolled in the Cardiac Rehab Program
Colorado Quit Line	Members who meet <b>all</b> the following criteria: a) not requesting combination therapy (Bupropion plus NRT) b) reporting no history of hypertension, or reporting current blood pressure < 160/100 c) reporting current alcohol use of no more than 14 drinks per week

\* If a **new member** wants to continue a course of Bupropion SR prescribed before joining the health plan, they should be referred to the New Member Pharmacy.

\*\* Members who report enrolling but not yet starting the Colorado Quit Line program may be provided an initial 8-week prescription of Bupropion SR.

**c. A pharmacist confirms that the patient meets the guideline requirements for Bupropion SR for tobacco cessation after reviewing the member’s informed consent and medical record. \* \*\***

<b>Programs</b>	<b>Responsible Pharmacy Team</b>
Stop Smoking Basics Freedom From Cigarettes	Clinical Pharmacy Cardiac Risk Services (CPCRS) or Clinical Pharmacy
Cardiac Rehab Tobacco Cessation Program	Clinical Pharmacy
Colorado Quit Line	CPCRS or Clinical Pharmacy

\* Where consent or medical record reveals stage 2 hypertension (>160/100, see below) the pharmacist will request review by the patient’s physician.

\*\* If there is no documented blood pressure reading in the patient’s medical record, the patient will be required to provide a current blood pressure reading. A verbal report of a blood pressure reading from a supermarket blood pressure machine or automated monitor is acceptable.

## **Follow-up Prescriptions**

Approved tobacco cessation counselors will initiate an order for follow-up 4-week Rx for Bupropion SR and send it to the patient's physician for co-signature if the following criteria are met:

**a. The patient continues to participate in an approved behavioral counseling program; AND**

<b>Approved Program</b>	<b>Participation measure:</b>
Stop Smoking Basics Freedom From Cigarettes	Attendance at a session of Tobacco Free Living <b>or</b> continued attendance at FFC <b>or</b> completion of a telephone counseling session with a tobacco counselor
Cardiac Rehab Tobacco Cessation Program	Cardiac Rehab Nurse's Assessment (8-week follow-up prescription if first Rx was a 4-week initial prescription from a hospitalist).
Colorado Quit Line	Confirmation from member of continuing participation with the Quit Line counseling sessions.

**b. The patient reports significant progress on his or her quit plan indicated by discontinuing or limiting tobacco; AND**

**c. The patient reports a blood pressure reading less than 160/100**

(A blood pressure is required only if the patient is at increased risk of elevated blood pressure).

Patients who may be at increased risk are those using combination therapy, those continuing to smoke more than 10 cigarettes per day, and those with uncontrolled hypertension before starting Bupropion SR.

Home reading or readings from commercial services (e.g. supermarket pharmacies) are acceptable.

## **Side Effects and Warnings**

1. **At any time, patients reporting blood pressure exceeding 160 (systolic) OR 100 (diastolic) should be advised to discontinue all use of tobacco cessation medication aids (including NRT and Bupropion SR) and call their physician.**

2. **Requests for follow-up prescriptions will be sent to the patient's physician if:**

- a) patient reports alcohol use of more than 14 drinks per week
- b) patient reports a head injury accompanied by loss of consciousness

<b>Guideline for Hypertension in Tobacco Users:</b>	
<b>Stage 2 hypertension</b>	>160 (systolic) or >100 (diastolic)
<b>Signs and Symptoms</b>	<b>Recommended Action</b>
<b>Emergent Signs and Symptoms:</b> Systolic blood pressure greater than 220 or Diastolic blood pressure greater than 120 with any of the following symptoms: <ul style="list-style-type: none"> <li>◆ Dizziness</li> <li>◆ Palpitations</li> <li>◆ Chest Pain</li> <li>◆ Mental status change</li> <li>◆ Headache</li> <li>◆ Visual changes</li> <li>◆ Shortness of breath</li> <li>◆ Profound weakness</li> <li>◆ Nausea or vomiting</li> </ul>	Call 3900 from any Kaiser Permanente facility and request "urgent" ambulance service to emergency department.  Patient SHOULD NOT drive self.
<b>Semi-Urgent Signs and Symptoms:</b> <ul style="list-style-type: none"> <li>◆ Blood pressure greater than 140/90 to 180/110 with any of the above symptoms and history of tobacco use or other predisposing factors.</li> <li>◆ Diastolic blood pressure greater than 120 with no symptoms.</li> </ul>	Needs appointment or visit with provider within 24 hours.

**Appendix 5: Protocol for Health Educators initiating orders for Nortriptyline for Tobacco Cessation and ordering refills of Nortriptyline as a delegated medical function.**

**Initial Prescriptions**

**Tobacco counselors approved by Eric France, MD or Juanita Redfield, MD will initiate orders for an 8-week prescription for Nortriptyline, and forward this order to the patient’s Physician if the following criteria are met:**

- a. The member completes and returns an informed consent form; AND**
- b. Member enrolls in an approved tobacco cessation program\* \*\*; AND**

<b>Approved Programs</b>	<b>Approved for:</b>
Stop Smoking Basics Freedom From Cigarettes	All members
Cardiac Rehab Tobacco Cessation Program	Patients enrolled in the Cardiac Rehab Program
Colorado Quit Line	All members

\* If a **new member** wants to continue a course of Nortriptyline prescribed before joining the health plan, they should be referred to the New Member Pharmacy.

\*\* Members who report enrolling but not yet starting the Colorado Quit Line program may be provided an initial 8-week prescription of Nortriptyline.

- c. A pharmacist confirms that the patient meets the guideline requirements for Nortriptyline for tobacco cessation after reviewing the member’s informed consent and medical record.**

<b>Programs</b>	<b>Responsible Pharmacy Team</b>
Stop Smoking Basics Freedom From Cigarettes	Clinical Pharmacy Cardiac Risk Services (CPCRS) or Clinical Pharmacy
Cardiac Rehab Tobacco Cessation Program	Clinical Pharmacy
Colorado Quit Line	CPCRS or Clinical Pharmacy

**Follow-up Prescriptions**

**Approved tobacco cessation counselors will initiate an order for follow-up 4-week Rx for Nortriptyline and send it to the patient’s physician for co-signature if the following criteria are met:**

- a. The patient continues to participate in an approved behavioral counseling program**

<b>Approved Program</b>	<b>Participation measure:</b>
Stop Smoking Basics Freedom From Cigarettes	Attendance at a session of Tobacco Free Living <b>or</b> continued attendance at FFC <b>or</b> completion of a telephone counseling session with a tobacco counselor
Cardiac Rehab Tobacco Cessation Program	Cardiac Rehab Nurse’s Assessment
Colorado Quit Line	Confirmation from member of continuing participation with the Quit Line counseling sessions.

- b. The patient reports significant progress on his or her quit plan indicated by discontinuing or limiting tobacco.**





## **What is an informed consent form?**

This form ensures that you understand the risks and benefits of using Bupropion SR and that your questions about this medication have been answered.

## **What is Bupropion SR?**

Bupropion SR (also known as *Wellbutrin SR* and *Zyban*) is a prescription medication that eases withdrawal symptoms and the urge to smoke or chew tobacco. Although Bupropion SR can be used to treat depression, you do not have to be depressed to take it.

## **Who should consider using Bupropion SR?**

Tobacco users who:

Are 18 years or older

Are enrolled in a stop-smoking program

Have been unsuccessful using the nicotine patch or gum

Because taking Bupropion SR can cause side-effects, including seizures and allergic reactions, we recommend you first try other methods, such as “the patch,” or nicotine gum.

## **How effective is Bupropion SR?**

People who attend a class *and* use medication are 3-8 times as likely to stay quit as those who try without help. If 100 smokers take Bupropion SR *and a stop-smoking class*, about 25 will be tobacco-free one year later. Smokers who use the nicotine patch and a class have similar success rates.

## **Why must I be enrolled in a stop-smoking class?**

Bupropion SR has not been shown to work on its own, without counseling.

## **Can I use the nicotine patch or gum while taking Bupropion SR?**

We do not recommend combining the patch/gum and Bupropion SR *unless* you have been unsuccessful using them separately. Combining Bupropion SR with extra nicotine from the patch, nicotine gum or cigarettes can increase your blood pressure. *Never smoke or chew tobacco if you use both medicines.*

## **Do I need to have my blood pressure checked?**

Have your blood pressure checked every two weeks if:

**You have a history of high blood pressure; or**

**You use both Bupropion SR and the nicotine “patch” or gum; or**

**After the first week of using Bupropion SR, you continue to smoke.**

Many supermarkets have convenient blood pressure machines. If your top number is higher than 160, or your bottom number is over 100, stop taking Bupropion SR and call your doctor as soon as possible.

## **What are possible side effects of taking Bupropion SR?**

*More common:* trouble sleeping or dry mouth.

*Less common:* nausea, constipation, loss of concentration, dizziness or anxiety (nervousness).

Persons suffering from depression may develop symptoms including delusions, hallucinations, concentration disturbance, paranoia or confusion while taking Bupropion SR.

**One out of every 1,000 people taking Bupropion SR has a seizure.**

**One out of every 3,000 people taking Bupropion SR has an allergic-like reaction, which may include itching, shortness of breath or difficulty breathing.**

## Who should NOT take Bupropion SR?

Do not take Bupropion SR if you

- have a seizure disorder (for example, epilepsy) or you are at risk of seizures
- have an eating disorder (for example, bulimia or anorexia nervosa)
- are already taking bupropion, ritonavir (Norvir) or a monoamine oxidase (MAO) inhibitor
- use the herbal remedy, St. John's Wort
- are pregnant, nursing or trying to become pregnant, unless closely monitored by your doctor
- are allergic to bupropion
- have bipolar disorder, unless closely monitored by your doctor
- have liver or kidney disease, unless closely monitored by your doctor

## Are some people more likely to have seizures?

The conditions in the box below may increase your risk of seizure when taking Bupropion SR. If any of these apply to you, you will need to weigh the risk of seizure against the benefits of quitting smoking.

Medical history or current conditions:	Use of alcohol, drugs or non-prescription medication:
History of head trauma	Excessive use of alcohol (14 or more drinks a week)
History of past seizures	Abrupt withdrawal from alcohol or other sedatives
Tumors of the brain or spine	Addiction to opiates, cocaine or stimulants
Diabetes with poor blood sugar control	Use of over-the-counter stimulants and weight-loss pills

## Can I take Bupropion SR with my other medications?

Taking certain medications with Bupropion SR may also increase your chance of having a seizure. A pharmacist will check your medical record and this form for medications that interact with Bupropion SR. **Please list any medications you are taking below.** If you are taking no medications, please write "none."

**Prescription Medications:** \_\_\_\_\_

**Over the Counter & Herbal Medications:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

## Informed Consent

I have read this informed consent and received answers to any questions I have about using Bupropion SR. By my signature, I certify that I do not have a seizure disorder, an eating disorder, any history of allergy to Bupropion SR, and I am not currently taking Bupropion SR or a monoamine oxidase inhibitor, nor am I pregnant or currently nursing. Further, if I have any of the patient factors or clinical situations as listed above, or I am taking other medications, I understand that I may be at increased risk for seizures while taking Bupropion SR. I understand that there are risks in taking Bupropion SR for tobacco cessation.

*I agree to participate in a tobacco cessation program while I am taking Bupropion SR.*

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Print Name**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Kaiser Permanente ID**

**Kaiser Permanente Pharmacy:** \_\_\_\_\_ **Your Physician's name:** \_\_\_\_\_

Staff use only:

Bupropion SR prescription:  Meets protocol  Does not meet protocol  Pending physician approval

Blood pressure \_\_\_\_/\_\_\_\_ per: patient/ chart/ in class. Pharmacist signature: \_\_\_\_\_ Date: \_\_\_\_

Patient advised to monitor blood pressure due to:  History of HTN  Combination therapy  NA

### What is an informed consent form?

This form ensures that you understand the risks and benefits of using Nortriptyline and that your questions about this medication have been answered.

### What is Nortriptyline?

Nortriptyline is a prescription medication that eases withdrawal symptoms and the urge to smoke or chew tobacco. Although Nortriptyline can be used to treat depression, you do not have to be depressed to take it.

### Who should consider using Nortriptyline?

Tobacco users who:

- Are 18 years or older
- Are enrolled in a stop-smoking program
- Have been unsuccessful using the nicotine patch or gum.

Because taking Nortriptyline can cause side-effects, including allergic reactions, we recommend you first try other methods, such as “the patch,” or nicotine gum.

### How effective is Nortriptyline?

People who attend a class *and* use medication are 3-8 times as likely to stay quit as those who try without help. If 100 smokers take Nortriptyline *and a stop-smoking class*, about 25 will be tobacco-free one year later. Smokers who use the nicotine patch and a class have similar success rates.

### Why must I be enrolled in a stop-smoking class?

Nortriptyline has been shown to be much more effective when paired with counseling.

### Can I use the nicotine patch or gum while taking Nortriptyline?

We do not recommend combining the patch/gum and Nortriptyline *unless* you have been unsuccessful using them separately.

### What are possible side effects of taking Nortriptyline?

Drowsiness, dry mouth, nausea, constipation, headache, dizziness, increased appetite, unpleasant taste, sensitivity to light, an allergic-like reaction, which may include itching, shortness of breath or difficulty breathing.

### Who should NOT take Nortriptyline?

Do not take Nortriptyline if you

- have had a heart attack within the past month.
- have narrow angle glaucoma.
- are already taking a monoamine oxidase (MAO) inhibitor or have taken one in the past 14 days.
- are pregnant or nursing.
- are allergic to Nortriptyline.

**Can I take Nortriptyline with my other medications?**

Taking certain medications with Nortriptyline may increase your risk of side effects. A pharmacist will check your medical record and this form for medications that interact with Nortriptyline. **Please list any medications you are taking below.** If you are taking no medications, please write “none.”

Prescription Medications:	Over the Counter & Herbal Medications

**Informed Consent**

I have read this informed consent and received answers to any questions I have about using Nortriptyline. By my signature, I certify that I have not had a heart attack in the past month, do not have any history of allergy to Nortriptyline, and I am not currently taking Nortriptyline or a monoamine oxidase inhibitor, nor am I pregnant or currently nursing. Further, if I have any of the patient factors or clinical situations as listed above, or I am taking other medications, I understand that I may be at increased risk for side effects while taking Nortriptyline. I understand that there are risks in taking Nortriptyline for tobacco cessation.

*I agree to participate in a tobacco cessation program while I am taking Nortriptyline.*

\_\_\_\_\_  
**Signature**                      **Print Name**                      **Date**                      **Kaiser Permanente ID**

**Name of Kaiser Permanente Pharmacy you prefer to use:** \_\_\_\_\_

Staff use only:

<p>Nortriptyline prescription: <input type="checkbox"/> Meets protocol <input type="checkbox"/> Does not meet protocol <input type="checkbox"/> Pending physician approval</p> <p>Pharmacist signature: _____ Date: _____</p>
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