

TOBACCO CESSATION THERAPY PROTOCOL

Approved 12-20-17

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of tobacco cessation therapies to individuals who have tobacco use disorder.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of tobacco cessation therapies under this protocol, pharmacist(s) must have received education and training in tobacco use disorder and tobacco cessation therapies, including review of the US Department of Health and Human Services, Public Health Services (USPHS), Clinical Practice Guideline for tobacco use treatment, from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _____

Date Training Completed: _____

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of tobacco cessation therapies will follow the most current USPHS, Clinical Practice Guideline for tobacco use treatment¹.

Inclusion criteria:

- Any individual, 18 years or older, who currently is using tobacco and is interested in cessation who does not meet the exclusion criteria below.

Exclusion criteria:

- Individuals who are pregnant are not eligible to receive therapies under this protocol and should be referred to their primary care or Ob/Gyn provider.

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of the following medications, in sufficient quantities to provide up to a 30-day supply of medication, as referenced in the attached pharmacologic product guide (Appendix 1; pages 5-6):

- 1) Nicotine replacement therapies, including:
 - a. patch
 - b. gum
 - c. inhaler

¹ Available at: http://www.ahrq.gov/sites/default/files/wysiwyg/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/treating_tobacco_use08.pdf

- d. lozenge
- e. nasal spray
- 2) Bupropion SR for oral administration
- 3) Varenicline for oral administration
- 4) Any other FDA-approved medication listed in the most current USPHS clinical practice guideline for treating tobacco use

PROCEDURES FOR INITIATION OF THERAPIES

Tobacco cessation therapy initiation will be individualized based on relevant medical and social history, patient preferences and consideration of contraindications and precautions of therapy as outlined below and in the Clinical Practice Guideline for tobacco use treatment and the attached pharmacologic product guide (Appendix 1; pages 5-6).

Relevant Medical and Social History

- Past medical history
- Current medications
- Allergies and hypersensitivities
- Other recreational substance use
- Previous tobacco cessation medication attempts, failures, intolerances

Contraindications and Precautions:

- History of seizure disorder (bupropion)
- History of eating disorder (bupropion)
- History of mental illness (bupropion or varenicline)
- Use of MAOI within 14 days (bupropion)
- Serious cardiac arrhythmias, recent history of MI (within 14 days), serious cardiac arrhythmias or severe or unstable angina (nicotine replacement)
- Abrupt discontinuation of alcohol, benzodiazepines, barbiturates or antiepileptic drugs (bupropion)
- Severe renal impairment (nicotine, varenicline)
- Moderate renal impairment (bupropion)
- Moderate to severe hepatic impairment (nicotine, bupropion)
- Hypersensitivity to any previous use of nicotine, bupropion or varenicline

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Follow-up monitoring and evaluation shall occur at a minimum of every 4 weeks to determine effectiveness, adverse effects and patient progress with therapy. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized until the recommended duration of therapy is complete as referenced in the attached medication guide (Appendix 1; pages 5-6). Treatment periods longer than 6 months of continuous therapy are not authorized under this protocol without explicit approval from the authorizing practitioner.

Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation and notification, will be followed.

EDUCATION REQUIREMENTS

Individuals receiving tobacco cessation therapies under the protocol will receive education regarding:

- 1) motivation to cease tobacco use
- 2) drug information related to the specific dosage form dispensed, including directions for use and adverse effects
- 3) nicotine withdrawal symptoms
- 4) lifestyle modifications, and
- 5) techniques to prevent relapse

DOCUMENTATION

Pharmacist(s) shall document via prescription record each person who receives a tobacco cessation medication prescription under this protocol, including:

- (a) Documentation as required in 201 KAR 2:170 for the dispensing of prescription medication; and
- (b) Documentation that the individual receiving the tobacco cessation therapy was provided with the required education pursuant to this administrative regulation.
- (c) Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and evaluation.

NOTIFICATION

Pharmacist(s) shall ask all persons receiving tobacco cessation therapies under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive tobacco cessation therapies under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing practitioner, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing practitioner of persons receiving tobacco cessation therapies under this protocol within 7 days of initiating dispensing]

TERMS

This protocol is effective as of the date all parties execute this document. It shall remain in effect for a period of one year and shall automatically renew for successive one year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

SIGNATURES

Practitioner Name

Date

Practitioner Signature

Pharmacist Name

Date

Pharmacist Signature



PHARMACOLOGIC PRODUCT GUIDE: FDA-APPROVED MEDICATIONS FOR SMOKING CESSATION

		NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS				BUPROPION SR	VARENICLINE
		GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER	
PRODUCT	Nicorette ¹ , ZONNIC ² , Generic OTC 2 mg, 4 mg original, cinnamon, fruit, mint	Nicorette Lozenge, ¹ Nicorette Mini Lozenge, ¹ Generic OTC 2 mg, 4 mg; cherry, mint	NicoDerm CQ ¹ , Generic OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)	Nicotrol NS ³ Rx Metered spray 10 mg/mL aqueous solution	Nicotrol Inhaler ³ Rx 10 mg cartridge delivers 4 mg inhaled vapor	Zyban ¹ , Generic Rx 150 mg sustained-release tablet	Chantix ³ Rx 0.5 mg, 1 mg tablet
PRECAUTIONS	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Temporomandibular joint disease Pregnancy⁴ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy⁴ and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Pregnancy⁴ (Rx formulations, category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) Severe reactive airway disease Pregnancy⁴ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Recent (≤ 2 weeks) myocardial infarction Serious underlying arrhythmias Serious or worsening angina pectoris Bronchospastic disease Pregnancy⁴ (category D) and breastfeeding Adolescents (<18 years) 	<ul style="list-style-type: none"> Concomitant therapy with medications/conditions known to lower the seizure threshold Hepatic impairment Pregnancy⁴ (category C) and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms⁵: BOXED WARNING REMOVED 12/2016 <p>Contraindications:</p> <ul style="list-style-type: none"> Seizure disorder Concomitant bupropion (e.g., Wellbutrin) therapy Current or prior diagnosis of bulimia or anorexia nervosa Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors 	<ul style="list-style-type: none"> Severe renal impairment (dosage adjustment is necessary) Pregnancy⁴ (category C) and breastfeeding Adolescents (<18 years) Treatment-emergent neuropsychiatric symptoms⁵: BOXED WARNING REMOVED 12/2016
DOSING	<p><i>1st cigarette ≤ 30 minutes after waking:</i> 4 mg</p> <p><i>1st cigarette >30 minutes after waking:</i> 2 mg</p> <p>Weeks 1–6: 1 piece q 1–2 hours</p> <p>Weeks 7–9: 1 piece q 2–4 hours</p> <p>Weeks 10–12: 1 piece q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 24 pieces/day Chew each piece slowly Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) Resume chewing when tingle fades Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) Park in different areas of mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p><i>1st cigarette ≤ 30 minutes after waking:</i> 4 mg</p> <p><i>1st cigarette >30 minutes after waking:</i> 2 mg</p> <p>Weeks 1–6: 1 lozenge q 1–2 hours</p> <p>Weeks 7–9: 1 lozenge q 2–4 hours</p> <p>Weeks 10–12: 1 lozenge q 4–8 hours</p> <ul style="list-style-type: none"> Maximum, 20 lozenges/day Allow to dissolve slowly (20–30 minutes for standard; 10 minutes for mini) Nicotine release may cause a warm, tingling sensation Do not chew or swallow Occasionally rotate to different areas of the mouth No food or beverages 15 minutes before or during use Duration: up to 12 weeks 	<p><i>>10 cigarettes/day:</i> 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks</p> <p><i>≤ 10 cigarettes/day:</i> 14 mg/day x 6 weeks 7 mg/day x 2 weeks</p> <ul style="list-style-type: none"> Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) Duration: 8–10 weeks 	<p>1–2 doses/hour (8–40 doses/day) One dose = 2 sprays (one in each nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa</p> <ul style="list-style-type: none"> Maximum <ul style="list-style-type: none"> – 5 doses/hour or – 40 doses/day For best results, initially use at least 8 doses/day Do not sniff, swallow, or inhale through the nose as the spray is being administered Duration: 3–6 months 	<p>6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours</p> <ul style="list-style-type: none"> Best effects with continuous puffing for 20 minutes Initially use at least 6 cartridges/day Nicotine in cartridge is depleted after 20 minutes of active puffing Inhale into back of throat or puff in short breaths Do NOT inhale into the lungs (like a cigarette) but “puff” as if lighting a pipe Open cartridge retains potency for 24 hours No food or beverages 15 minutes before or during use Duration: 3–6 months 	<p>150 mg po q AM x 3 days, then 150 mg po bid</p> <ul style="list-style-type: none"> Do not exceed 300 mg/day Begin therapy 1–2 weeks prior to quit date Allow at least 8 hours between doses Avoid bedtime dosing to minimize insomnia Dose tapering is not necessary Duration: 7–12 weeks, with maintenance up to 6 months in selected patients 	<p>Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid</p> <ul style="list-style-type: none"> Begin therapy 1 week prior to quit date Take dose after eating and with a full glass of water Dose tapering is not necessary Dosing adjustment is necessary for patients with severe renal impairment Duration: 12 weeks; an additional 12-week course may be used in selected patients May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks

	NICOTINE REPLACEMENT THERAPY (NRT) FORMULATIONS					BUPROPION SR	VARENICLINE
	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER		
ADVERSE EFFECTS	<ul style="list-style-type: none"> ▪ Mouth/jaw soreness ▪ Hiccups ▪ Dyspepsia ▪ Hypersalivation ▪ Effects associated with incorrect chewing technique: <ul style="list-style-type: none"> – Lightheadedness – Nausea/vomiting – Throat and mouth irritation 	<ul style="list-style-type: none"> ▪ Mouth irritation ▪ Nausea ▪ Hiccups ▪ Heartburn ▪ Headache ▪ Sore throat ▪ Dizziness 	<ul style="list-style-type: none"> ▪ Local skin reactions (erythema, pruritus, burning) ▪ Headache ▪ Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption 	<ul style="list-style-type: none"> ▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Rhinitis ▪ Tearing ▪ Sneezing ▪ Cough ▪ Headache 	<ul style="list-style-type: none"> ▪ Mouth and/or throat irritation ▪ Cough ▪ Headache ▪ Rhinitis ▪ Dyspepsia ▪ Hiccups 	<ul style="list-style-type: none"> ▪ Insomnia ▪ Dry mouth ▪ Nervousness/difficulty concentrating ▪ Nausea ▪ Dizziness ▪ Constipation ▪ Rash ▪ Seizures (risk is 0.1%) ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Constipation ▪ Flatulence ▪ Vomiting ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)
ADVANTAGES	<ul style="list-style-type: none"> ▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Once-daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others ▪ Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours 	<ul style="list-style-type: none"> ▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges 	<ul style="list-style-type: none"> ▪ Twice-daily oral dosing is simple and associated with fewer adherence problems ▪ Might delay weight gain ▪ Might be beneficial in patients with depression ▪ Can be used in combination with NRT agents 	<ul style="list-style-type: none"> ▪ Twice-daily oral dosing is simple and associated with fewer adherence problems ▪ Offers a different mechanism of action for patients who have failed other agents
DISADVANTAGES	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome 	<ul style="list-style-type: none"> ▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis) 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease 	<ul style="list-style-type: none"> ▪ Need for frequent dosing can compromise adherence ▪ Cost of treatment ▪ Cartridges might be less effective in cold environments ($\leq 60^{\circ}\text{F}$) 	<ul style="list-style-type: none"> ▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ▪ Patients should be monitored for potential neuropsychiatric symptoms⁵ (see PRECAUTIONS) 	<ul style="list-style-type: none"> ▪ Cost of treatment ▪ Patients should be monitored for potential neuropsychiatric symptoms⁵ (see PRECAUTIONS)
COST/DAY ⁶	2 mg or 4 mg: \$1.90–\$3.60 (9 pieces)	2 mg or 4 mg: \$3.33–\$3.60 (9 pieces)	\$1.52–\$2.90 (1 patch)	\$7.30 (8 doses)	\$12.42 (6 cartridges)	\$2.58–\$8.25 (2 tablets)	\$11.88 (2 tablets)

¹ Marketed by GlaxoSmithKline.

² Marketed by Nicovom USA (a subsidiary of Reynolds American, Inc.)

³ Marketed by Pfizer.

⁴ The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.

⁵ In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.

⁶ Approximate cost based on the recommended initial dosing for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, June 2017.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the manufacturers' package inserts.

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