Pharmacy Name: _____

Pharmacy Permit Number: _____

TOBACCO CESSATION THERAPY PROTOCOL
v3
Approved 05/28/2025

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 U.S. Preventative Services Task Force (USPSTF) Tobacco Cessation,[1] and Clinical Practice Guideline for tobacco use treatment,[2] from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of tobacco cessation therapies will follow the most current, Clinical Practice Guideline for tobacco use treatment[2].

Inclusion criteria:
- Any individual 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):

- Nicotine replacement therapies

[1] Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions

[2] Available at: https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/treating_tobacco_use08.pdf

- Bupropion SR for oral administration
- Varenicline for oral administration
- 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).

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). Treatment periods longer than 6 months of continuous therapy are not authorized under this protocol without explicit approval from the authorizing prescriber.

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:

- Motivation to cease tobacco use
- Drug information related to the specific dosage form dispensed, including directions for use and adverse effects
- Nicotine withdrawal symptoms
- Lifestyle modifications, and
- 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:

- Documentation of parental consent for individuals under age 18
- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication
- Documentation that the individual receiving the tobacco cessation therapy was provided with the required education pursuant to this administrative regulation
- 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 prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving tobacco cessation therapies under this protocol within 7 days of initiating dispensing]

TERMS
This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____
Prescriber Name Date

_____
Prescriber Kentucky License Number

_____
Prescriber Signature

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled: _____
and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

APPENDIX 1

Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations				Bupropion SR	Varenicline
	Gum	**Lozenge**	**Transdermal Patch**	**Nasal Spray**		
Product	**Nicorette[1], Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint (various)	**Nicorette[1], Generic; Nicorette[1] Mini** OTC 2 mg, 4 mg; cinnamon, cherry, mint	**Habitrol[2], NicoDerm CQ[1], Generic** OTC 7 mg, 14 mg, 21 mg (24-hr release)	**Nicotrol NS[3]** Rx Metered spray 10 mg/mL nicotine solution	**Generic** (formerly Zyban) Rx 150 mg sustained-release tablet	**Generic** (formerly Chantix[3]) Rx 0.5 mg, 1 mg tablet
Precautions	■ Recent (≤ 2 weeks) myocardial infarction ■ Serious underlying arrhythmias ■ Serious or worsening angina pectoris ■ Temporomandibular joint disease ■ Pregnancy[4] and breastfeeding ■ Adolescents (<18 years)	■ Recent (≤ 2 weeks) myocardial infarction ■ Serious underlying arrhythmias ■ Serious or worsening angina pectoris ■ Pregnancy[4] and breastfeeding ■ Adolescents (<18 years)	■ Recent (≤ 2 weeks) myocardial infarction ■ Serious underlying arrhythmias ■ Serious or worsening angina pectoris ■ Pregnancy[4] and breastfeeding ■ Adolescents (<18 years)	■ 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 ■ Pregnancy[4] and breastfeeding ■ Adolescents (<18 years)	■ Concomitant therapy with medications/conditions known to lower the seizure threshold ■ Hepatic impairment ■ Pregnancy[4] and breastfeeding ■ Adolescents (<18 years) ■ Treatment-emergent neuropsychiatric symptoms[5] **Contraindications:** ■ 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	■ Severe renal impairment (dosage adjustment is necessary) ■ Pregnancy[4] and breastfeeding ■ Adolescents (<18 years) ■ Treatment-emergent neuropsychiatric symptoms[5]
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours* Weeks 7–9: 1 piece q 2–4 hours* Weeks 10–12: 1 piece q 4–8 hours* **while awake* ■ Maximum, 24 pieces/day ■ During initial 6 weeks of treatment, use at least 9 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	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours* Weeks 7–9: 1 lozenge q 2–4 hours* Weeks 10–12: 1 lozenge q 4–8 hours* **while awake* ■ Maximum, 20 lozenges/day ■ During initial 6 weeks of treatment, use at least 9 lozenges/day ■ Allow to dissolve slowly (20–30 minutes) ■ 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	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ■ 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); before recommending, rule out other factors that might be contributing (e.g., drug interaction between caffeine and tobacco smoke, other medications, and lifestyle factors) ■ Duration: 8–10 weeks	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 **while awake* ■ Maximum – 5 doses/hour or – 40 doses/day ■ During intial 6-8 weeks of treatment, use at least 8 doses/day ■ Gradually reduce daily dosage over an additional 4-6 weeks ■ Do not sniff, swallow, or inhale through the nose as the spray is being administered ■ Duration: 12 weeks	150 mg po q AM x 3 days, then 150 mg po bid ■ 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 ■ Duration: 7–12 weeks, with maintenance up to 6 months in selected patients ■ Dose tapering is not necessary	Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid ■ Begin therapy 1 week **prior** to quit date ■ Take each dose after eating and with a full glass of water ■ 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		
Adverse Effects	▪ Mouth and throat irritation ▪ Jaw muscle soreness ▪ Hiccups ▪ GI complaints (dyspepsia, nausea) ▪ May stick to dental work ▪ Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release): – Lightheadedness/dizziness – Nausea/vomiting – Hiccups – Mouth and throat irritation	▪ Mouth and throat irritation ▪ Hiccups ▪ GI complaints (dyspepsia, nausea)	▪ Local skin reactions (erythema, pruritus, burning) ▪ Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Ocular irritation/tearing ▪ Sneezing ▪ Cough	▪ Insomnia ▪ Dry mouth ▪ Nausea ▪ Anxiety/difficulty concentrating ▪ Constipation ▪ Tremor ▪ Rash ▪ Seizures (risk is 0.15%) ▪ Neuropsychiatric symptoms (rare; see Precautions)	▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Headache ▪ Flatulence ▪ Constipation ▪ Taste alteration ▪ Neuropsychiatric symptoms (rare; see Precautions)
Advantages	▪ 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 ▪ Relatively inexpensive	▪ 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 ▪ Relatively inexpensive	▪ 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 ▪ Relatively inexpensive	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ 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 ▪ Relatively inexpensive (generic formulations)	▪ 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 ▪ Most effective cessation agent when used as monotherapy
Disadvantages	▪ 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	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ 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)	▪ 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 ▪ Cost of treatment	▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see Precautions) ▪ Patients should be monitored for potential neuropsychiatric symptoms[5] (see Precautions)	▪ Patients should be monitored for potential neuropsychiatric symptoms[5] (see Precautions) ▪ Cost of treatment
Cost/day[6]	2 mg or 4 mg: $2.97–$3.69 (9 pieces)	2 mg or 4 mg: $3.42–$4.05 (9 pieces)	$1.83–$2.84 (1 patch)	$10.88 (8 doses)	$0.46 (2 tablets)	$6.82 (2 tablets)

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Dr. Reddy's.
[3] Chantix, formerly marketed by Pfizer, was voluntarily recalled and has been unavailable since 9/16/2021, due to the presence of N-nitroso-varenicline at levels exceeding the FDA's acceptable intake limit.
[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 tobacco users 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 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 average wholesale acquisition prices for generic and brand formulations from Red Book Online. Thomson Reuters, January 2025.

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.