NICOTINE REPLACEMENT THERAPY

STATEWIDE PROTOCOL

Arkansas State Board of Pharmacy

I. Purpose

The purpose of this protocol is to reduce tobacco-related morbidity and mortality in Arkansas by allowing Arkansas-licensed pharmacists to initiate nicotine replacement therapy (NRT) including ordering, dispensing, and/or administering NRT products, along with any necessary supplies for administration, to persons eligible to receive NRT.

II. Authority

This protocol is issued pursuant to Act 651 of 2019 (HB 1263) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order, dispense, and/or administer all FDA-approved NRT products according to the provisions of Arkansas Code § 17-92-101(16) and the requirements of this protocol. Pharmacists may continue to provide over-the-counter smoking cessation products without use of this protocol.

III. Initial Patient Screening

When a patient requests NRT or when a pharmacist, in his or her professional judgement, decides to initiate smoking cessation treatment and counseling, the pharmacist shall assess, at a minimum, the following patient criteria in determining the appropriate therapy to initiate:

- Current tobacco use and prior attempts to quit
- Medical and social history, including current medications
- Allergies / hypersensitivities
- Precautions of potential medication treatments
- Patient preferences regarding treatment options
- Ask the patient the following screening questions:
    - Are you pregnant or plan to become pregnant?
        - *If yes, do not furnish NRT and refer to appropriate health care provider*
    - Have you had a heart attack within the last 2 weeks?
        - *If yes, furnish NRT with caution and refer to appropriate healthcare provider*
    - Do you have any history of heart palpitations, irregular heartbeats, or have you been diagnosed with a serious arrhythmia?
        - *If yes, furnish NRT with caution and refer to appropriate healthcare provider*
    - Do you currently experience frequent chest pain or heave you been diagnosed with unstable angina?
        - *If yes, furnish NRT with caution and refer to appropriate healthcare provider*
    - Do you have any history of allergic rhinitis (e.g., nasal allergies)?
        - *If yes, avoid nasal spray*
    - Have you been diagnosed with temporal mandibular joint (TMJ) dysfunction?
        - *If yes, avoid nicotine gum*

IV. Precautions/Contraindications

The pharmacist shall assess the patient for the following precautions/contraindications and, if any identified, the pharmacist is authorized to dispense at the professional discretion of the pharmacist only if the patient has identified a primary care provider with whom the pharmacist has conferred prior to dispensing.

- Recent history of myocardial infarction (within 14 days)
- Known serious cardiac arrhythmia, unstable or severe angina
- Known moderate/severe hepatic or renal impairment

NRT initiation will be individualized based on relevant medical and social history obtained and patient preferences, involving consideration of contraindications and precautions of therapy as outlined in **Appendix 1**.

V. Dispensing Guidelines

A. Medications Authorized

This protocol authorizes Arkansas-licensed pharmacists, upon assessment of the patient and determination that a nicotine replacement smoking cessation product is appropriate, to initiate dispensing of NRT products (alone or in combination) as provided in **Appendix 1 or from FDA approved product labeling**.

> NRT Product Selection: The pharmacist, in consultation with the patient, may select any NRT product (alone or in combination) from all FDA approved NRT products including by not limited to the list of therapies either specified in this protocol in Appendix 1 or from FDA approved product labeling. Generic equivalent products may be furnished.

B. Patient Education and Follow-Up

Follow-up monitoring and evaluation shall occur at a minimum of every four 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 as appropriate. Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapy, including education, documentation, and notification, shall be followed.

Patients receiving NRT under this protocol shall 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
- Techniques to prevent relapse

C. Labeling

A prescription label shall be affixed to the nicotine replacement product dispensed.

D. Records

Pharmacists shall document in the patient medication record the dispensing of NRT products.

E. Prescriber Notification

Within a reasonable amount of time, the pharmacist shall provide notification to the patient's primary care provider of the NRT product dispensed to the patient under the protocol. If a patient does not identify a primary care provider, the pharmacist shall provide the patient with a written record of the dispensing and refer the patient to consult an appropriate health care professional of the patient's choice.

Appendix 1*: Pharmacologic Product Guide of FDA-Approved NRT Products

	Nicotine Replacement Therapy (NRT) Formulations				
	Gum	**Lozenge**	**Oral Inhaler**	**Nasal Spray**	**Transdermal Patch**
Product	**Nicorette, Zonnic, Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint	**Nicorette Lozenge, Nicorette Mini Lozenge, Generic** OTC 2 mg, 4 mg cherry, mint	**Nicotrol Inhaler** Rx 10 mg cartridge Delivers 4 mg inhaled vapor	**Nicotrol NS** Rx Metered spray 10 mg/mL aqueous solution	**NicoDerm CQ, Generic** OTC (NicoDerm CQ, generic) Rx (generic) 7 mg, 14 mg, 21 mg (24-hr release)
Precautions	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious / worsening angina pectoris • Temporomandibular joint disease • Pregnancy / breastfeeding • Adolescents (<18 years)	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious / worsening angina pectoris • Pregnancy / breastfeeding • Adolescents (<18 years)	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious / worsening angina pectoris	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious / worsening angina pectoris	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious / worsening angina pectoris
Dosing	*NRT: immediate release*				*NRT: sustained release*
	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 • Max: 24 pieces/day • Chew each piece slowly • Park between cheek & gum when peppery / 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; ~30 minutes) • 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 • Max: 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	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours • 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	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 • Max: – 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	*>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) Duration: 8– 10 weeks

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Appendix 1* *(continued)*

	Nicotine Replacement Therapy (NRT) Formulations *(continued)*				
	Gum	**Lozenge**	**Oral Inhaler**	**Nasal Spray**	**Transdermal Patch**
Adverse Effects	• Mouth/jaw soreness • Hiccups • Dyspepsia • Hypersalivation • Effects associated with incorrect chewing technique: – lightheadedness – nausea/vomiting – throat & mouth irritation	• Nausea • Hiccups • Cough • Heartburn • Headache • Flatulence • Insomnia	• Mouth / throat irritation (hot, peppery, or burning sensation) • Cough • Headache • Rhinitis • Dyspepsia • Hiccups	• Nasal / throat irritation (hot, peppery, or burning sensation) • Rhinitis • Tearing • Sneezing • Cough • Headache	• Local skin reactions (erythema, pruritus, burning) • Headache • Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption
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		• 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	• Can be titrated to rapidly manage withdrawal symptoms • Can be used in combination with other agents to manage situational urges	• 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
Disadvantages	• Need for frequent dosing can compromise adherence • Might be problematic for patients with significant dental work • Proper chewing technique is necessary for effectiveness & 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	• Need for frequent dosing can compromise adherence • Cartridges might be less effective in cold environments (≤60°F)	• 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	• When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms • Not recommended for use by patients with dermatologic conditions (psoriasis, eczema, atopic dermatitis, etc.)

*This protocol authorizes licensed pharmacists in Arkansas to order, dispense, and/or administer all FDA-approved NRT products either specified in this protocol or according to indications, dosing and contraindications of FDA approved package labeling.