NICOTINE REPLACEMENT TOBACCO CESSATION STATEWIDE PROTOCOL
Iowa Board of Pharmacy

I. Purpose

This protocol is intended to ensure the timely provision of nicotine replacement tobacco cessation products and to ensure an adult patient receives information to appropriately initiate nicotine replacement therapy for the treatment of tobacco use and dependence. This protocol specifies the criteria and procedures to assists pharmacists in providing safe and effective tobacco cessation therapy in Iowa.

II. Authority

Pursuant to Iowa Code section 155A.46, in collaboration with the Iowa Department of Public Health, a pharmacist may order and dispense to a patient 18 years or older a nicotine replacement tobacco cessation product, only in accordance with this protocol. For the purpose of this protocol, the pharmacist's order shall constitute a prescription. For the purpose of this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification).

III. Qualification

A pharmacist shall document successful completion of an Accreditation Council for Pharmacy Education (ACPE)-approved continuing education program of at least one-hour duration related to nicotine replacement tobacco cessation product utilization prior to dispensing nicotine replacement tobacco cessation products pursuant to this protocol.

IV. General requirements

A pharmacist shall follow the most current version of the United States Department of Health and Human Services, Public Health Services, Clinical Practice Guideline – Treating Tobacco Use and Dependence.

A pharmacist shall implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco.

Pharmacist services shall include an educational component to include counseling on medication therapies and cessation strategies as well as referral to other evidence-based resources for assistance, including but not limited to the Quitline Iowa (1-800-QUIT-NOW).

A pharmacist participating in this protocol shall have access to the most current nicotine replacement tobacco cessation protocol authorized by the board of pharmacy in collaboration with the department of public health.

A pharmacist shall ensure a patient's privacy and confidentiality shall be protected.

A pharmacist may continue to provide over-the-counter tobacco cessation products to tobacco users without the use of this protocol.

V. Initial patient screening

When a patient, aged 18 years or older, requests nicotine replacement tobacco cessation therapy or when a pharmacist, in his or her professional judgment, decides to initiate tobacco cessation treatment and counseling, the pharmacist shall assess, at a minimum, the following patient criteria in determining the appropriate therapy to initiate:

1. Current tobacco use and prior attempts to quit.
2. Medical and social history, including current medications.
3. Previous medication attempts, failures, intolerances.
4. Allergies and hypersensitivities.
5. Potential drug interactions with potential medication treatments.
6. Precautions of potential medication treatments.
7. Patient preferences with regard to treatment options.

VI. Medications authorized

This protocol authorizes the pharmacist, upon assessment of the patient and determination that a nicotine replacement tobacco cessation product is appropriate, to initiate the dispensing, in sufficient quantities to provide up to a 30-day supply, of nicotine replacement therapy as provided in Appendix 1.

VII. 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 but shall not exceed six months. Treatment periods longer than six 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 therapy, including education, documentation, and notification, shall be followed.

Patients receiving nicotine replacement tobacco cessation therapy under this protocol shall 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.

VIII. Labeling

A prescription label shall be affixed to the nicotine replacement tobacco cessation product as required in Iowa Administrative Code (IAC) rule 657—6.10(155A), except that the expiration date of the product shall not be rendered illegible.

IX. Records

The pharmacist shall document in the patient medication record the dispensing of a nicotine replacement tobacco cessation therapy pursuant to IAC rule 657—6.8(155A).

X. Prescriber notification

Within two weeks, the pharmacist shall provide notification to the patient's primary care provider of the nicotine replacement tobacco cessation 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 advise the patient consult an appropriate health care professional of the patient's choice.

XI. Effective date

This protocol is effective June 28, 2022 and shall be in effect for a period of one year and shall automatically renew for subsequent one year periods unless otherwise amended or terminated by the board.

Appendix 1

NICOTINE REPLACEMENT THERAPY (NRT) MEDICATIONS FOR SMOKING CESSATION

	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER
PRODUCT	**Nicorette®, generic** OTC 2 mg, 4 mg Original, cinnamon, fruit, mint	**Nicorette® Lozenge, Nicorette® Mini Lozenge, generic** OTC 2 mg, 4 mg Cherry, mint	**NicoDerm CQ®, Habitrol, generic** OTC 7 mg, 14 mg, 21 mg (24-hr release)	**Nicotrol® NS** Rx Metered spray 10 mg/ml aqueous solution	**Nicotrol® Inhaler** Rx 10 mg cartridge Delivers 4 mg inhaled vapor
PRECAUTIONS	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Temporomandibular joint disease • Pregnancy[1] and breastfeeding	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Pregnancy and breastfeeding	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Pregnancy and breastfeeding	• 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 (Category D) and breastfeeding	• Recent (≤ 2 weeks) myocardial infarction • Serious underlying arrhythmias • Serious or worsening angina pectoris • Bronchospastic disease • Pregnancy (Category D) and breastfeeding
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 • 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 min 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 • 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	*>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 for at least one week • May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime) • 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 nicotine to the nasal mucosa • Maximum - 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	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] 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.

	GUM	LOZENGE	TRANSDERMAL PATCH	NASAL SPRAY	ORAL INHALER
ADVERSE EFFECTS	• Mouth/jaw soreness • Hiccups • Dyspepsia • Hypersalivation • Effects associated with incorrect chewing technique: - Lightheadedness - Nausea/vomiting - Throat and mouth irritation	• Mouth irritation • Nausea • Hiccups • Heartburn • Headache • Sore throat • Dizziness	• Local skin reactions (erythema, pruritis, burning) • Headache • Sleep disturbances (insomnia, abnormal/vivid dreams); associated with nocturnal nicotine absorption	• Nasal and/or throat irritation (hot, peppery, or burning sensation) • Rhinitis • Tearing • Sneezing • Cough • Headache	• Mouth and/or throat irritation • Cough • Headache • Rhinitis • Dyspepsia • Hiccups
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 • Might delay weight gain • Can be titrated to 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	• Can be titrated to rapidly 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
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	• Need for frequent dosing can compromise adherence • Cost of treatment • Cartridges might be less effective in cold environments (≤ 60° F)

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